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

FORM 10-Q

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

For the quarterly period ended June 30, 2019

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

For the transition period from to

Commission File Number: 001-36721

Coherus BioSciences, Inc.

(Exact name of registrant as specified in its charter)

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

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	CHRS	The Nasdaq Global Market

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 every Interactive Data File required to be submitted 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). Yes ☒ No ☐

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

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

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

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

As of July 31, 2019, 69,763,968 shares of the registrant's common stock were outstanding.

COHERUS BIOSCIENCES, INC.
FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2019
INDEX

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 within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts contained in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by words such as "aim," "anticipate," "assume," "attempt," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "seek," "should," "strive," "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:

- whether we will be able to continue to increase sales for UDENYCA® (pegfilgrastim-cbqv) in the United States;
- whether we will be able to commercialize directly or through partners UDENYCA® in Europe;
- our ability to continue to build the sales and marketing infrastructure for UDENYCA®;
- whether the results of our trials will be sufficient to support domestic or global regulatory approvals for CHS-1420 (our adalimumab (Humira®) biosimilar candidate), CHS-0214 (our etanercept (Enbrel®) biosimilar candidate) and CHS-131 (our therapeutic small molecule candidate);
- whether additional trials will be required to support domestic or global regulatory approvals for CHS-1420, CHS-0214 and CHS-131;
- whether we will be able to continue the preclinical development for CHS-2020 (our aflibercept (Eylea®) biosimilar candidate) and initiate the clinical development for CHS-3351 (our ranibizumab (Lucentis®) biosimilar candidate);
- our ability to obtain and maintain regulatory approval of any product candidates;
- our expectations regarding government and third-party payer coverage and reimbursement;
- our ability to manufacture our product candidates in conformity with regulatory requirements and to scale up manufacturing capacity of these products for commercial supply;
- our reliance on third-party contract manufacturers to supply our product candidates for us;
- 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 capital resources will be sufficient to fund our operations for at least the next 12 months;
- 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;
- the cost, timing and outcomes of litigation involving our product candidates;
- our reliance on third-party contract research organizations to conduct clinical trials of our product candidates;
- the benefits of the use of our product candidates;
- the U.S. government's policy mandating healthcare insurance coverage for pre-existing conditions will continue for the foreseeable future and will increase demand for high-quality biosimilars;
- the rate and degree of market acceptance of our current or any future product candidates;
- our ability to compete with companies currently producing the reference products, including Neulasta, Humira, Enbrel, Lucentis and Eylea;

- our financial performance, including, but not limited to, maintaining profitability for the future, as well as the 2019 and future performance of our gross margins, research and development expenses and selling and general administrative expenses; 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)
(unaudited)

	June 30, 2019 (unaudited)	December 31, 2018 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 105,927	$ 72,356
Investments in marketable securities	5,991	—
Restricted cash	50	50
Trade receivables, net	77,385	—
Inventory	4,333	1,659
Prepaid manufacturing	6,748	7,906
Other prepaid and other assets	5,196	2,462
Total current assets	205,630	84,433
Property and equipment, net	5,646	6,660
Inventory, non-current	18,465	4,012
Operating lease right-of-use assets	6,353	—
Intangible assets	2,620	2,620
Goodwill	943	943
Restricted cash, non-current	785	785
Other assets, non-current	14	14
Total assets	$ 240,456	$ 99,467
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 19,223	$ 15,294
Accounts payable - related parties	50	—
Accrued rebates, fees and reserve	20,650	—
Accrued compensation	10,810	10,540
Accrued liabilities	8,295	7,008
Other liabilities	2,198	419
Total current liabilities	61,226	33,261
Contingent consideration, non-current	64	60
Convertible notes	77,916	77,319
Convertible notes - related parties	25,972	25,773
Term loan	73,286	—
Lease liabilities, non-current	5,977	—
Other liabilities, non-current	—	1,645
Total liabilities	244,441	138,058
Commitments and contingencies (Note 8)		
Stockholders' deficit:		
Preferred stock	—	—
Common stock	7	7
Additional paid-in capital	977,787	946,515
Accumulated other comprehensive loss	(511)	(282)
Accumulated deficit	(981,268)	(984,831)
Total stockholders' deficit	(3,985)	(38,591)
Total liabilities and stockholders' deficit	$ 240,456	$ 99,467

(1) The consolidated balance sheet as of December 31, 2018 has been derived from the audited consolidated balance sheet included in the Company's 2018 Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2019.

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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue:				
Net product revenue	$ 83,433	$ —	$ 120,531	$ —
Operating expenses:				
Cost of goods sold	601	—	2,826	—
Research and development (includes related party of $50 and $0 for the three months ended June 30, 2019 and 2018, respectively; and $50 and $1,479 for the six months ended June 30, 2019 and 2018, respectively)	18,883	26,519	37,672	51,974
Selling, general and administrative (includes related party of $1 and $66 for the three months ended June 30, 2019 and 2018, respectively; and $1 and $100 for the six months ended June 30, 2019 and 2018, respectively)	36,456	18,391	69,139	34,968
Total operating expenses	55,940	44,910	109,637	86,942
Income (loss) from operations	27,493	(44,910)	10,894	(86,942)
Interest expense (includes related party of $613 and $604 for the three months ended June 30, 2019 and 2018, respectively; and $1,224 and $1,206 for the six months ended June 30, 2019 and 2018, respectively)	(4,433)	(2,417)	(8,649)	(4,825)
Other income, net	558	3,642	1,369	3,780
Net income (loss) before income taxes	23,618	(43,685)	3,614	(87,987)
Income tax provision	51	—	51	—
Net income (loss)	23,567	(43,685)	3,563	(87,987)
Net loss attributable to non-controlling interest	—	47	—	52
Net income (loss) attributable to Coherus	$ 23,567	$ (43,638)	$ 3,563	$ (87,935)
Net income (loss) per share attributable to Coherus:				
Basic	$ 0.34	$ (0.68)	$ 0.05	$ (1.42)
Diluted	$ 0.32	$ (0.68)	$ 0.05	$ (1.42)
Weighted-average number of shares used in computing net income (loss) per share attributable to Coherus:				
Basic	69,479,016	63,960,567	69,310,791	62,051,912
Diluted	72,963,972	63,960,567	72,281,564	62,051,912

See accompanying notes to condensed consolidated financial statements.

Coherus BioSciences, Inc.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net income (loss)	$ 23,567	$ (43,685)	$ 3,563	$ (87,987)
Other comprehensive income (loss):				
Unrealized gain on available-for-sale securities, net of tax	—	1	—	—
Foreign currency translation adjustments, net of tax	(93)	226	(229)	213
Comprehensive income (loss)	23,474	(43,458)	3,334	(87,774)
Comprehensive loss attributable to non-controlling interest	—	47	—	52
Comprehensive income (loss) attributable to Coherus	$ 23,474	$ (43,411)	$ 3,334	$ (87,722)

See accompanying notes to condensed consolidated financial statements.

Coherus BioSciences, Inc.

Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(in thousands, except share and per share data)
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balances at December 31, 2018	68,302,681	$ 7	$ 946,515	$ (282)	$ (984,831)	$ (38,591)
Issuance of common stock in connection with common stock offerings, net	761,130	—	8,228	—	—	8,228
Issuance of common stock upon exercise of stock options	143,523	—	825	—	—	825
Issuance of common stock upon vesting of RSUs	22,195	—	—	—	—	—
Issuance of common stock upon 2018 bonus payout	109,168	—	1,350	—	—	1,350
Stock-based compensation expense	—	—	9,813	—	—	9,813
Other comprehensive income - cumulative translation adjustment	—	—	—	(136)	—	(136)
Net income (loss)	—	—	—	—	(20,004)	(20,004)
Balances at March 31, 2019	69,338,697	7	966,731	(418)	(1,004,835)	(38,515)
Issuance of common stock upon exercise of stock options	108,374	—	674	—	—	674
Issuance of common stock upon ESPP purchase	180,077	—	1,878	—	—	1,878
Stock-based compensation expense	—	—	8,504	—	—	8,504
Other comprehensive income - cumulative translation adjustment	—	—	—	(93)	—	(93)
Net income	—	—	—	—	23,567	23,567
Balances at June 30, 2019	69,627,148	$ 7	$ 977,787	$ (511)	$ (981,268)	$ (3,985)

See accompanying notes to condensed consolidated financial statements.

Coherus BioSciences, Inc.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(in thousands, except share and per share data)
(unaudited)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Coherus Stockholders' Equity	Non-controlling	Total Stockholders' Equity
	Shares	Amount	Capital	Loss	Deficit	(Deficit)	Interest	(Deficit)
Balances at December 31, 2017	59,840,467	$ 6	$ 808,060	$ (750)	$ (775,492)	$ 31,824	$ (1,289)	$ 30,535
Issuance of common stock in connection with common stock offerings, net	192,642	—	1,748	—	—	1,748	—	1,748
Issuance of common stock upon exercise of stock options	121,116	—	225	—	—	225	—	225
Stock-based compensation expense	—	—	8,720	—	—	8,720	—	8,720
Other comprehensive loss - unrealized gain in marketable securities	—	—	—	(1)	—	(1)	—	(1)
Other comprehensive loss - cumulative translation adjustment	—	—	—	(13)	—	(13)	—	(13)
Distributions to non-controlling interest	—	—	—	—	—	—	(5)	(5)
Net loss - attributable to Coherus	—	—	—	—	(44,297)	(44,297)	—	(44,297)
Balances at March 31, 2018	60,154,225	6	818,753	(764)	(819,789)	(1,794)	(1,294)	(3,088)
Issuance of common stock in connection with common stock offerings, net	7,399,411	1	98,638	—	—	98,639	—	98,639
Issuance of common stock upon exercise of stock options	89,296	—	284	—	—	284	—	284
Issuance of common stock upon vesting of RSUs	5,000	—	—	—	—	—	—	—
Issuance of common stock upon ESPP purchase	95,099	—	764	—	—	764	—	764
Stock-based compensation expense	—	—	8,690	—	—	8,690	—	8,690
Other comprehensive loss - unrealized gain in marketable securities	—	—	—	1	—	1	—	1
Other comprehensive loss - cumulative translation adjustment	—	—	—	226	—	226	—	226
Distributions to non-controlling interest	—	—	—	—	—	—	(47)	(47)
Net loss - attributable to Coherus	—	—	—	—	(43,638)	(43,638)	—	(43,638)
Balances at June 30, 2018	67,743,031	$ 7	$ 927,129	$ (537)	$ (863,427)	$ 63,172	$ (1,341)	$ 61,831

See accompanying notes to condensed consolidated financial statements.

Coherus BioSciences, Inc.

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

	Six Months Ended June 30,	
	2019	**2018**
Operating activities		
Net income (loss)	$ 3,563	$ (87,987)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	1,365	1,824
Remeasurement of fair-value contingent consideration	4	(3,195)
Stock-based compensation expense	17,486	17,410
Non-cash accretion of discount on marketable securities	(127)	(114)
Non-cash interest expense from amortization of debt discount	1,127	725
Excess and obsolete inventory	410	—
Non-cash operating lease expense	818	—
Changes in operating assets and liabilities:		
Trade receivables, net	(77,385)	—
Inventory	(16,706)	—
Prepaid manufacturing	1,158	4,699
Other prepaid and current assets	(2,630)	893
Accounts payable	4,024	(2,333)
Accounts payable - related parties	50	(233)
Accrued rebates, fees and reserve	20,650	—
Accrued compensation	1,620	3,111
Accrued and other liabilities	1,317	(3,697)
Lease liabilities	(1,020)	—
Other liabilities, non-current	(30)	(217)
Net cash used in operating activities	(44,306)	(69,114)
Investing activities		
Purchases of property and equipment	(517)	(86)
Purchases of investments in marketable securities	(14,864)	(42,869)
Proceeds from maturities of investments in marketable securities	9,000	13,170
Net cash used in investing activities	(6,381)	(29,785)
Financing activities		
Proceeds from common stock offering, net of underwriters discounts, commissions and offering costs	8,153	100,497
Proceeds from term loan, net of issuance costs	73,061	—
Proceeds from issuance of common stock upon exercise of stock options	1,395	509
Proceeds from ESPP purchase	1,878	764
Net cash provided by financing activities	84,487	101,770
Effect of exchange rate changes in cash, cash equivalents and restricted cash	(229)	213
Net increase in cash, cash equivalents and restricted cash	33,571	3,084
Cash, cash equivalents and restricted cash at beginning of period	73,191	127,756
Cash, cash equivalents and restricted cash at end of period	$ 106,762	$ 130,840
Supplemental disclosure of cash flow information		
Non-cash 2018 bonus payment settled in common stock	$ 1,350	$ —

See accompanying notes to condensed consolidated financial statements.

1. Organization and Operations

Description of the Business

Coherus BioSciences, Inc. (the "Company", "Coherus", "we", our" or "us") is a commercial-stage biotherapeutics company, focused on the global biosimilar market. The Company's headquarters and laboratories are located in Redwood City, California and in Camarillo, California, respectively.

On September 25, 2018, the Company received regulatory approval for the marketing of UDENYCA® (pegfilgrastim-cbqv), a biosimilar to Neulasta, a long-acting granulocyte-colony stimulating factor, from the European Commission, and received regulatory approval for UDENYCA® from the U.S. Food and Drug Administration ("FDA") on November 2, 2018. The Company initiated U.S. sales of UDENYCA® on January 3, 2019.

Need to Raise Additional Capital

As of June 30, 2019, the Company had an accumulated deficit of $981.3 million and cash and cash equivalents and short-term investments in marketable securities of $111.9 million. In January 2019, the Company issued and sold 761,130 shares of common stock at a weighted average price of $11.17 per share through its ATM Offering Program and received total net proceeds of $8.2 million (see Note 10). As of January 19, 2019, the Company's Shelf Registration Statement expired and accordingly the ATM Program was terminated. The Company also entered into a credit agreement (the "Term Loan") with affiliates of Healthcare Royalty Partners consisting of a six-year term loan facility for an aggregate principal of $75.0 million in January 2019. The Company believes that its current available cash, cash equivalents, short-term investments in marketable securities and cash collected from UDENYCA® sales will be sufficient to fund its planned expenditures and meet the Company's obligations for at least 12 months following our financial statement issuance date. Although the Company was profitable for the three and six months ended June 30, 2019, the Company may 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 generate sufficient cash from product sales or 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 June 30, 2019: Coherus Intermediate Corp, InteKrin Therapeutics Inc. ("InteKrin"), and InteKrin's wholly-owned subsidiary, InteKrin Russia. Unless otherwise specified, references to the Company are references to Coherus and its consolidated subsidiaries. All intercompany transactions and balances have been eliminated upon consolidation. 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 (the "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 consolidated 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 28, 2019.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgements, estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenue and expenses, and related disclosures. 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 income, net in the condensed consolidated statements of operations for the three months ended June 30, 2019 and 2018, were a net gain of $61,000 and a net loss of $270,000, respectively, and for the six months ended June 30, 2019 and 2018 were a net gain of $230,000 and a net loss of $278,000, respectively.

Segment Reporting

The Company operates and manages its business as one reportable and operating segment, which is the business of developing and commercializing biosimilar products, and, 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. See Note 6 for disclosures about product sales and revenue from major customers.

Cash, Cash Equivalents and Restricted Cash

Cash, cash equivalents and restricted cash is comprised of cash and highly liquid investments with remaining maturities of 90 days or less at the date of purchase. The Company limits cash investments to financial institutions with high credit standings; therefore, management believes that there is no significant exposure to any credit risk in the Company's cash, cash equivalents and restricted cash.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets and which, in aggregate, represent the amount reported in the condensed consolidated statements of cash flows.

	June 30, 2019	June 30, 2018
Cash and cash equivalents	$ 105,927	$ 130,005
Restricted cash	50	50
Restricted cash - non-current	785	785
Total cash, cash equivalents and restricted cash	$ 106,762	$ 130,840

Restricted cash consists of cash held in money market accounts at banks. The restricted cash is used as collateral against the Company's corporate credit cards and is classified as current; restricted cash – non-current is held to cover the standby letter of credit issued by the Company's landlord to drawdown on in the event the facility lease is breached.

Trade Receivables

Trade receivables are recorded net of allowances for chargebacks and cash discounts for prompt payment. The Company's estimate of the allowance for doubtful accounts is based on an evaluation of the aging of its receivables. Trade receivable balances are written off against the allowance when it is probable that the receivable will not be collected. To date, the Company has determined that an allowance for doubtful accounts is not required.

Investments in Marketable Securities

Management determines the appropriate classification of investments in marketable securities at the time of purchase based upon management's intent with regards to such investments and reevaluates such designation as of each balance sheet date. All investments in marketable securities are held as "available-for-sale" and are carried at the estimated fair value as determined based upon quoted market prices or pricing models for similar securities.

The Company classifies investments in marketable securities as short-term when they have remaining contractual maturities of one year or less from the balance sheet date. Unrealized gains and losses are excluded from earnings and are reported as a component of accumulated comprehensive income (loss). Realized gains and losses and declines in value judged to be other than temporary, if any, on available-for-sale securities are included in other income, net, based on the specific identification method.

Inventory

Prior to the regulatory approval of its product candidates, the Company incurred expenses for the manufacture of drug products that could potentially be available to support the commercial launch of its products. The Company began to capitalize inventory costs associated with UDENYCA® after receiving regulatory approval for UDENYCA® in November 2018 when it was determined that the inventory had a probable future economic benefit.

Inventory is stated at the lower of cost or estimated net realizable value with cost determined under the first-in first-out method. Inventory costs include third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process and indirect overhead costs. The Company primarily uses actual costs to determine the cost basis for inventory. The determination of whether inventory costs will be realizable requires management review of the expiration dates of UDENYCA® compared to its forecasted sales. If actual market conditions are less favorable than projected by management, write-downs of inventory may be required which would be recorded as cost of goods sold in the condensed consolidated statement of operations.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use assets, other liabilities, and lease liabilities, non-current in the condensed consolidated balance sheets. Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, the Company uses the incremental borrowing rate based on the information available at the lease commencement date. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term.

Revenue Recognition

The Company adopted ASU 2014-09, *Revenue from Contracts with Customers* (Topic 606), ASU 2014-09: ASU No. 2016-08, *Revenue from Contracts with Customers* (Topic 606): *Principal versus Agent Considerations*; ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*; and ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*, (collectively, the "New Revenue Standard") on January 1, 2018 using the modified retrospective method.

Topic 606 supersedes all previous revenue recognition requirements in accordance with generally accepted accounting principles. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration to which the entity is entitled to in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines is within the scope of Topic 606, it performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the performance obligation is satisfied. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods or services it transferred to the customer.

Net Product Revenue

The Company sells UDENYCA® to wholesalers and distributors, (collectively, "Customers"). The Customers then resell UDENYCA® to hospitals and clinics (collectively, "Healthcare Providers") pursuant to contracts with the Company. In addition to distribution agreements with Customers and contracts with Healthcare Providers, the Company enters into arrangements with group purchasing organizations ("GPOs") that provide for U.S. government-mandated or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of UDENYCA®. The Company also enters into rebate arrangements with payers, which consist primarily of commercial insurance companies and government entities, to cover the reimbursement of UDENYCA® to Healthcare Providers. The Company provides co-payment assistance to patients who have commercial insurance and meet certain eligibility requirements. Revenue from product sales is recognized when a Customer controls the product, which occurs upon delivery of UDENYCA® to and acceptance by that Customer.

Product Sales Discounts and Allowances

Revenues from product sales are recorded at the net sales price ("transaction price"), which includes estimates of variable consideration for which reserves are established and that result from chargebacks, rebates, co-pay assistance, prompt-payment discounts, returns and other allowances that are offered within contracts between the Company and its Customers, Healthcare Providers, payers and GPOs relating to the sales of UDENYCA®. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of trade receivables (if the amount is payable to a Customer) or a current liability (if the amount is payable to a party other than a Customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as historical experience, current contractual and statutory requirements, specifically known market events and trends, industry data and forecasted Customer buying and payment patterns. Overall, these reserves reflect the best estimates of the amount of consideration to which the Company is entitled based on the terms of its contracts. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from its estimates. If actual results in the future vary from the Company's estimates, the estimates will be adjusted, which would affect net product revenue in the period that such variances become known.

Chargebacks: Chargebacks are discounts that occur when Healthcare Providers purchase directly from a Customer. Healthcare Providers, which belong to Public Health Service institutions, non-profit clinics, government entities, GPOs, and health maintenance organizations, generally purchase the product at a discounted price. The Customer, in turn, charges back to the Company the difference between the price initially paid by the Customer and the discounted price paid by the Healthcare Providers to the Customer. The allowance for chargebacks is based on an estimate of sales through to Healthcare Providers from the Customer.

Discounts for Prompt Payment: The Company provides for prompt payment discounts to its Customers, which are recorded as a reduction in revenue in the same period that the related product revenue is recognized.

Rebates: Rebates include mandated discounts under the Medicaid Drug Rebate Program, other government programs and commercial contracts. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with these public sector benefit providers. Certain rebate amounts commensurate with share utilization of UDENYCA relative to other pegfilgrastim products. The accrual for rebates is based on statutory or contractual discount rates and expected utilization. The estimates for the expected utilization of rebates are based on Customer and commercially available payer data, as well as data collected from the Healthcare Providers, Customers, GPOs, and historical utilization rates. Rebates invoiced by payers, Healthcare Providers and GPOs are paid in arrears. If actual future rebates vary from estimates, the Company may need to adjust its accruals, which would affect net product revenue in the period of adjustment.

Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue.

Product Returns: The Company offer to its Customers limited product return right, which is principally based upon damaged, defective or the product's expiration date. Product return allowance is estimated and recorded at the time of sale.

Other Allowances: The Company pays fees to Customers and GPOs for account management, data management and other administrative services. To the extent that the services received are distinct from the sale of products to the customer, these payments are classified in selling, general and administrative expense in the Company's condensed consolidated statements of operations, otherwise they are included as a reduction to product revenue.

Cost of Goods Sold

Cost of goods sold consists primarily of third-party manufacturing, distribution, and overhead costs associated with UDENYCA®. A portion of the costs of producing UDENYCA® sold to date was expensed as research and development prior to the FDA approval of UDENYCA® and therefore it is not reflected in the cost of goods sold.

On May 2, 2019, the Company and Amgen settled a trade secret action brought by Amgen. The Company will pay a mid-single digit royalty on net product revenue to Amgen beginning on July 1, 2019 for five years.

Cost of goods sold for the six months ended June 30, 2019, included write-off of prepaid manufacturing costs of $1.3 million due to the cancellation of certain manufacturing reservations, and $0.4 million due to the write-off of excess and obsolete inventory.

Research and Development Expense

Research and development costs are charged to expense as incurred. Research and development expense includes, among other costs, salaries and other personnel-related costs, consultant fees, preclinical costs, cost to manufacture drug candidates and clinical trial costs and supplies, laboratory supplies costs and facility-related costs. Costs incurred under agreements with third parties are charged to expense as incurred in accordance with the specific contractual performance terms of such agreements. Costs of third parties include costs associated with manufacturing drug candidates, preclinical and clinical support activities. Advance payments for goods or services to be received in the future and utilized in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are received.

The Company considers regulatory approval of product candidates to be uncertain, and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. The Company expenses manufacturing costs as incurred to research and development expense for product candidates prior to regulatory approval. If, and when, regulatory approval of a product is obtained, the Company will begin capitalizing manufacturing costs related to the approved product into inventory.

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 (deficit), but are excluded from net income (loss). The Company's other comprehensive income (loss) includes unrealized gains and losses from available-for-sale marketable securities and foreign currency translation adjustments for the six months ended June 30, 2019 and 2018.

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 diluted potential common shares outstanding for the period determined using the treasury stock method for options, RSUs and ESPP and using the if-converted method for the convertible notes (see Note 11).

Income Taxes

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The Company does not expect its unrecognized tax benefits to change significantly over the next twelve months.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had accrued no amounts for interest and penalties related to income tax matters in the Company's consolidated balance sheet at June 30, 2019 and December 31, 2018.

For the three and six months ended June 30, 2019, the Company recorded income tax provision of $51,000, which comprised of state taxes in jurisdictions outside of California for which the Company has a limited operating history. Income tax provision during interim periods is based on applying an estimated annual effective income tax rate to year-to-date income, plus any significant unusual or infrequently occurring items which are recorded in the interim period in accordance with ASC 740-270. The income tax provision for the three months ended June 30, 2019 differs from the U.S. federal statutory rate of 21% primarily due to effect of change in the valuation allowance against the Company's federal deferred tax assets which reduced the Company's net tax expense. The Company maintains a full valuation allowance against its net deferred tax assets due to the Company's history of losses as of June 30, 2019.

Recent Accounting Pronouncements

The following are the recent accounting pronouncements adopted by the Company in 2019:

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU 2016-02). ASU 2016-02 aims to make leasing activities more transparent and comparable, and requires substantially 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 2016-02 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. In July 2018, FASB issued additional authoritative guidance, ASU 2018-11, providing companies with an optional prospective transition method. The Company adopted the new standards on January 1, 2019 using the optional prospective transition method and recognized right-of-use assets of $7.2 million and lease liabilities of $9.2 million on the adoption date on its condensed consolidated balance sheet, comprised of facility lease agreements for its corporate headquarters and laboratory facilities in California. The Company elected the package of practical expedients upon transition, which allows it to apply the guidance prospectively, without reassessing prior conclusions related to contracts containing leases, lease classification and initial direct costs. Accordingly, the results for the six months ended June 30, 2019 are presented under Topic 842, and the results for the six months ended June 30, 2018 and other prior period amounts were not adjusted and continue to be reported in accordance with the historical accounting under prior lease guidance, ASC Topic 840: *Leases* ("Topic 840")." The Company also elected an accounting policy that does not recognize right-of-use assets and lease liabilities related to short-term leases. The Company did not elect to apply the hindsight expedient.

The impact of the adoption of Topic 842 on the accompanying condensed consolidated balance sheet as of January 1, 2019 was as follows (in thousands):

	December 31, 2018	Adjustments Due to the Adoption of Topic 842	January 1, 2019
Operating lease right-of-use asset	$ —	$ 7,172	$ 7,172
Operating lease liabilities:			
Other current liabilities[1]	$ 419	$ 1,665	$ 2,084
Other lease liabilities, non-current[2]	$ 1,645	$ 5,466	$ 7,111

(1) Includes current portion of deferred rent and current portion of operating lease liabilities.

(2) Non-current portion of deferred rent and operating lease liabilities.

The impact of the adoption of Topic 842 on the accompanying condensed consolidated statement of operations as of and for the three and six months ended June 30, 2019 were as follows (in thousands):

	Three Months Ended June 30, 2019		
	As Reported	Higher (Lower)	Balance without the Adoption
Research and development	$ 18,883	$ 39	$ 18,922
Selling, general and administrative	$ 36,456	$ 43	$ 36,499
Total operating expenses	$ 55,940	$ 82	$ 56,022
Income from operations	$ 27,493	$ (82)	$ 27,411
Net income	$ 23,567	$ (82)	$ 23,485
Net income attributable to Coherus	$ 23,567	$ (82)	$ 23,485

	Six Months Ended June 30, 2019		
	As Reported	Higher (Lower)	Balance without the Adoption
Research and development	$ 37,672	$ 83	$ 37,755
Selling, general and administrative	$ 69,139	$ 87	$ 69,226
Total operating expenses	$ 109,637	$ 170	$ 109,807
Income from operations	$ 10,894	$ (170)	$ 10,724
Net income	$ 3,563	$ (170)	$ 3,393
Net income attributable to Coherus	$ 3,563	$ (170)	$ 3,393

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-07), which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-

based payment to employees, with certain exceptions. The amendments in ASU 2018-07 are 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. The Company's early adoption of ASU 2018-07 on January 1, 2019 did not have a material impact on its condensed consolidated financial statements and related disclosures.

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, *Disclosure Update and Simplification.* These amendments eliminate, modify, or integrate into other SEC requirements certain disclosure rules. Among the amendments is the requirement to present an analysis of changes in stockholders' equity in the interim financial statements included in quarterly reports on Form 10-Q. The analysis, which can be presented as a footnote or separate statement, is required for the current and comparative quarter and year-to-date interim periods. The amendments are effective for all filings made on or after November 5, 2018. In light of the anticipated timing of effectiveness of the amendments and expected proximity of effectiveness to the filing date for most filers' quarterly reports, the SEC's Division of Corporate Finance issued a Compliance and Disclosure Interpretation related to Exchange Act Forms, or CDI – Question 105.09, that provides transition guidance related to this disclosure requirement. CDI – Question 105.09 states that the SEC would not object if the filer's first presentation of the changes in stockholders' equity is included in its Form 10-Q for the quarter that begins after the effective date of the amendments. As such, the Company adopted these SEC amendments on November 5, 2018 and has presented the analysis of changes in stockholders' equity in its interim financial statements in its June 30, 2019 Form 10-Q. The Company adopted the Securities Act Release No. 33-10532 on January 1, 2019 and such adoption did not have a material effect on the Company's financial position, results of operations, cash flows or stockholders' equity.

The following are the recent accounting pronouncements that the Company has not yet adopted:

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326) (ASU 2016-13).* ASU 2016-13 implements an impairment model, known as the current expected credit loss model that is based on expected losses rather than incurred losses. Under the new guidance, an entity will recognize as an allowance its estimate of expected credit losses. ASU 2016-13 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-13 will have on its consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other: Simplifying the Test for Goodwill Impairment* (ASU 2017-04), which simplifies the current requirements for testing goodwill for impairment by eliminating the second step of the two-step impairment test to measure the amount of an impairment loss. ASU 2017-04 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2017-04 will have on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurements* (ASU 2018-13), which eliminates certain disclosure requirements for fair value measurements, and requires public entities to disclose certain new information and modifies some disclosure requirements. The new guidance is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2018-13 will have on its consolidated financial statements and related disclosures.

The Company has reviewed other recent accounting pronouncements and concluded they are either not applicable to the business or that no material effect is expected on the 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, restricted cash, investments in marketable securities, 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.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The Company's financial instruments consist of Level 1 and Level 2 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.

When quoted market prices are not available for the specific security, then the Company estimates the fair value by using quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third party data providers, including but not limited to, benchmark yields, interest rate curves, reported trades, broker/dealer quotes and market reference data. Level 2 assets consist of corporate notes and commercial paper. Level 2 inputs for the valuations are limited to quoted prices for similar assets or liabilities in active markets and inputs other than quoted prices that are observable for the asset or liability.

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.

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented.

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 June 30, 2019			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Money market funds	$ 83,326	$ 83,326	$ —	$ —
Restricted cash (money market funds)	835	835	—	—
Corporate notes and commercial paper	12,573	—	12,573	—
Total financial assets	$ 96,734	$ 84,161	$ 12,573	$ —
Financial Liabilities:				
Contingent consideration	$ 64	$ —	$ —	$ 64

	Fair Value Measurements December 31, 2018			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Money market funds	$ 71,062	$ 71,062	$ —	$ —
Restricted cash (money market funds)	835	835	—	—
Total financial assets	$ 71,897	$ 71,897	$ —	$ —
Financial Liabilities:				
Contingent consideration	$ 60	$ —	$ —	$ 60

Cash equivalents, investments in marketable securities, which are classified as available-for-sale securities, and restricted cash, consisted of the following (in thousands):

	June 30, 2019			
	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Money market funds	$ 83,326	$ —	$ —	$ 83,326
Corporate notes and commercial paper	6,582	—	—	6,582
Classified as cash equivalents	$ 89,908	$ —	$ —	$ 89,908
Corporate notes and commercial paper	$ 5,991	$ —	$ —	$ 5,991
Classified as investments in marketable securities	$ 5,991	$ —	$ —	$ 5,991
Restricted cash (money market funds)	$ 835	$ —	$ —	$ 835
Classified as restricted cash	$ 835	$ —	$ —	$ 835

	December 31, 2018			
	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Money market funds	$ 71,062	$ —	$ —	$ 71,062
Classified as cash equivalents	$ 71,062	$ —	$ —	$ 71,062
Restricted cash (money market funds)	$ 835	$ —	$ —	$ 835
Classified as restricted cash	$ 835	$ —	$ —	$ 835

As of June 30, 2019, the remaining contractual maturities of available-for-sale securities were less than one year. The average maturity of investments in marketable securities available-for-sale as of June 30, 2019 was approximately four months. The gross realized gains were $145,000 and $143,000 for the three months ended June 30, 2019 and 2018, respectively, and $257,000 and $226,000 for the six months ended June 30, 2019 and 2018, respectively, in the condensed consolidated statement of operations. There were no gross realized losses for the three and six months ended June 30, 2019 and 2018, in the condensed consolidated statement of operations.

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 (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”). The contingent consideration related to the Earn-Out Payment was settled on March 6, 2015.

The 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 as of June 30, 2019 applied a 20% risk-adjusted discount rate to measure the present value and also captured an additional 8% credit spread for counterparty credit risk given the cash payment. The expected cash flow is based on estimates provided by the Company’s management including the timing and probability of occurrence. The value of the consideration is tiered based on the value of a license or similar agreement with a third party and the timing of such agreement. 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 an immaterial fair value fluctuation.

The change in the fair value of the Compound Transaction Payment was recognized in other income, net within the condensed consolidated statement of operations of $0 and $3.4 million for the three months ended June 30, 2019 and 2018, respectively, and $4,000 and $3.2 million for the six months ended June 30, 2019 and 2018, respectively.

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

Balance as of December 31, 2018	$	60
Change in fair value of the contingent consideration liability		4
Balance as of June 30, 2019	$	64

Convertible Notes

The estimated fair value of the 8.2% Convertible Senior Notes due in March 2022, which the Company issued on February 29, 2016 (see Note 7) is based on an income approach. The estimated fair value was approximately $131.9 million (par value $100.0 million) as of June 30, 2019 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. Inventory

The Company began capitalizing inventory in November 2018 upon the FDA approval of UDENYCA®. Inventory consisted of the following (in thousands):

		June 30, 2019		December 31, 2018
Raw Materials	$	3,911	$	2,851
Work in process		15,587		1,576
Finished goods		3,300		1,244
Total	$	22,798	$	5,671

Balance sheet classifications (in thousand):

		June 30, 2019		December 31, 2018
Inventory	$	4,333	$	1,659
Inventory, non-current		18,465		4,012
Total	$	22,798	$	5,671

Inventory expected to be sold in periods more than twelve months from the balance sheet date is classified as inventory, non-current on the balance sheet. As of June 30, 2019, the non-current portion of inventory consisted of raw materials, work in process and a portion of the finished goods. As of December 31, 2018, the non-current portion of inventory consisted of raw materials and a portion of work in process.

Prepaid manufacturing of $6.3 million and $6.6 million on the condensed consolidated balance sheet as of June 30, 2019 and December 31, 2018, respectively, includes a prepayment made to a contract manufacturing organization ("CMO") for manufacturing services and raw materials, which the Company expects to be converted into inventory within the next twelve months.

5. Balance Sheet Components

Property and Equipment, Net

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

	June 30, 2019	December 31, 2018
Machinery and equipment	$ 11,676	$ 11,505
Computer equipment and software	2,880	1,651
Furniture and fixtures	714	714
Leasehold improvements	4,364	4,364
Construction in progress	414	1,463
Total property and equipment	20,048	19,697
Accumulated depreciation and amortization	(14,402)	(13,037)
Property and equipment, net	$ 5,646	$ 6,660

Depreciation and amortization expense was $674,000 and $902,000 for the three months ended June 30, 2019 and 2018, respectively, and $1.4 million and $1.8 million for the six months ended June 30, 2019 and 2018, respectively.

Accrued Liabilities

Accrued liabilities are as follows (in thousands):

	June 30, 2019	December 31, 2018
Accrued clinical and manufacturing	$ 4,884	$ 3,950
Accrued other	3,411	3,058
Accrued liabilities	$ 8,295	$ 7,008

6. Revenue

The Company initiated U.S. sales of UDENYCA® on January 3, 2019. The Company recorded net product revenue of $83.4 million and $120.5 million during the three and six months ended June 30, 2019, respectively. There was no product revenue during the three or six months ended June 30, 2018.

Revenue by significant Customer was distributed as follows:

	Three Months Ended June 30, 2019 Percent of Total	Six Months Ended June 30, 2019 Percent of Total
McKesson	42%	43%
AmeriSource-Bergen Corp	31%	32%
Cardinal	25%	23%
Others	2%	2%
Total revenue	100%	100%

Product Sales Discounts and Allowances

The activities and ending reserve balances for each significant category of discounts and allowances, which constitute variable consideration, were as follows (in thousands):

	Chargebacks and Discounts for Prompt Payment	Rebates	Other Fees, Co-pay Assistance and Returns	Total
Balance at December 31, 2018	$ —	$ —	$ —	$ —
Activity related to 2019 sales	65,726	8,593	22,843	97,162
Payments and customer credits issued	(42,368)	(1,095)	(9,692)	(53,155)
Balance at June 30, 2019	$ 23,358	$ 7,498	$ 13,151	$ 44,007

Chargebacks and discounts for prompt payment are recorded as a reduction of trade receivables, and the remaining reserve balances are classified as current liabilities in the accompanying condensed consolidated balance sheets except for the co-pay assistance, which is reflected as a net prepayment in other prepaid assets on the condensed consolidated balance sheets.

7. Convertible Notes and Term Loan

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"). 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. 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 negative covenants and 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 Note. As of June 30, 2019, 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 following table summarizes information about the components of the Convertible Notes (in thousands):

	June 30, 2019	December 31, 2018
Principal amount of the Convertible Notes	$ 81,750	$ 81,750
Unamortized debt discount and debt issuance costs	(3,834)	(4,431)
Convertible Notes	$ 77,916	$ 77,319
Principal amount of the Convertible Notes - related parties	$ 27,250	$ 27,250
Unamortized debt discount and debt issuance costs - related parties	(1,278)	(1,477)
Convertible Notes - related parties	$ 25,972	$ 25,773
Total Convertible Notes	$ 103,888	$ 103,092

If the Convertible Notes were to be converted on June 30, 2019, the holders of the Convertible Notes would receive common shares with an aggregate value of $98.9 million based on the Company's closing stock price of $22.10.

The following table presents the components of interest expense (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Stated coupon interest	$ 1,538	$ 1,538	$ 3,075	$ 3,075
Accretion of debt discount and debt issuance costs	302	275	597	544
Interest expense	$ 1,840	$ 1,813	$ 3,672	$ 3,619
Stated coupon interest - related parties	$ 512	$ 512	$ 1,025	$ 1,025
Accretion of debt discount and debt issuance costs - related parties	101	92	199	181
Interest expense - related parties	$ 613	$ 604	$ 1,224	$ 1,206
Total interest expense	$ 2,453	$ 2,417	$ 4,896	$ 4,825

The remaining unamortized debt discount and debt offering costs related to the Company's Convertible Notes of approximately $5.1 million as of June 30, 2019, will be amortized using the effective interest rate over the remaining term of the Convertible Notes of 2.75 years. The annual effective interest rate is 9.48% for the Convertible Notes. The Company recognized total interest expense of $2.5 million and $2.4 million for the three months ended June 30, 2019 and 2018, respectively, and $4.9 million and $4.8 million for the six month periods ended June 30, 2019 and 2018, respectively, related to the Convertible Notes' accrued interest and amortization of the debt discount.

Future payments on the Convertible Notes as of June 30, 2019 are as follows (in thousands):

Year ending December 31,	
Remainder of 2019	$ 4,100
2020	8,200
2021	8,200
2022	111,050
Total minimum payments	131,550
Less amount representing interest	(22,550)
Convertible Notes, principal amount	109,000
Less debt discount and debt issuance costs on Convertible Notes	(5,112)
Net carrying amount of Convertible Notes	$ 103,888

Term Loan

On January 7, 2019 ("the "Term Loan Closing Date"), the Company entered into a credit agreement (the "Term Loan") with affiliates of Healthcare Royalty Partners (together, the "Lender"). The Term Loan consists of a six-year term loan facility for an aggregate principal amount of $75.0 million (the "Borrowings"). The obligations of the Company under the loan documents are guaranteed by the Company's material domestic U.S. subsidiaries.

The Borrowings under the Term Loan bear interest through maturity at 7.00% per annum plus three month LIBOR ("LIBOR"). If the consolidated net sales for UDENYCA® for the fiscal year ending December 31, 2019, are in excess of $250.0 million, then the interest rate will be reduced as of January 1, 2020 to 6.75% per annum plus LIBOR. Interest is payable quarterly in arrears and varies with LIBOR. The Company adopted the prospective method to account for future cash payments. Under the prospective method, the effective interest rate is not constant, and any change in the expected cash flows is recognized prospectively as an adjustment to the effective yield. As of June 30, 2019, the effective interest rate is 10.7%.

The Company is required to pay principal on the Borrowings in equal quarterly installments beginning on the four year anniversary of the Term Loan Closing Date (or, if consolidated net sales of UDENYCA® in the fiscal year ending December 31, 2021 are less than $375.0 million, beginning on the three year anniversary of the Term Loan Closing Date), with the outstanding balance to be repaid on January 7, 2025, the maturity date.

The Company is also required to make mandatory prepayments of the Borrowings under the Term Loan, subject to specified exceptions, with the proceeds of asset sales, extraordinary receipts, debt issuances and specified other events including the occurrence of a change in control.

If all or any of the Borrowings are prepaid or required to be prepaid under the Term Loan, then the Company shall pay, in addition to such prepayment, a prepayment premium equal to (i) with respect to any prepayment paid or required to be paid on or prior to the three year anniversary of the Credit Agreement Closing Date, 5.00% of the Borrowings prepaid or required to be prepaid, plus all required interest payments that would have been due on the Borrowings prepaid or required to be prepaid through and including the three year anniversary of the Term Loan Closing Date, (ii) with respect to any prepayment paid or required to be paid after the three year anniversary of the Term Loan Closing Date but on or prior to the four year anniversary of the Term Loan Closing Date, 5.00% of the Borrowings prepaid or required to be prepaid, (iii) with respect to any prepayment paid or required to be paid after the four year anniversary of the Term Loan Closing Date but on or prior to the five year anniversary of the Term Loan Closing Date, 2.50% of the Borrowings prepaid or required to be prepaid, and (iv) with respect to any prepayment paid or required to be prepaid thereafter, 1.25% of the Borrowings prepaid or required to be prepaid.

In connection with the Term Loan, the Company paid a fee to the Lender of approximately $1.1 million at closing in the form of an original issue discount. Upon the prepayment or maturity of the Borrowings (or upon the date such prepayment or repayment is required to be paid), it is required to pay an additional exit fee in an amount equal to 4.00% of the total principal amount of the Borrowings.

The obligations under the Term Loan are secured by a lien on substantially all of the Company's and its Guarantors' tangible and intangible property, including intellectual property. The Term Loan contains certain affirmative covenants, negative covenants and events of default, including, covenants and restrictions that among other things, restrict the ability of the Company and its subsidiaries to, incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, in asset sales, and declare dividends or redeem or repurchase capital stock. Additionally, the consolidated net sales for UDENYCA® must not be lower than $70.0 million for the fiscal year ending December 31, 2019, (b) $125.0 million for the fiscal year ending December 31, 2020, and (c) $150.0 million for each fiscal year thereafter. A failure to comply with these covenants could permit the Lender under the Term Loan to declare the Borrowings, together with accrued interest and fees, to be immediately due and payable.

The following table summarizes information about the components of the Term Loan (in thousands):

	June 30, 2019
Principal amount of the Term Loan	$ 75,000
Unamortized debt discount and debt issuance costs	(1,714)
Term Loan	$ 73,286

The following table presents the components of interest expense (in thousands):

	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Stated coupon interest	$ 1,801	$ 3,421
Accretion of debt discount and debt issuance costs	179	332
Interest expense	$ 1,980	$ 3,753

The remaining unamortized debt discount and debt offering costs related to the Term Loan of approximately $4.7 million as of June 30, 2019, will be amortized using the effective rate over the remaining term of the Term Loan of 5.5 years. During the three and six months ended June 30, 2019, the Company recognized total interest expense of $2.0 million and $3.8 million, respectively, related to the Term Loan's accrued interest and amortization of the debt discount.

Future payments on the Term Loan as of June 30, 2019 are as follows (in thousands):

Year ending December 31,		
Remainder of 2019	$	3,641
2020		7,244
2021		7,224
2022		7,224
2023		39,346
2024 and beyond		47,495
Total minimum payments		112,174
Less amount representing interest		(34,174)
Term Loan, gross		78,000
Less debt discount and debt issuance costs on Term Loan		(4,714)
Net carrying amount of Term Loan	$	73,286

8. Commitments and Contingencies

Purchase Commitments

The Company entered into agreements with a vendor and a CMO for the supplies of raw materials and manufacturing of commercial supply of UDENYCA®. As of June 30, 2019, the Company's contractual obligations under the terms of the agreements were as follows (in thousands):

Years ending December 31,		
Remainder of 2019	$	9,845
2020		24,975
2021		600
2022		600
Total obligations	$	36,020

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 for the manufacture of clinical trial materials. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would only be obligated for products or services that the Company had received as of the effective date of the termination and any applicable cancellation fees.

Contingencies

On March 3, 2017, Amgen Inc. and Amgen USA Inc. (collectively "Amgen") filed an action against the Company, KBI BioPharma Inc., the Company's employee Howard S. Weiser and Does 1-20 in the Superior Court of the State of California, County of Ventura. The complaint alleges that the Company engaged in unfair competition and improperly solicited and hired certain former Amgen employees in order to acquire and access trade secrets and other confidential information belonging to Amgen. On June 1, 2017, Amgen filed a Second Amended Complaint, which alleges as to Coherus (i) unfair competition under California Business and Professions Code Section 17200 et seq., (ii) misappropriation of trade secrets, (iii) aiding and abetting breach of duty of loyalty and (iv) tortious interference with contract. As to defendant Weiser, the Second Amended Complaint alleges (i) unfair competition under California Business and Professions Code Section 17200 et seq., (ii) misappropriation of trade secrets, (iii) breach of contract, (iv) violation of Penal Code Section 502 and (v) breach of duty of loyalty. KBI BioPharma Inc. is not named as a defendant in the Second Amended Complaint. The Second Amended Complaint seeks injunctive relief and monetary damages. Although Amgen has indicated it intends to seek a preliminary injunction, no motion has been filed yet. The court has set a trial date of April 22, 2019. On May 2, 2019, the Company and Amgen settled the trade secret action brought by Amgen. The details of the settlement are confidential but the Company will continue to market UDENYCA® and will pay a mid-single digit royalty to Amgen for five years beginning on July 1, 2019 (see Note 12).

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.

9. Leases

In July 2015, the Company entered into the office lease space for its corporate headquarters in Redwood City, California under operating lease agreement, which has been subject to an amendment to secure additional space such that the total headquarters lease space is approximately 40,341 square feet. The lease agreement, as amended, provided for aggregate tenant improvement allowance of $1.4 million, which was amortized as a reduction to rent expense on a straight-line basis over the lease term prior to the adoption of Topic 842 (see Note 2). Additionally, the lease agreement, as amended, provides for certain limited rent abatement and contains annual scheduled rent increases over the lease term. The lease terminates in November 2022 and contains a one-time option to extend the lease term for five years. As part of the lease agreement, the Company obtained a standby letter of credit (the "Letter of Credit") in an amount of approximately $0.8 million, which may be drawn down by the landlord to be applied for certain purposes upon the Company's breach of any provisions under of the lease. The Company will be entitled to periodically reduce the amount of the Letter of Credit during the lease term. The Letter of Credit of $0.8 million is recorded as restricted cash, non-current within the consolidated balance sheet at June 30, 2019 and December 31, 2018.

The Company also leases laboratory facilities in Camarillo, California under an operating lease agreement, which has been subject to several amendments necessary to secure additional space and extend the lease term to June 30, 2020, and December 31, 2020 on the two facility structures.

Effective upon the adoption of Topic 842, the Company evaluated the above facility leases and determined that they were all operating leases. In determining the present value of the lease payments, the Company used the incremental borrowing rate based on the information available at the adoption date. The lease option to extend the lease term for five years was not included as part of the right-of-use asset or lease liability as the Company was not reasonably certain it would exercise this option. The Company also performed an evaluation of its other contracts with Customers and suppliers in accordance with Topic 842 and determined that, except for the facility leases described above, none of its contracts contain a lease.

The balance sheet classification of the lease liabilities was as follows (in thousands):

	June 30, 2019
Operating lease liabilities	
Other liabilities	$ 2,198
Lease liabilities, non-current	5,977
Total operating lease liabilities	$ 8,175

Operating lease costs were $0.5 million and $1.1 million for the three and six months ended June 30, 2019, respectively. Cash paid for amounts included in the measurement of the lease liabilities for the three and six months ended June 30, 2019 was $0.7 million and $1.3 million, respectively, and was included in net cash used in operating activities in the condensed consolidated statements of cash flows.

As of June 30, 2019, the maturities of the operating lease liabilities were as follows (in thousands):

Years ending December 31,	Operating leases
Remainder of 2019	$ 1,333
2020	2,695
2021	2,672
2022	2,518
Total lease payments	9,218
Less imputed interest	(1,043)
Operating lease liabilities	$ 8,175

As of June 30, 2019, the weighted average remaining lease term was 3.4 years and the weighted average operating discount rate used to determine the operating lease liabilities was 7.0%.

10. Common Stock and Stock-Based Compensation

Common Stock Offerings

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.

In the first quarter of 2019, the Company sold 761,130 shares of common stock at a weighted average price of $11.17 per share through its ATM Offering Program and received total gross proceeds of $8.5 million. After deducting commission and offering expenses of $0.3 million, the net proceeds were $8.2 million. As of January 19, 2019, the Company's Shelf Registration Statement expired and accordingly the ATM Offering Program was terminated.

Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	$ 2,963	$ 4,072	$ 6,622	$ 7,835
Selling, general and administrative	5,028	4,618	10,864	9,575
	$ 7,991	$ 8,690	$ 17,486	$ 17,410

Stock-based compensation of $0.5 million and $0 was capitalized into inventory for the three months ended June 30, 2019, and 2018, respectively, and $0.8 million and $0 for the six months ended June 30, 2019 and 2018, respectively. Stock-based compensation capitalized into inventory is recognized as cost of goods sold when the related product is sold.

11. 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 the Company (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Basic net income (loss) per share				
Numerator:				
Net income (loss) attributable to Coherus	$ 23,567	$ (43,638)	$ 3,563	$ (87,935)
Denominator:				
Weighted-average common shares outstanding	69,479,016	63,960,567	69,310,791	62,051,912
Basic net income (loss) per share attributable to Coherus	$ 0.34	$ (0.68)	$ 0.05	$ (1.42)
Diluted net income (loss) per share				
Numerator:				
Net income (loss) attributable to Coherus	$ 23,567	$ (43,638)	$ 3,563	$ (87,935)
Denominator:				
Denominator for basic net income (loss) per share attributable to Coherus	69,479,016	63,960,567	69,310,791	62,051,912
Add effect of potential dilutive securities:				
Stock options	3,469,172	—	2,953,049	—
Restricted stock units	15,784	—	17,724	—
Denominator for diluted net income (loss) per share attributable to Coherus	72,963,972	63,960,567	72,281,564	62,051,912
Diluted net income (loss) per share attributable to Coherus	$ 0.32	$ (0.68)	$ 0.05	$ (1.42)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Stock options, including purchases from contributions to ESPP	10,341,798	13,901,836	10,195,378	13,901,836
Restricted stock units	-	115,064		115,064
Shares issuable upon conversion of Convertible Notes	4,473,871	4,473,871	4,473,871	4,473,871
Total	14,815,669	18,490,771	14,669,249	18,490,771

12. Related Party Transactions

Transactions Associated with Medpace Agreement

A prior member of the Company's board of directors is also the president and chief executive officer of Medpace. As such, Medpace was deemed to be a related party until the director's resignation on March 1, 2018. As a result, the Company no longer reflects balances and transactions associated with Medpace as related party in its consolidated financial statements as of March 31, 2018. The Company recognized $0 and $1.5 million during the three and six months ended June 30, 2018, 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 firm that provides recruiting services to the Company. As such, the recruiting services provided were deemed to be related party transactions. As of June 30, 2019, and December 31, 2018, the Company had $50,000 and $0 in accounts payable - related parties reflected on its condensed consolidated balance sheet, respectively. The Company recorded in research and development in its condensed consolidated statement of operations $50,000 for both the three and six months ended June 30, 2019, and $0 for both the three and six months ended June 30, 2018. The Company recorded in selling, general and administrative in its condensed consolidated statement of operations $1,000 for both the three and six months ended June 30, 2019, and $60,000 and $100,000 for the three and six months ended June 30, 2018, respectively.

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 7 for related party disclosure).

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, 2018, 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 28, 2019. 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 commercial-stage biotherapeutics company focused on the global biosimilar market. Biosimilars are a class of protein-based therapeutics with high similarity to approved originator products on the basis of various structural and biologic properties, as well as in terms of safety and efficacy. 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.

On September 20, 2018, we received regulatory approval for the marketing of UDENYCA® (pegfilgrastim-cbqv), a biosimilar to Neulasta, a long-acting granulocyte-colony stimulating factor, from the European Commission. On November 2, 2018, we received regulatory approval for UDENYCA® from the U.S. Food and Drug Administration ("FDA"). We initiated U.S. sales of UDENYCA® in January 2019.

On January 3, 2019, we initiated the U.S. sales of UDENYCA®, our first commercial product. While we have incurred significant losses historically, we have reached profitability for the three and six months ended June 30, 2019 as a result of UDENYCA® sales increases since January 3, 2019. We anticipate that we will remain profitable if we are able to maintain operating expenses relatively constant and provided that sales of UDENYCA® do not decline in the future. Our net income was $3.6 million for the six months ended June 30, 2019 and our net loss was $43.7 million for the six months ended June 30, 2018. As of June 30, 2019, we had an accumulated deficit of approximately $981.3 million.

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

- CHS-1420 (our adalimumab (Humira) biosimilar candidate). We are developing CHS-1420, an anti-TNF product candidate, as an adalimumab (Humira) biosimilar. In August 2016, we announced positive data from our Phase 3 study in psoriasis patients, followed by confirmatory 24-week results in January 2017, to support a 351(k) BLA in the U.S. In January 2017, we initiated a PK study bridging CHS-1420 to European manufactured Humira and a PK study comparing U.S. Humira to E.U. Humira. We completed two PK bridging studies of CHS-1420, one comparing the Phase 3 CHS-1420 material to U.S. manufactured adalimumab (Humira) in March 2017, and the other comparing CHS-1420 to European manufactured Humira in August 2017. We anticipate that additional investment in manufacturing activities will be required prior to any BLA or MAA submissions. To enable competitive market entry, we plan to set the timing of the 351(k) BLA submission in a manner to be able to launch CHS-1420 in the U.S. on or after July 1, 2023.
- CHS-0214 (our etanercept (Enbrel) biosimilar candidate). 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 anticipate that additional investment in manufacturing activities will be required prior to any MAA or 351(k) BLA submissions for CHS-0214. We have worldwide development and commercial rights to this product except for certain Caribbean and Latin American countries. 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 until expiration, 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 or invalidation.
- CHS-131 (our oral, small-molecule drug candidate). CHS-131 is a potential novel, first-in-class, well-tolerated, once-daily oral drug candidate under development for non-alcoholic steatohepatitis ("NASH") and other metabolic conditions. In June 2019, we opened an investigational new drug application with the FDA for CHS-131 and we plan to initiate a clinical program in NASH patients for CHS-131.

Our preclinical-stage pipeline includes the following product candidates:

- CHS-3351 (our ranibizumab (Lucentis) biosimilar candidate). We are conducting process development, preclinical and manufacturing exercises for CHS-3351, an anti-vascular endothelial growth factor ("anti-VEGF"); and
- CHS-2020 (our aflibercept (Eylea) biosimilar candidate). We have initiated the preclinical development of CHS-2020, our second anti-VEGF biosimilar candidate.

In February 2016, we issued and sold $100.0 million aggregate principal amount of our 8.2% Convertible Senior Notes due in March 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 October 2016, we entered into a sales agreement with Cowen and Company, LLC ("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. In the first quarter of 2019, we sold 761,130 shares of common stock at a weighted average price of $11.17 per share under the ATM Offering Program for aggregate net proceeds of $8.2 million. As of January 19, 2019, our Shelf Registration Statement expired and accordingly the ATM Offering Program expired.

On January 7, 2019 (the "Term Loan Closing Date"), we entered into a credit agreement (the "Term Loan") with affiliates of Healthcare Royalty Partners (together, the "Lender"). The Term Loan consists of a six-year term loan facility for an aggregate principal amount of $75.0 million (the "Borrowings"). Our obligations under the loan documents are guaranteed by our material domestic U.S. subsidiaries.

The Borrowings under the Term Loan bear interest through maturity at 7.00% per annum plus LIBOR (customarily defined). If the consolidated net sales (customarily defined) for UDENYCA® for the fiscal year ending December 31, 2019, are in excess of $250.0 million, then the interest rate will be reduced as of January 1, 2020 to 6.75% per annum plus LIBOR. Interest is payable quarterly in arrears.

We are required to pay principal on the Borrowings in equal quarterly installments beginning on the four year anniversary of the Term Loan Closing Date (or, if consolidated net sales of UDENYCA® in the fiscal year ending December 31, 2021 are less than $375.0 million, beginning on the three year anniversary of the Term Loan Closing Date), with the outstanding balance to be repaid on January 7, 2025, the maturity date.

We are also required to make mandatory prepayments of the Borrowings under the Term Loan, subject to specified exceptions, with the proceeds of asset sales, extraordinary receipts, debt issuances and specified other events including the occurrence of a change in control.

If all or any of the Borrowings are prepaid or required to be prepaid under the Term Loan, then we shall pay, in addition to such prepayment, a prepayment premium equal to (i) with respect to any prepayment paid or required to be paid on or prior to the three year anniversary of the Term Loan Closing Date, 5.00% of the Borrowings prepaid or required to be prepaid, plus all required interest payments that would have been due on the Borrowings prepaid or required to be prepaid through and including the three year anniversary of the Term Loan Closing Date, (ii) with respect to any prepayment paid or required to be paid after the three year anniversary of the Term Loan Closing Date but on or prior to the four year anniversary of the Term Loan Closing Date, 5.00% of the Borrowings prepaid or required to be prepaid, (iii) with respect to any prepayment paid or required to be paid after the four year anniversary of the Term Loan Closing Date but on or prior to the five year anniversary of the Term Loan Closing Date, 2.50% of the

Borrowings prepaid or required to be prepaid, and (iv) with respect to any prepayment paid or required to be prepaid thereafter, 1.25% of the Borrowings prepaid or required to be prepaid.

In connection with the Term Loan, we paid a fee to the Lender of approximately $1.1 million at closing in the form of an original issue discount. Upon the prepayment or maturity of the Borrowings (or upon the date such prepayment or repayment is required to be paid), we are required to pay an additional exit fee in an amount equal to 4.00% of the total principal amount of the Borrowings.

The obligations under the Term Loan are secured by a lien on substantially all of our and our Guarantors' tangible and intangible property, including intellectual property. The Term Loan contains certain affirmative covenants, negative covenants and events of default, including, covenants and restrictions that among other things, restrict our ability and our subsidiaries to, incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, in asset sales, and declare dividends or redeem or repurchase capital stock. Additionally, the consolidated net sales for UDENYCA® must not be lower than $70.0 million for the fiscal year ending December 31, 2019, (b) $125.0 million for the fiscal year ending December 31, 2020, and (c) $150.0 million for each fiscal year thereafter. A failure to comply with these covenants could permit the Lender under the Term Loan to declare the Borrowings, together with accrued interest and fees, to be immediately due and payable.

Financial Operations Overview

Revenue

Our first FDA approved product, UDENYCA®, was approved by the U.S. FDA in November 2018, and we initiated U.S. sales of UDENYCA® on January 3, 2019. We recorded net product revenue of $83.4 million and $120.5 million during the three and six months ended June 30, 2019, respectively. There was no product revenue during the three or six months ended June 30, 2018.

Cost of Goods Sold

Cost of goods sold consists primarily of third-party manufacturing, distribution, and overhead costs associated with UDENYCA®. A portion of the costs of producing UDENYCA® sold to date was expensed as research and development prior to the FDA approval of UDENYCA® and therefore it is not reflected in the cost of goods sold.

Research and Development Expense

Research and development expense represents 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 expense consists primarily of:

- expense incurred under agreements with consultants, third-party contract research organizations ("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 ("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 expense, which include salaries, benefits and stock-based compensation; and
- facilities and other allocated expense, which include direct and allocated expense 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 expense has historically been our investment in research and development activities, including the clinical development and manufacturing process development of our product candidates. We have received regulatory approval for UDENYCA®, as a result, all of our manufacturing costs for this product are capitalized as inventory and subsequently expensed as costs of goods sold when the inventory is sold. For the remainder of 2019, we expect our research and development expense to be similar or slightly higher than in the first half of 2019 as our late-stage product candidates work their way through the regulatory approval process and we prepare for commercialization by increasing manufacturing activities which are expensed as research and development costs.

We consider regulatory approval of product candidates to be uncertain, and any products manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. We expense manufacturing costs as incurred for product candidates prior to regulatory approval as research and development expense. If, and when, regulatory approval of a product candidate is obtained, we will begin capitalizing manufacturing costs related to the approved product into inventory.

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, 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

Selling, General and Administrative Expense

Selling, general and administrative expense consists primarily of personnel costs, allocated facilities costs and other expense for outside professional services, including legal, insurance, human resources, outside marketing, advertising, audit and accounting services, as well as costs associated with establishing commercial capabilities in support of the commercialization of UDENYCA®. Personnel costs consist of salaries, benefits and stock-based compensation.

Interest Expense

Interest expense consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount and debt issuance costs associated with our various outstanding debt agreements.

Other Income, Net

Other income, net consists primarily of gains and losses resulting from the remeasurement of our contingent consideration, interest earned from our investments in marketable securities and foreign exchange gains and losses resulting from currency fluctuations. We will 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 consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles (“U.S. GAAP”). The preparation of financial statements in conformity with U.S. GAAP requires us to make judgements, estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenue and expenses, and related disclosures. As appropriate, we periodically evaluate our critical accounting policies and estimates. Our estimates are based on historical experience and on various other factors that we believed to be reasonable under the circumstances. These estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Accounting estimates and judgements are inherently uncertain and actual results could differ from these estimates.

Leases

We adopted ASU 2016-02, *Leases* on January 1, 2019. We determine if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use assets, other liabilities, and lease liabilities, non-current in the condensed consolidated balance sheets. Right-of-use assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, we use the incremental borrowing rate based on the information available at the lease commencement date. Lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term

Revenue Recognition

We adopted ASU 2014-09, *Revenue from Contracts with Customers* (Topic 606), ASU 2014-09: ASU No. 2016-08, *Revenue from Contracts with Customers* (Topic 606): *Principal versus Agent Considerations*; ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*; and ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*, (collectively, the "New Revenue Standard") on January 1, 2018 using the modified retrospective method.

Topic 606 supersedes all previous revenue recognition requirements in accordance with generally accepted accounting principles. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration to which the entity is entitled to in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of Topic 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the performance obligation is satisfied. We apply the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods or services it transferred to the customer.

Net Product Revenue

We sell UDENYCA® to wholesalers and distributors, (collectively, "Customers"). Our Customers resell UDENYCA® to hospitals and clinics (collectively, "Healthcare Providers") under set contracts with us. In addition to distribution agreements with Customers and contracts with Healthcare Providers, we enter into arrangements with group purchasing organizations ("GPOs") that provide for government-mandated or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of UDENYCA®. We also enter into rebate arrangements with payers, which consist primarily of commercial insurance companies, to cover the reimbursement of UDENYCA® to Healthcare Providers. We provide co-payment assistance to patients who have commercial insurance and meet certain eligibility requirements. Revenue from product sales is recognized when a Customer controls the product, which occurs upon delivery of UDENYCA® to and acceptance by that Customer.

Product Sales Discounts and Allowances

Revenues from product sales are recorded at the net sales price ("transaction price"), which includes estimates of variable consideration for which reserves are established and that result from discounts, chargebacks, rebates, co-pay assistance, returns and other allowances that are offered within contracts between us and our Customers, Healthcare Providers, payers and GPOs relating to the sales of UDENYCA®. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of trade receivables (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as historical experience, current contractual and statutory requirements, specifically known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the best estimates of the amount of consideration to which we are entitled based on the term of our contracts. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from its estimates. If actual results in the future vary from our estimates, the estimates will be adjusted, which would affect net product revenue in the period that such variances become known.

Chargebacks: Chargebacks are discounts that occur when Healthcare Providers purchase directly from a Customer. Healthcare Providers, which belong to Public Health Service institutions, non-profit clinics, government entities, GPOs, and health maintenance organizations, generally purchase the product at a discounted price. The Customer, in turn, charges back to us the difference between the price initially paid by the Customer and the discounted price paid by the Healthcare Providers to the Customer. The allowance for chargebacks is based on an estimate of sales to contracted Customers.

Discounts for Prompt Payment: We provide prompt payment discounts to our Customers, which are recorded as a reduction in revenue in the same period that the related product revenue is recognized.

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program, other government programs and commercial contracts. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. Certain rebate amounts commensurate with share utilization of UDENYCA® related to other pegfilgrastim products. The allowance for rebates is based on statutory or contractual discount rates and expected utilization. Our estimates for the expected utilization of rebates are based on customer and payer data received from the pharmacies and distributors and historical utilization rates. Rebates are generally invoiced by the payer and paid in arrears, such that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's shipments to our Customers, plus an accrual balance for known prior quarters' unpaid rebates. If actual future rebates vary from estimates, we may need to adjust our accruals, which would affect net product revenue in the period of adjustment.

Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue.

Product Returns: We offer our Customers limited product return right, which is principally based upon damaged, defective or the product's expiration date. Product return allowance is estimated and recorded at the time of sale.

Other Allowances: We pay fees to Customers for account management, data management and other administrative services. To the extent that the services received are distinct from the sale of products to the customer, these payments are classified in selling, general and administrative expenses in our condensed consolidated statements of operations, otherwise they are included as a reduction to product revenue.

There have been no significant changes to our accounting policies during the six months ended June 30, 2019, as compared to the significant accounting policies described in our Annual Report on Form 10-K filed with the SEC on February 28, 2019. 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

The following are the recent accounting pronouncements we adopted in 2019:

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU 2016-02). ASU 2016-02 aims to make leasing activities more transparent and comparable, and requires substantially 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 2016-02 is effective for our interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. In July 2018, FASB issued additional authoritative guidance, ASU 2018-11, providing companies with an optional prospective transition method. We adopted the new standards on January 1, 2019 using the optional prospective transition method and recognized right-of-use assets of $7.2 million and lease liabilities of $9.2 million on the adoption date on our condensed consolidated balance sheet, comprised of facility lease agreements for our corporate headquarters and laboratory facilities in California. We elected the package of practical expedients upon transition, which allows us to apply the guidance prospectively, without reassessing prior conclusions related to contracts containing leases, lease classification and initial direct costs. Accordingly, the results for the six months ended June 30, 2019 are presented under Topic 842, and the results for the six months ended June 30, 2018 and other prior period amounts were not adjusted and continue to be reported in accordance with the historical accounting under prior lease guidance, ASC Topic 840: *Leases* ("Topic 840")." We also elected an accounting policy that does not recognize right-of-use assets and lease liabilities related to short-term leases. We did not elect to apply the hindsight expedient.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-07), which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payment to employees, with certain exceptions. The amendments in ASU 2018-07 are effective for our interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. We early adopted ASU 2018-07 on January 1, 2019 and the adoption did not have a material impact on our condensed consolidated financial statements and related disclosures.

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, *Disclosure Update and Simplification.* These amendments eliminate, modify, or integrate into other SEC requirements certain disclosure rules. Among the amendments is the requirement to present an analysis of changes in stockholders' equity in the interim financial statements included in quarterly reports on Form 10-Q. The analysis, which can be presented as a footnote or separate statement, is required for the current and comparative quarter and year-to-date interim periods. The amendments are effective for all filings made on or after November 5, 2018. In light of the anticipated timing of effectiveness of the amendments and expected proximity of effectiveness to the filing date for most filers' quarterly reports, the SEC's Division of Corporate Finance issued a Compliance and Disclosure Interpretation related to Exchange Act Forms, or CDI – Question 105.09, that provides transition guidance related to this disclosure requirement. CDI – Question 105.09 states that the SEC would not object if the filer's first presentation of the changes in stockholders' equity is included in its Form 10-Q for the quarter that begins after the effective date of the amendments. As such, we adopted these SEC amendments on November 5, 2018 and have presented the analysis of changes in stockholders' equity in our interim financial statements in our June 30, 2019 Form 10-Q. We adopted the Securities Act Release No. 33-10532 on January 1, 2019 and the adoption did not have a material effect on our financial position, results of operations, cash flows or stockholders' equity.

The following are the recent accounting pronouncements that we have not yet adopted.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326) (ASU 2016-13).* ASU 2016-13 implements an impairment model, known as the current expected credit loss model that is based on expected losses rather than incurred losses. Under the new guidance, an entity will recognize as an allowance its estimate of expected credit losses. ASU 2016-13 is effective for our interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting periods thereafter. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-13 will have on our consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles - Goodwill and Other: Simplifying the Test for Goodwill Impairment* (ASU 2017-04), which simplifies the current requirements for testing goodwill for impairment by eliminating the second step of the two-step impairment test to measure the amount of an impairment loss. ASU 2017-04 is effective for our interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting periods thereafter. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2017-04 will have on our consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurements* (ASU 2018-13), which eliminates certain disclosure requirements for fair value measurements, and requires public entities to disclose certain new information and modifies some disclosure requirements. The new guidance is effective for our interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting periods thereafter. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2018-13 will have on our consolidated financial statements and related disclosures.

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 our condensed consolidated financial statements as a result of future adoptions.

Results of Operations

Comparison of Three and Six Months Ended June 30, 2019 and 2018

Revenue

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	Change	2019	2018	Change
	(in thousands)					
Net product revenue	$ 83,433	$ —	$ 83,433	$ 120,531	$ —	$ 120,531

Net product revenue for the three and six months ended June 30, 2019 was $83.4 million and $120.5 million, respectively, due to the U.S. sales of UDENYCA®, which commenced in January 2019. There were no product sales during the three or six months ended June 30, 2018.

Cost of goods sold

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	Change	2019	2018	Change
	(in thousands)					
Cost of goods sold	$ 601	$ —	$ 601	$ 2,826	$ —	$ 2,826
Gross margin	99%	0%	99%	98%	0%	98%

The cost of goods sold for the three and six months ended June 30, 2019 was $0.6 million and $2.8 million, respectively. Cost of goods sold consists primarily of third-party manufacturing, distribution and overhead costs associated with the sale of UDENYCA®. Portions of the manufacturing costs for inventory were incurred prior to the regulatory approval of UDENYCA® and, therefore, were expensed as research and development costs when incurred, rather than capitalized as inventory. Cost of goods sold for the six months ended June 30, 2019 included write-down of manufacturing costs of $1.3 million due to the cancellation of certain manufacturing reservations, and $0.4 million due to the write-off of excess and obsolete inventory.

We expect our gross margin to decrease as a result of paying a mid-single digit royalty on net product revenue to Amgen beginning on July 1, 2019.

Research and Development Expense

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	Change	2019	2018	Change
	(in thousands)					
Research and development	$ 18,883	$ 26,519	$ (7,636)	$ 37,672	$ 51,974	$ (14,302)

Research and development expense for the three months ended June 30, 2019 was $18.9 million compared to $26.5 million for the same period in 2018, a decrease of $7.6 million. The decrease in research and development expense was primarily due to the following:

- a decrease of $10.2 million in UDENYCA® manufacturing costs as we began capitalizing these costs as inventory after receiving FDA approval for UDENYCA® in November 2018, which was offset by development expense associated with an on-body device for UDENYCA®;
- a decrease of $1.1 million in stock-based compensation expense from fully-vested options granted company-wide in April 2015 with higher option price partially offset by additional stock options granted since the first half of 2018;
- a decrease of $0.5 million for CHS-0214 development costs due to close-out activities for our Phase 3 open-label extension study, which was completed in the first half of 2018; and
- a decrease of $0.2 million in facilities, supplies and materials and other infrastructure.

The decrease in research and development expense for the three months ended June 30, 2019 was partially offset by the following:

- an increase of $2.1 million in costs for CHS-1420 related to the preparation of our BLA and activities related to inspection readiness;
- an increase of $1.2 million in costs related to the development of our other biosimilar product candidates as we continue to advance our preclinical stage pipeline;
- an increase of $0.6 million in personnel, consulting and other related costs as a result of hiring personnel in research and development to advance our programs; and

- an increase of $0.5 million in costs related to CHS-131 in connection with opening an IND application with the FDA and preparing a clinical program in NASH patients.

Research and development expense for the six months ended June 30, 2019 was $37.7 million compared to $52.0 million for the same period in 2018, a decrease of $14.3 million. The decrease in research and development expense was primarily due to the following:

- a decrease of $17.3 million in UDENYCA® manufacturing costs as we began capitalizing these costs as inventory after receiving FDA approval for UDENYCA® in November 2018, which was offset by development expense associated with an on-body device for UDENYCA®;
- a decrease of $2.1 million for CHS-0214 development costs due to close-out activities for our Phase 3 open-label extension study, which was completed in the first quarter of 2018;
- a decrease of $1.2 million in stock-based compensation expense from fully-vested options granted company-wide in April 2015 with higher option price partially offset by additional stock options granted since the first half of 2018; and
- a decrease of $0.5 million in facilities, supplies and materials and other infrastructure.

The decrease in research and development expense for the six months ended June 30, 2019 was partially offset by the following:

- an increase of $2.6 million in costs related to the development of our other biosimilar product candidates as we continue to advance our preclinical stage pipeline;
- an increase of $2.2 million for CHS-1420 development costs related to the preparation of our BLA and activities related to inspection readiness;
- an increase of $1.2 million in personnel, consulting and other related costs as a result of hiring personnel in research and development to advance our programs; and
- an increase of $0.8 million in costs related to CHS-131 in connection with preparing and opening an IND application in June 2019 with the FDA and preparing a clinical program in NASH patients.

We expect our research and development expense to increase in the future as our product candidates advance through clinical development or the regulatory approval process.

Selling, General and Administrative Expense

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	Change	2019	2018	Change
	(in thousands)					
Selling, general and administrative	$ 36,456	$ 18,391	$ 18,065	$ 69,139	$ 34,968	$ 34,171

Selling, general and administrative expense for the three months ended June 30, 2019 was $36.5 million compared to $18.4 million for the same period in 2018, an increase of $18.1 million. The increase in selling, general and administrative expense was primarily due to the following:

- an increase of $13.3 million for personnel, consulting and other related expenses due to an increase in sales force personnel and related commercial functions to enable the ongoing commercialization of UDENYCA®;
- an increase of $3.7 million for legal, marketing, advertising, recruiting and other professional services associated with commercial and marketing initiatives to support on-going litigations and the commercialization of UDENYCA®;
- an increase of $0.6 million in facility related expenses to support our growing commercial infrastructure for UDENYCA®; and
- an increase of $0.4 million in stock-based compensation expense due to an increase in commercial-related headcount and additional stock options granted since the first half of 2018. The increase was partially offset by a decrease resulting from the fully-vested options granted company-wide in April 2015 with higher option price.

Selling, general and administrative expense for the six months ended June 30, 2019 was $69.1 million compared to $35.0 million for the same period in 2018, an increase of $34.2 million. The increase in selling, general and administrative expense was primarily due to the following:

- an increase of $23.5 million for personnel, consulting and other related expenses due to an increase in sales force personnel and related commercial functions to enable the ongoing commercialization of UDENYCA®;
- an increase of $8.3 million for legal, marketing, advertising, recruiting and other professional services associated with commercial and marketing initiatives to support on-going litigations and the commercialization of UDENYCA®;
- an increase of $1.3 million in stock-based compensation expense due to an increase in commercial-related headcount and additional stock options granted since the first half of 2018. The increase was partially offset by a decrease resulting from the fully-vested options granted company-wide in April 2015 with higher option price; and
- an increase of $1.1 million in facility related expenses to support our growing commercial infrastructure for UDENYCA®.

We expect future selling, general and administrative expense to stay relatively the same in future periods.

Interest Expense

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	Change	2019	2018	Change
	(in thousands)					
Interest expense	$ 4,433	$ 2,417	$ 2,016	$ 8,649	$ 4,825	$ 3,824

Interest expense for the three months ended June 30, 2019 was $4.4 million compared to $2.4 million for the same period in 2018, an increase of $2.0 million. Interest expense for the six months ended June 30, 2019 was $8.6 million compared to $4.8 million for the same period in 2018, an increase of $3.8 million. The increase in interest expense for both periods is primarily due to the interest related to our Term Loan we entered into in January 2019.

Other Income, Net

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	Change	2019	2018	Change
	(in thousands)					
Other income, net	$ 558	$ 3,642	$ (3,084)	$ 1,369	$ 3,780	$ (2,411)

Other income, net for the three months ended June 30, 2019 was $0.6 million compared to $3.6 million for the same period in 2018, a decrease of $3.1 million. The decrease for the three months ended June 30, 2019 was primarily due to a decrease of $3.4 million in the fair value of our contingent consideration related to the Compound Transaction Payment associated with our InteKrin acquisition as a result of a decrease in the probability of occurrence from 33% to 10% and an extension in the timing of occurrence to a later date. The decrease was partially offset by an increase in foreign exchange fluctuation of $0.3 million.

Other income, net for the six months ended June 30, 2019 was $1.4 million compared to $3.8 million for the same period in 2018, a decrease of $2.4 million. The decrease for the six months ended June 30, 2019 was primarily due to a decrease of $3.2 million in the fair value of our contingent consideration related to the Compound Transaction Payment associated with our InteKrin acquisition as a result of a decrease in the probability of occurrence from 33% to 10% and an extension in the timing of occurrence to a later date. The decrease was partially offset by an increase in foreign exchange fluctuation of $0.5 million and an increase on interest earned on investments in marketable securities of $0.2 million

Income Tax Provision

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	Change	2019	2018	Change
	(in thousands)					
Income tax provision	$ 51	$ —	$ 51	$ 51	$ —	$ 51

Income tax provision for the three and six months ended June 30, 2019 was $51,000 compared to $0 for the same period in 2018, an increase of $51,000. Income tax provision primarily relates to state taxes in jurisdictions outside of California, for which we

have a limited operating history. Our historical losses are sufficient to fully offset any federal taxable income. Income tax provision during interim periods is based on applying an estimated annual effective income tax rate to year-to-date income, plus any significant unusual or infrequently occurring items which are recorded in the interim period. The income tax provision for the three months ended June 30, 2019 differed from the U.S. federal statutory rate of 21% primarily due to effect of change in the valuation allowance against our federal deferred tax assets which reduced our net tax expense. We maintain a full valuation allowance against our net deferred tax assets due to our history of losses.

Liquidity and Capital Resources

Due to our significant research and development expenditures, and although we are profitable for the three and six months ended June 30, 2019, we have previously 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 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. In January 2019, we issued and sold an aggregate of 761,130 shares of common stock at a weighted average price of $11.17 per share under the ATM Offering Program for aggregate net proceeds of $8.2 million. As of January 19, 2019, our Shelf Registration Statement expired and accordingly the ATM Offering Program expired.

On January 7, 2019 (the “Term Loan Closing Date”), we entered into a credit agreement (the “Term Loan”) with affiliates of Healthcare Royalty Partners (together, the “Lender”). The Term Loan consists of a six-year term loan facility for an aggregate principal amount of $75.0 million (the “Borrowings”). Our obligations under the loan documents are guaranteed by our material domestic U.S. subsidiaries.

The Borrowings under the Term Loan bear interest through maturity at 7.00% per annum plus LIBOR (customarily defined). If the consolidated net sales (customarily defined) for UDENYCA® for the fiscal year ending December 31, 2019, are in excess of $250.0 million, then the interest rate will be reduced as of January 1, 2020 to 6.75% per annum plus LIBOR. Interest is payable quarterly in arrears.

We are required to pay principal on the Borrowings in equal quarterly installments beginning on the four year anniversary of the Term Loan Closing Date (or, if consolidated net sales of UDENYCA® in the fiscal year ending December 31, 2021 are less than $375.0 million, beginning on the three year anniversary of the Term Loan Closing Date), with the outstanding balance to be repaid on January 7, 2025, the maturity date.

We are also required to make mandatory prepayments of the Borrowings under the Term Loan, subject to specified exceptions, with the proceeds of asset sales, extraordinary receipts, debt issuances and specified other events including the occurrence of a change in control.

If all or any of the Borrowings are prepaid or required to be prepaid under the Term Loan, then we shall pay, in addition to such prepayment, a prepayment premium equal to (i) with respect to any prepayment paid or required to be paid on or prior to the three year anniversary of the Term Loan Closing Date, 5.00% of the Borrowings prepaid or required to be prepaid, plus all required interest payments that would have been due on the Borrowings prepaid or required to be prepaid through and including the three year anniversary of the Term Loan Closing Date, (ii) with respect to any prepayment paid or required to be paid after the three year anniversary of the Term Loan Closing Date but on or prior to the four year anniversary of the Term Loan Closing Date, 5.00% of the Borrowings prepaid or required to be prepaid, (iii) with respect to any prepayment paid or required to be paid after the four year anniversary of the Term Loan Closing Date but on or prior to the five year anniversary of the Term Loan Closing Date, 2.50% of the Borrowings prepaid or required to be prepaid, and (iv) with respect to any prepayment paid or required to be prepaid thereafter, 1.25% of the Borrowings prepaid or required to be prepaid.

In connection with the Term Loan, we paid a fee to the Lender of approximately $1.1 million at closing in the form of an original issue discount. Upon the prepayment or maturity of the Borrowings (or upon the date such prepayment or repayment is required to be paid), we are required to pay an additional exit fee in an amount equal to 4.00% of the total principal amount of the Borrowings.

The obligations under the Term Loan are secured by a lien on substantially all of our and our Guarantors’ tangible and intangible property, including intellectual property. The Term Loan contains certain affirmative covenants, negative covenants and

events of default, including, covenants and restrictions that among other things, restrict our ability and our subsidiaries to, incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, in asset sales, and declare dividends or redeem or repurchase capital stock. Additionally, the consolidated net sales for UDENYCA® must not be lower than $70.0 million for the fiscal year ending December 31, 2019, (b) $125.0 million for the fiscal year ending December 31, 2020, and (c) $150.0 million for each fiscal year thereafter. A failure to comply with these covenants could permit the Lender under the Term Loan to declare the Borrowings, together with accrued interest and fees, to be immediately due and payable.

In the first half of 2019, we purchased investments in marketable securities in accordance with our investment policy in order to obtain interest income on our cash balances.

As of June 30, 2019, we had an accumulated deficit of $981.3 million and cash and cash equivalents and investments in marketable securities of $111.9 million. We believe that our current available cash, cash equivalents, investments in marketable securities and cash collected from UDENYCA® sales will be sufficient to fund our planned expenditures and meet our obligations for at least the next 12 months following our financial statement issuance date. Although we are profitable for the three and six months ended June 30, 2019, we may 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**:**

	Six Months Ended June 30,	
	2019	**2018**
	(in thousands)	
Net cash used in operating activities	$ (44,306)	$ (69,114)
Net cash used in investing activities	(6,381)	(29,785)
Net cash provided by financing activities	84,487	101,770
Effect of exchange rate changes in cash, cash equivalents and restricted cash	(229)	213
Net increase in cash, cash equivalents and restricted cash	$ 33,571	$ 3,084

Net cash used in operating activities

Cash used in operating activities was $44.3 million for the six months ended June 30, 2019, which was primarily due to the following:

- an increase in trade receivables of $77.4 million due to sales of UDENYCA® in the U.S. starting January 3, 2019;
- an increase in inventory of $16.7 million as we began capitalizing inventory in November 2018 upon receiving FDA approval for UDENYCA®;
- an increase in other prepaid and assets of $2.6 million primarily due to the launch of our co-pay assistance program for UDENYCA® of $1.9 million and the timing of vendor payments; and
- a decrease in lease liabilities of $1.0 million due to lease payments in the first half of 2019 and amortization.

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

- non-cash charges related to stock-based compensation of $17.5 million and depreciation and amortization of property and equipment of $1.4 million, non-cash interest expense from amortization of debt issuance discounts of $1.1 million, non-cash operating lease expense of $0.8 million and excess and obsolete inventory of $0.4 million;
- net income of $3.6 million;
- an increase in accrued rebates, fees and reserve of $20.7 million as a result of initiating UDENYCA® sales;
- a decrease in prepaid manufacturing services of $1.1 million primarily due to the progress of our CHS-1420 manufacturing activities;
- an increase in accrued and other liabilities of $1.3 million primarily due to our accruals for our UDENYCA® manufacturing;

- an increase in accounts payable and accounts payable - related parties of $4.1 million primarily due to the timing of invoices and vendor payments related to legal costs and the distribution service fees related to the sales of UDENYCA®; and
- an increase in accrued compensation of $1.6 million primarily due to increased compensation and bonus accrual associated with our UDENYCA® sales force, which was partially offset by the settlement of our 2018 bonus payment in the first quarter of 2019.

Cash used in operating activities was $69.1 million for the six months ended June 30, 2018, which was primarily due to the following:

- a net loss of $88.0 million;
- non-cash charges related to the fair value remeasurement of our contingent consideration obligation of $3.2 million; and
- a decrease in accounts payable, accounts payable - related parties, and accrued and other liabilities of $6.5 million primarily due to the payments to our clinical research organizations and clinical manufacturing organizations as a result of the progression of our clinical trial programs that are winding down, and the timing of vendor payments.

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

- non-cash charges related to stock-based compensation of $17.4 million, depreciation and amortization of property and equipment of $1.8 million and non-cash interest related to the amortization of debt discount and debt issuance cost of $0.7 million;
- a net decrease in prepaid manufacturing and other prepaid assets of $5.6 million primarily due to the utilization of a prepayment balance to manufacture UDENYCA®; and
- an increase in accrued compensation of $3.1 million primarily due to the first half of 2018 bonus accrual.

Net cash used in investing activities

Cash used in investing activities of $6.4 million for the six months ended June 30, 2019 was primarily due to the purchase of short-term investments in marketable securities of $14.9 million and purchases of property and equipment of $0.5 million, which was partially offset by proceeds from maturities of short-term investments of $9.0 million.

Cash used in investing activities of $29.8 million for the six months ended June 30, 2018 was primarily due to the purchase of short-term investments in marketable securities of $43.0 million, partially offset by proceeds from the maturities of investments in marketable securities of $13.2 million.

Net cash provided by financing activities

Cash provided by financing activities of $84.5 million for the six months ended June 30, 2019 was primarily related to $73.1 million in proceeds from our term loan, net of issuance costs, $8.1 million from the issuance of our common stock from our ATM Offering Program, net of underwriting discounts, commissions and offering costs, $1.9 million in proceeds related to ESPP, and $1.4 million from the exercise of stock options.

Cash provided by financing activities of $101.8 million for the six months ended June 30, 2018 was primarily related to proceeds of $100.8 million from the issuance of our common stock from an underwritten public offering and our ATM Offering Program, net of underwriting discounts and commissions, $0.8 million in proceeds related to ESPP and $0.5 million from the exercise of stock options. The proceeds were partially offset by payments of $0.3 million for offering expenses related to the issuance of common stock.

Funding Requirements

We believe that our current available cash, cash equivalents, investments in marketable securities, and cash collected from UDENYCA® sales will be sufficient to fund our planned expenditures and meet our obligations for the foreseeable future, beyond the 12 months following our financial statement issuance date. 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. 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:

- cash proceeds from UDENYCA® sales;
- the costs of manufacturing, distributing and marketing UDENYCA®;
- the cost of manufacturing clinical supplies and any products that we may develop;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from any product candidates that are approved in the future;
- the number and characteristics of product candidates that we pursue;
- the scope, rate of progress, results and cost of our clinical trials, preclinical testing and other related activities;
- 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 cost, timing and outcomes of regulatory approvals;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- 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.

If the proceeds from UDENYCA® sales are insufficient or are not collected in a timely manner, we may 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 or research and development programs. 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. We may 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 additional 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

The following table summarizes our contractual obligations as of June 30, 2019:

Contractual Obligations	Payments Due by Period (1)				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
	(in thousands)				
Long-term debt obligations - Convertible notes (2)	$ 131,550	$ 4,100	$ 16,400	$ 111,050	$ —
Long-term debt obligations - Term loan (2)	112,174	3,641	14,468	46,570	47,495
Non-cancelable purchase commitments (3)	36,020	9,845	25,575	600	—
Operating lease obligations (4)	9,218	1,333	5,367	2,518	—
Contingent payments to InteKrin Stockholders	64	—	—	64	—
Total contractual liabilities	$ 289,026	$ 18,919	$ 61,810	$ 160,802	$ 47,495

(1) "Less than 1 year" represents the remainder of 2019 calendar year obligations, "1 to 3 years" represents 2020 and 2021 calendar year obligations, "3 to 5 years" represents 2022 and 2023 calendar year obligations, and "More than 5 years" represents the 2024 and beyond calendar year obligations.
(2) The long-term debt obligation is comprised of future minimum payments related to our Convertible notes and Term loan.
(3) These amounts are comprised of purchase commitments to our CMO's and material purchase commitments.
(4) These amounts are comprised of the rent payments on our facility leases.

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.

On January 7, 2019, we entered into a credit agreement (the "Term Loan") with affiliates of Healthcare Royalty Partners (together, the "Lender"). The Term Loan consists of a six-year term loan facility for an aggregate principal amount of $75.0 million (the "Borrowings"). Our obligations under the loan documents are guaranteed by our material domestic U.S. subsidiaries (the "Guarantors"). See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

We enter into contracts in the normal course of business with CROs for preclinical studies and clinical trials and CMOs for the manufacture of drug materials. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, we would only be obligated for products or services that we had received as of the effective date of the termination and any applicable cancellation fees.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

As of June 30, 2019, we had cash, cash equivalents and investments in marketable securities of $111.9 million consisting of cash, money market funds and corporate notes and commercial paper of institutions with investment grade ratings. A portion of our cash equivalents and investments in marketable securities may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our cash equivalents and investments in marketable securities 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 do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure.

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.

During the six months ended June 30, 2019, we implemented certain internal controls in connection with our product launch and our adoption of Topic 842. There were no other changes in our internal control over financial reporting that occurred during our most recent fiscal quarter 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 a party to the following legal proceedings:

On March 3, 2017, Amgen Inc. and Amgen USA Inc. (collectively "Amgen") filed an action against us, KBI Biopharma Inc., our employee Howard S. Weiser and Does 1-20 in the Superior Court of the State of California, County of Ventura. The complaint alleges that we engaged in unfair competition and improperly solicited and hired certain former Amgen employees in order to acquire and access trade secrets and other confidential information belonging to Amgen. On June 1, 2017, Amgen filed a Second Amended Complaint, which alleges as to Coherus (i) unfair competition under California Business and Professions Code Section 17200 et seq., (ii) misappropriation of trade secrets, (iii) aiding and abetting breach of duty of loyalty and (iv) tortious interference with contract. As to defendant Weiser, the Second Amended Complaint alleges (i) unfair competition under California Business and Professions Code Section 17200 et seq., (ii) misappropriation of trade secrets, (iii) breach of contract, (iv) violation of Penal Code Section 502 and (v) breach of duty of loyalty. KBI Biopharma Inc. is not named as defendant in the Second Amended Complaint. The Second Amended Complaint seeks injunctive relief and monetary damages. Although Amgen has indicated it intends to seek a preliminary injunction, no motion has been filed yet. On May 19, 2017, Amgen dismissed Defendant KBI Biopharma Inc. without prejudice. In December 2018, the court set a trial date of April 22, 2019. On April 9, 2019, Defendant Howard S. Weiser settled with Amgen and was dismissed. On May 2, 2019, we and Amgen settled the trade secret action brought by Amgen. The details of the settlement are confidential but the Company will continue to market UDENYCA® and will pay a mid-single digit royalty to Amgen for five years starting on July 1, 2019.

On May 10, 2017, Amgen Inc. and Amgen Manufacturing Inc. filed an action against us in the U.S. District Court for the District of Delaware (the "District Court") alleging infringement of one or more claims of Amgen's U.S. patent 8,273,707 (the "'707 patent") under 35 U.S.C. § 271. The complaint seeks injunctive relief, monetary damages and attorney fees. On December 7, 2017, the U.S. Magistrate Judge issued under seal a Report and Recommendation to the District Court recommending that the District Court grant, with prejudice, the Company's pending motion to dismiss Amgen Inc. and Amgen Manufacturing Inc.'s complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). On March 26, 2018, Judge Stark of the District Court adopted the U.S. Magistrate Judge's Report and Recommendation to grant the motion of the Company pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss with prejudice the patent infringement complaint alleging infringement of the '707 patent on the grounds that such complaint failed to state a claim upon which relief may be granted. In May 2018, Amgen filed a Notice of Appeal in the U.S. Court of Appeals for the Federal Circuit. Amgen and Coherus filed briefs in this matter and oral argument was held on May 8, 2019. On July 29, 2019, the Federal Circuit issued a precedential opinion affirming the District Court's judgment in the Company's favor. The Federal Circuit held that the doctrine of prosecution history estoppel barred Amgen from succeeding on its infringement claim and affirmed the District Court's dismissal. This case is currently pending, as Amgen may seek further appellate relief at the Federal Circuit or file a petition for writ of certiorari to the Supreme Court of the United States.

On January 24, 2019, we filed suit against Amgen in the United States District Court of Delaware alleging that the manufacture of Amgen's Humira® biosimilar, Amgevita™, infringes Coherus' U.S. patents 10,155,039; 10,159,732; and 10,159,733. Each of the asserted Coherus patents is directed to stable formulations of adalimumab. On March 5, 2019, we filed an amended complaint asserting an additional patent, U.S. patent 10,207,000. On April 18, 2019, Amgen filed its answer and counterclaims. On June 24, 2019, we filed our answer to Amgen's counterclaims. The case is currently pending.

We are not a party to any other material legal proceedings on the date of this report.

ITEM 1A. Risk Factors

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. The risks described below are not the only risks facing the Company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.

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 $209.4 million, $238.8 million and $127.8 million for the years ended December 31, 2018, 2017 and 2016, respectively, and $88.0 million for the six months ended June 30, 2018. However, for the six months ended June 30, 2019, we had net income of $3.6 million. As of June 30, 2019, we had an accumulated deficit of $981.3 million.

The amount of our future net losses or net income will depend, in part, on the rate of our future product sales, offset by the rate of 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 completed Phase 3 or other BLA-enabling development with all our lead products, UDENYCA® (pegfilgrastim-cbqv), CHS-1420 (our adalimumab (Humira) biosimilar candidate) and CHS-0214 (our etanercept (Enbrel) biosimilar candidate). Our BLA for UDENYCA® was accepted for review by the FDA in October 2016, and we received a CRL from the FDA in June 2017. We resubmitted our BLA for UDENYCA® on May 3, 2018 and the FDA accepted our resubmission on May 14, 2018. Our MAA for UDENYCA® was accepted for review by the EMA in November 2016, and on September 20, 2018, the European Commission ("EC") approved the MAA of UDENYCA®. On November 2, 2018, the FDA approved UDENYCA® as a biosimilar to Neulasta to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. It may be several months before we submit an application for market approval with the relevant regulatory agencies for CHS-1420 and CHS-0214. We have not yet initiated clinical trials for CHS-3351 (our ranibizumab (Lucentis) biosimilar) or for CHS- 2020 (our aflibercept (Eylea) 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 payers, and adequate market share for our product candidates in those markets. However, even additional product candidates beyond UDENYCA® gain regulatory approval and are commercialized, we may not remain profitable.

Our expenses will increase substantially if and as we:

- establish a sales, marketing and distribution infrastructure to commercialize UDENYCA® or any of our product candidates for which we may obtain marketing approval;
- continue our nonclinical and clinical development of our product candidates;
- initiate additional nonclinical, clinical or other studies for our product candidates;
- expand the scope of our current clinical studies for our product candidates;
- advance our programs into more expensive clinical studies;
- 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;
- 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 IPR proceedings 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 or analyses in order to pursue marketing approval.

Further, the net losses or net income 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 may be unable to maintain or increase profitability.

Although we reported net income of $23.6 million and $3.6 million for the three and six months ended June 30, 2019, respectively, we may not be able to maintain or increase profitability on a quarterly or annual basis, and we are unable to predict the extent of our long-range future profits or losses. The amount of net profits or losses will depend, in part, on the level of sales of UDENYCA® in the United States and the level of our expenses as we expand our product pipeline. To offset these expenses, we will need to generate substantial revenue. If expenses exceed our expectations, or if we fail to achieve expected revenue targets, the market value of our common stock may decline.

We are heavily dependent on the ability to raise 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 and commercialization efforts or other operations.

As of June 30, 2019, our cash, cash equivalents and investments in marketable securities were $111.9 million. We expect that our existing cash, cash equivalents, the cash collected from UDENYCA® sales, together with the $75 million term loan executed in January 2019 and investments in marketable securities will be sufficient to fund our current operations for the foreseeable future and beyond the next 12 months. We have financed our operations primarily through the sale of equity securities, convertible notes, credit facilities, license agreements, and to a lesser extent, through recent product sales of UDENYCA®.

However, 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:

- our ability to continue to successfully commercialize UDENYCA®, and to compete against new pegfilgrastim biosimilar commercial entrants;
- the scope, rate of progress, results and cost of any clinical studies, nonclinical testing and other related activities;
- the cost of manufacturing clinical drug 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 licensing or other arrangements to acquire intellectual property rights that we may establish, including any milestone and royalty payments thereunder; and
- the cost, timing and outcomes of any litigation that we may file against third parties 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, stay profitable or increase our net profits, 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.

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

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 rolling three-year period), such corporation's ability to use its pre-change net operating loss carryforwards ("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 (some of which changes 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 may 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 as we attained 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.

Additionally, the Tax Cuts and Jobs Act of 2017 (the "Tax Act"), which was signed into law on December 22, 2017, changed the rules governing the use of U.S. federal NOLs, including by imposing a reduction to the maximum deduction allowed for NOLs generated in tax years beginning after December 31, 2017. In addition, NOL carryforwards arising in tax years ending after December 31, 2017 can be carried forward indefinitely, but carryback is generally prohibited. Such limitations may significantly impact our ability to use NOL carryforwards generated after December 31, 2017, as well as the timing of any such use, and could adversely affect our future cash flows.

Risks Related to Launch and Commercialization of UDENYCA® and our Other Product Candidates

We have a limited operating history in an emerging regulatory environment on which to assess our business.

We are a biotherapeutics company with a limited operating history in an emerging regulatory environment of biosimilar products. Although we have received upfront payments, milestone and other contingent payments and/or funding for development from some of our collaboration and license agreements, UDENYCA® (pegfilgrastim-cbqv) is our only product approved for commercialization in the United States ("U.S.") and European Union ("E.U."), and we have no products approved in any other territories. The U.S. Food and Drug Administration ("FDA") approved UDENYCA® on November 2, 2018, as a biosimilar to Amgen's Neulasta®, to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. The European Commission ("EC"), through the European Medicines Agency ("EMA"), approved UDENYCA® on September 20, 2018 for substantially the same indication as approved by the FDA.

On January 3, 2019, we initiated the sale of UDENYCA® in the U.S.

Our ability to generate meaningful revenue and remain profitable depends on our ability, alone or with strategic collaboration partners, to successfully market and sell UDENYCA®, and to complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our other product pipeline candidates, which include:

- CHS-1420 (our adalimumab (Humira) biosimilar candidate;
- CHS-0214 (our etanercept (Enbrel) biosimilar candidate);
- CHS-3351 (our ranibizumab (Lucentis) biosimilar)
- CHS-2020 (our aflibercept (Eylea) biosimilar); and
- CHS-131 (a small molecule for nonalcoholic steatohepatitis ("NASH") and multiple sclerosis).

We may not be able to continue to generate meaningful revenue from product sales, as this depends heavily on our success in many areas, including but not limited to:

- our ability to successfully commercialize UDENYCA® ;
- competing against current and future pegfilgrastim products;

- healthcare providers, payers, and patients adopting our product candidates once approved and launched;
- obtaining additional regulatory and marketing approvals for product candidates for which we complete clinical studies;
- obtaining adequate third-party coverage and reimbursements for our products;
- obtaining market acceptance of our product candidates as viable treatment options;
- completing nonclinical and clinical development of our product candidates;
- developing and testing of our product formulations;
- attracting, hiring and retaining qualified personnel;
- 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;
- 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 or trade secret infringement lawsuits, that may be filed against us, or achieving successful outcomes in Inter Partes Review ("IPR") petitions 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 FDA, 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 additional 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 payers) 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 additional regulatory approval for our products, our business may suffer.

Our ability to generate revenue relies substantially on the successful launch and commercialization of UDENYCA®, which is currently our only commercial product offering.

Our ability to generate revenue will be primarily dependent on the sale of UDENYCA® to healthcare providers, and we expect that the sales of UDENYCA® will account for substantially all of our revenue for the foreseeable future. While we are in various stages of research and development with other biosimilar and pharmaceutical products, there can be no assurance that we will be able to successfully develop and commercialize any new product candidates. In order to substantially increase our revenue, we will need to educate community oncology clinics and hospitals, group purchasing organizations ("GPOs"), wholesalers, and insurance payers about UDENYCA®. We had limited contact with these entities to date because UDENYCA® was not approved by regulatory authorities until late 2018. If we are unable to contract and increase prescriptions of UDENYCA® with our customers, expand payer coverage and reimbursement, or successfully develop and commercialize new products or services, our revenue and our ability to achieve and sustain profitability would be impaired.

We hired new marketing and sales team members to launch and market UDENYCA®. If we fail to develop, organize, and execute an effective marketing and sales strategy, as well as retain a significant number our sales and marketing team members, we may fail to generate meaningful sales or achieve expected commercial results.

In 2018, we substantially increased the size of our marketing and sales team to help us launch and sell UDENYCA®. While we believe our sales and marketing team is comprised of individuals with proven industry experience, technical expertise, and supporting distribution capabilities to commercialize UDENYCA®, we will have no experience selling or marketing UDENYCA®. To successfully commercialize UDENYCA®, we will need to develop, grow, and retain our sales and marketing team members, as well as increase our brand recognition, value proposition, and commercial outreach efforts, either on our own or with others. Doing so may be expensive, difficult, time consuming, and require active learning and adaptation. Any failure or delay in the development, cohesion, or execution of our sales and marketing efforts or supply and distribution capabilities may adversely impact sales of UDENYCA®. Further, given our lack of prior experience in marketing and selling biosimilar 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 UDENYCA® or we may incur excess costs as a result of hiring more sales representatives than necessary. With respect to certain geographical markets, such as the E.U., 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.

The commercial success of UDENYCA®, or any future product candidate, will depend upon the degree of market acceptance and adoption by healthcare providers, patients, third-party payers and others in the medical community.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of UDENYCA®, or any of our future product candidates, if approved, will depend in part on the medical community, patients and third-party payers 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 payers 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 payers provide adequate third-party coverage and reimbursement for our product candidates, if approved;
- the price at which we sell our products;
- the actions taken by competitors to delay, restrict or block customer usage of the product; and
- our ability to maintain compliance with regulatory requirements.

Market acceptance of UDENYCA®, and our other future product candidates, if approved, 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 payers 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 payers and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

The third-party coverage and reimbursement status of UDENYCA® (or our other product candidates, if approved) 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 UDENYCA®, or any 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 as a result, we may not be profitable in the future. Accordingly, the availability and adequacy of coverage and reimbursement by governmental and private payers are essential for most patients to be able to afford expensive treatments such as ours. Sales will depend substantially, both domestically and abroad, on the extent to which the costs of our products 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 payers. If coverage and reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize UDENYCA® or any of our product candidates, if approved. 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 U.S., third-party payers, including private and governmental payers 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 payers and other governmental payers develop their coverage and reimbursement policies for drugs and biologics. It is difficult to predict what third-party payers will decide with respect to the coverage and reimbursement for any newly approved product. In addition, in the U.S., no uniform policy of coverage and reimbursement for biologics exists among third-party payers. Therefore, coverage and reimbursement for biologics can differ significantly from payer to payer. 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 payer separately, with no assurance that coverage and adequate reimbursement will be obtained. For example, CMS issued a proposed Medicare 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 ASP of all biosimilar products that reference a common biological product's license application. However, on November 2, 2017, CMS adopted a final policy to no longer group biological products with a common reference product into the same billing code, which became effective January 1, 2018.

Effective January 2018, CMS assigned a product specific Q-Code to UDENYCA®, which is necessary to allow UDENYCA® to have its own reimbursement rate and average selling price with Medicare or other third-party payers. However, reimbursement is not guaranteed and rates may vary based on product life cycle, site of care, type of payer, coverage decisions, and provider contracts. Furthermore, while third-party payers may adopt the Q-Code assigned by CMS for UDENYCA®, there remains uncertainty as to whether such payers will ultimately cover and pay providers for the administration and use of the product with each patient. If UDENYCA®, or any of our future product candidates, are not covered or adequately reimbursed by third-party payers, including Medicare, then the cost of the relevant product may be absorbed by healthcare providers or charged to patients. If this is the case, our expectations of the pricing we expect to achieve for such product and the related potential revenue, may be significantly diminished.

Outside the U.S., 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 U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

Increasing efforts by governmental and third-party payers in the U.S. 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 UDENYCA® or any of 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 UDENYCA® and any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

UDENYCA® and our other product candidates, even if approved, 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 U.S. 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 ("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, original BLA, 351(k) BLA 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.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Competitive Activity

UDENYCA®, or our other biosimilar product candidates if approved, will face significant competition from the reference products and from other biosimilar products or 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 operate in 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 multinational pharmaceutical and biotechnology companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel, marketing resources, and the benefits of mergers and acquisitions.

Specifically, some of the pharmaceutical and biotechnology companies we expect to compete with include: Apotex Inc. ("Apotex"), Sandoz International GmbH ("Sandoz"), Amgen Inc. ("Amgen"), Pfizer Inc. ("Pfizer"), Boehringer Ingelheim GmbH ("Boehringer Ingelheim"), Teva Pharmaceutical Industries, Ltd. ("Teva"), and Samsung Bioepis, Ltd. ("Samsung Bioepis"), (a Merck/Biogen/Samsung biosimilar venture), Mylan N.V. ("Mylan"), and Cinfa Biotech S.L. ("Cinfa"), as well as other smaller companies. We are currently aware that such competitors are engaged in the development and commercialization of biosimilar product candidates to pegfilgrastim (Neulasta), adalimumab (Humira) and etanercept (Enbrel).

Mylan and Biocon Ltd., Mylan's partner, received approval for a Neulasta biosimilar candidate (Fulphila (pegfilgrastim-jmdb)) in the U.S. in June 2018. We understand that Sandoz and Apotex have each submitted a Neulasta biosimilar product candidate for market approval in the U.S. and that Sandoz received a Complete Response Letter from the FDA at the end of June 2016. The European Commission ("EC") granted marketing authorization to five Neulasta biosimilar candidates from Intas Pharmaceuticals LTD. ("Intas"), USV Biologics ("USV"), Mylan and its partner Biocon, Sandoz and Cinfa.

Similarly, Pfizer, Boehringer Ingelheim, Amgen, Sandoz and Samsung Bioepis are examples of companies engaged in development of biosimilar product candidates for adalimumab (Humira). Samsung Bioepis received approval for a Humira biosimilar candidate (Hadlima (adalimumab-bwwd)) in the U.S. in July 2019 and plans to launch its product after June 30, 2023. We understand Pfizer completed its Phase 3 program in 2017, and that Samsung Bioepis' Humira biosimilar was approved in the E.U. in August 2017. Boehringer Ingelheim's Humira biosimilar (Cyltezo, adalimumab-admb) was approved in the U.S. in August 2017, Sandoz's Humira biosimilar (Hyrimoz, adalimumab-adaz) was approved in the U.S. in October 2018. In addition, in September 2016, the FDA approved Amgen's adalimumab biosimilar (Amjevita, adalimumab-atto).

On January 16, 2016, the EC approved Samsung Bioepis' etanercept biosimilar (Benepali) for the treatment of rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis (ankylosing spondylitis and non-radiographic axial spondyloarthritis) and plaque

psoriasis. In June and August 2016, the EC and FDA, respectively, approved Sandoz' etanercept biosimilar (Erelzi, etanercept-szzs) for multiple inflammatory diseases.

CHS-3351 may face competition from Genentech USA, Inc. (the holder of rights to Lucentis, the reference product of CHS-3351), as well as Pfenex Inc., Samsung Bioepis, Xbrane Biopharma AB (in collaboration with STADA Arzneimittel AG) and Bioeq IP AG (in collaboration with Formycon AG). Each of these companies has disclosed development plans for a Lucentis biosimilar candidate.

CHS-2020 may face competition from Regeneron Pharmaceuticals, Inc. (the holder of rights to Eylea, the reference product of CHS-2020), as well as Momenta Pharmaceuticals, Inc. (in collaboration with Mylan) and Santo Holding GmbH (in collaboration with Formycon AG), each of which has disclosed development plans for an Eylea biosimilar candidate.

These companies also have greater brand recognition and more experience in conducting preclinical testing and clinical trials of product candidates, obtaining FDA and other regulatory approvals of products and marketing and commercializing products once approved.

Additionally, 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, or refusing to settle, patent lawsuits with biosimilar companies, resulting in such patents remaining an obstacle for biosimilar approval;
- 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 U.S. 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, payers, 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 payer 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 U.S. 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.

UDENYCA® and our other 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.

Successful competitors in the biosimilar market have the ability to effectively compete on price with healthcare providers, and through payers and their third-party administrators, who exert downward pricing pressure on our price offerings. It is possible our biosimilar competitors' compliance with price discounting demands in exchange for market share or volume requirements could exceed our capacity to respond in kind and reduce market prices beyond our expectations. Such practices may limit our ability to increase market share and may also impact profitability.

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.

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.

If other biosimilars of pegfilgrastim (Neulasta), adalimumab (Humira), etanercept (Enbrel), ranibizumab (Lucentis) or aflibercept (Eylea) are approved and successfully commercialized before UDENYCA® or our product candidates for these originator products (CHS-1420, CHS-0214, CHS-3351 or CHS-2020, respectively), our business would suffer.

We expect other companies to seek approval to manufacture and market biosimilar versions of Neulasta, Humira, Enbrel, Lucentis or Eylea. If other biosimilars of Neulasta, Humira, Enbrel, Lucentis or Eylea are approved and successfully commercialized before UDENYCA®, CHS-1420, CHS-0214, CHS-3351 or CHS-2020, respectively, we may never achieve meaningful market share for these products, our revenue would be reduced and, as a result, our business, prospects and financial condition could suffer. For instance, Mylan received FDA approval for its pegfilgrastim biosimilar in June 2018, and in July 2018, Mylan initiated the commercialization in the U.S. of this biosimilar. Furthermore, in October 2018, the EC granted marketing authorization to UDENYCA® and to a pegfilgrastim biosimilar candidate from Intas. In November and December 2018, the EC granted marketing authorizations to three additional pegfilgrastim biosimilar candidates from Sandoz, Mylan and Cinfa. In June 2019, the EU granted marketing authorization to a pegfilgrastim biosimilar candidate from USV Biologics.

If an improved version of an originator product, such as Neulasta, Humira, Enbrel, Lucentis or Eylea, 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 submitted to 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, sales of the reference originator product 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.

Risks Related to Our Ability to Hire and Retain Highly Qualified Personnel

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, commercial 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 June 30, 2019, we had 257 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.

Risks Related to Reliance on Third-Party Vendors

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, good clinical practices ("GCP"), and Good Laboratory Practices ("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 GCPs, 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 GCP regulations. In addition, our clinical studies must be conducted with product generated under cGMP

regulations. Failure to comply by any of the participating parties or ourselves with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process. Moreover, our business may be implicated if our CRO or any other participating parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, a transition period is necessary when a new CRO commences work, which can materially impact our ability to meet our desired clinical development timelines. Though we strive to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects and financial condition.

We rely on third parties, and in some cases a single third party, to manufacture nonclinical, clinical and commercial drug 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 as well as to establish commercial supplies of our product candidates. 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 U.S. 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 are dependent on Orox for the commercialization of our biosimilar product candidates in certain markets and we intend to seek additional commercialization partners for major markets, and the failure to commercialize in those markets could have a material adverse effect on our business and operating results.

Our exclusive licensee, Orox, is responsible for commercialization of certain of our products and product candidates, including UDENYCA®, CHS-1420 and CHS-0214, in certain Caribbean and Latin American countries (excluding Brazil, and in the case of UDENYCA®, also excluding Argentina). We intend to seek commercialization partners for all products in Europe and other jurisdictions outside the U.S. (excluding certain Caribbean and Latin American countries). Our license with Orox, or other future license or collaboration agreements, may not be successful. Factors that may affect the success of our licenses and collaborations include, but are not limited to, the following:

- our existing and potential licensees and collaboration partners may fail to exercise commercially reasonable efforts to market and sell our products in their respective licensed jurisdictions or they may be ineffective in doing so;
- our existing and potential licensees and collaboration partners may incur financial, legal or other difficulties that force them to limit or reduce their participation in our joint projects;
- our existing and potential licensees and collaboration partners may terminate their licenses or collaborations with us, which could make it difficult for us to attract new partners and/or adversely affect perception of us in the business and financial communities; and
- our existing and potential licensees and collaboration partners may choose to pursue alternative, higher priority programs, which could affect their commitment to us.

Moreover, any disputes with our licensees and collaboration partners 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. If we cannot maintain successful license and collaboration arrangements, our business, financial condition and operating results may be adversely affected.

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.

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.

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.

Risks Related to Manufacturing and Supply Chain

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.

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 UDENYCA® and each of our lead product candidates, CHS-1420 and CHS-0214, 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. For example, in December 2015, we entered into a strategic manufacturing agreement with KBI Biopharma, Inc. for long-term commercial manufacturing of UDENYCA®. 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 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, NDA 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. For example, a FDA inspection in the fourth quarter of 2016 of KBI Biopharma, our contract manufacturer for UDENYCA® bulk drug substance, resulted in various form 483 observations. KBI Biopharma submitted corrective actions to the FDA. The FDA completed its review and has stated that the inspection is now closed. 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, inspect or 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, NDA 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.

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.

Risks Related to Adverse Events

UDENYCA® or our product candidates may cause undesirable side effects or have other properties that could, as applicable, 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 UDENYCA® or 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 ("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 for our product candidates, 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.

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.

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. 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 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 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, 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 UDENYCA® and our lead product candidates, CHS-1420 and CHS-0214, as well as our pipeline candidates, 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 U.S. 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. Moreover, some U.S. patents may issue without any prior publication in cases where the patent applicant does not also make a foreign 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 U.S., 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.

On May 10, 2017, Amgen Inc. and Amgen Manufacturing Inc. filed an action against us in the U.S. District Court for the District of Delaware alleging infringement of one or more claims of Amgen's US patent 8,273,707 (the "'707 patent") under 35 U.S.C. § 271. The complaint seeks injunctive relief, monetary damages and attorney fees. On December 7, 2017, the U.S. Magistrate Judge issued under seal a Report and Recommendation to the District Court recommending that the District Court grant, with prejudice, the Company's pending motion to dismiss Amgen's complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). On March 26, 2018, Judge Stark of the District Court adopted the U.S. Magistrate Judge's Report and Recommendation to grant the motion of the Company pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss with prejudice the patent infringement complaint alleging infringement of the '707 patent on the grounds that such complaint failed to state a claim upon which relief may be granted. In May 2018, Amgen filed a Notice of Appeal in the U.S. Court of Appeals for the Federal Circuit. Amgen and Coherus filed briefs in this matter and oral argument was held on May 8, 2019. On July 29, 2019, the Federal Circuit issued a precedential opinion affirming the District Court's judgment in the Company's favor. The Federal Circuit held that the doctrine of prosecution history estoppel barred Amgen from succeeding on its infringement claim and affirmed the District Court's dismissal. This case is currently pending, as Amgen may seek further appellate relief at the Federal Circuit or file a petition for writ of certiorari to the Supreme Court of the United States.

On January 24, 2019, we entered into settlement and license agreements with AbbVie, that grant us global, royalty-bearing, non-exclusive license rights under AbbVie's intellectual property to commercialize CHS-1420, our proposed adalimumab (Humira)

biosimilar. The global settlements resolve all pending disputes between the parties related to CHS-1420. Under the U.S. settlement, our license period in the U.S. commences on July 1, 2023.

In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, 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.

IPR filings, including our IPR filings, are a matter of public record and can be viewed at the USPTO PTAB website.

Third parties may submit applications for patent term extensions in the U.S. 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.

We do not know whether any of our pending patent applications will result in the issuance of any patents or whether the rights granted under any patents issuing from these applications will prevent any of our competitors from marketing similar products that may be competitive with our own. Moreover, even if we do obtain issued patents, they will not guarantee us the right to use our patented technology for commercialization of our product candidates. Third parties may have blocking patents that could prevent us from commercializing our own products, even if our products use or embody our own, patented inventions.

The validity and enforceability of patents are generally uncertain and involve complex legal and factual questions. Any patents that may issue on our pending applications may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing products similar to ours. Furthermore, our competitors may develop similar or alternative technologies not covered by any patents that may issue to us.

For technologies for which we do not seek patent protection, we may rely on trade secrets to protect our proprietary position. However, trade secrets are difficult to protect. We seek to protect our technology and product candidates, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, consultants, advisors, contractors or collaborators. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. 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. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, advisors, contractors and collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions

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 these patents are not successfully challenged (such as in IPRs or in district court litigation), and licenses to them are not available to us, they 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 U.S. 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 U.S. 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.

We may be involved in lawsuits or IPR proceedings to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

We may discover that competitors are infringing our issued patents. Expensive and time-consuming litigation may be required to abate such infringement. For example, we recently filed a complaint against Amgen alleging that Amgen's Humira biosimilar infringes certain of our patents. Proceedings, such as the Amgen complaint, to enforce our patent rights, 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. If we or one of our collaboration partners 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 U.S., 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. Mr. Lanfear and Dr. Watler were employed at Amgen during periods when Amgen's operations included the development and commercialization of Neupogen, Neulasta and Enbrel. Our former Chief Medical Officer, Barbara K. Finck, M.D., is a former employee of Immunex Corporation ("Immunex"), the company that initially developed 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. Senior members of our commercial team who will be responsible for any launch of our Neulasta biosimilar formerly held positions at Amgen. 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, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. 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.

On March 3, 2017, Amgen Inc. and Amgen USA Inc. (collectively "Amgen") filed an action against us, KBI Biopharma Inc., our employee Howard S. Weiser and Does 1-20 in the Superior Court of the State of California, County of Ventura. The complaint alleges that we engaged in unfair competition and improperly solicited and hired certain former Amgen employees in order to acquire and access trade secrets and other confidential information belonging to Amgen. On June 1, 2017, Amgen filed a Second Amended Complaint, which alleges as to Coherus (i) unfair competition under California Business and Professions Code Section 17200 et seq., (ii) misappropriation of trade secrets, (iii) aiding and abetting breach of duty of loyalty and (iv) tortious interference with contract. As to defendant Weiser, the Second Amended Complaint alleges (i) unfair competition under California Business and Professions Code Section 17200 et seq., (ii) misappropriation of trade secrets, (iii) breach of contract, (iv) violation of Penal Code Section 502 and (v) breach of duty of loyalty. KBI Biopharma Inc. is not named as defendant in the Second Amended Complaint. The Second Amended Complaint seeks injunctive relief and monetary damages. Although Amgen has indicated it intends to seek a preliminary injunction, no motion has been filed yet. On May 19, 2017, Amgen dismissed Defendant KBI Biopharma Inc. without prejudice. In December 2018, the court set a trial date of April 22, 2019. On April 9, 2019, Defendant Howard S. Weiser settled with Amgen and was dismissed. On May 2, 2019, we and Amgen settled the trade secret action brought by Amgen. The details of the settlement are confidential but the Company will continue to market UDENYCA® and will pay a mid-single digit royalty to Amgen for five years starting on July 1, 2019.

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 U.S. 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 U.S. 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. 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 U.S. 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, changes to U.S. patent laws 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 U.S. 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 U.S. 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 U.S. resulting from the Leahy-Smith America Invents Act (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 and on avoiding infringing valid and enforceable rights of third parties, we have filed a number of patent applications seeking patents that cover various proprietary elements of our product candidates when we have believed securing such patents may afford a competitive advantage. Our patent portfolio includes pending patent applications and issued patents, in the U.S. and globally, covering etanercept and adalimumab products and methods of making them. We cannot guarantee that our proprietary technologies will avoid infringement of third party patents. Moreover, because competitors may be able to develop their own proprietary technologies, it is uncertain whether any of our issued patents or pending patent applications directed to etanercept and adalimumab would cover the etanercept and adalimumab products of any competitors. The product and patent landscape is highly uncertain and we cannot predict whether our patent filings will afford us a competitive advantage against third parties or if our etanercept and adalimumab 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 U.S. can be less extensive than those in the U.S. 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 U.S. 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 U.S. or importing products made using our inventions into the U.S. 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 U.S. 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 U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent 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 U.S. 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 U.S., 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 Selexis SA and other vendors (pertaining to cell lines for CHS-1420 and CHS-0214) and with AbbVie (pertaining to AbbVie's intellectual property related to CHS-1420) that are important to our business, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the 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-1420 and CHS-0214. 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 U.S. 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, (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 U.S. or could substantially delay such launches. However, even if we elect not to implement this mechanism, the launch of our products in the U.S. could still be prevented or substantially delayed by intellectual property disputes with originator companies that market the reference products on which our biosimilar products are based.

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 U.S. Supreme Court, 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 June 12, 2017, the Supreme Court issued its decision in *Amgen v. Sandoz*, holding that (i) the "patent dance" is optional; and (ii) the 180-day pre-marketing notification may be given either before or after receiving FDA approval of the biosimilar product. The Supreme Court declined to rule whether a state injunctive remedy may be available to the originator and remanded that question to the Federal Circuit for further consideration. On December 14, 2017, the Federal Circuit decided that state law claims are preempted by the BPCIA on both field and conflict grounds.

A significant legal risk for a biosimilar applicant that pursues regulatory approval under the 351(k) regulatory approval route, and also elects 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-0214), may be able to apply substantially greater legal and financial resources to this process than we could.

If we submit a 351(k) BLA 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 U.S.

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 U.S.

Risks Related to the Discovery and Development of Our Product Candidates

We are heavily dependent on the development, 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.

We 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 of our product candidates. We currently do not have any approved products, other than UDENYCA®.

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. For example, CHS-1420 and CHS-0214 have completed Phase 3 clinical trials or other 351(k) BLA-enabling clinical development. We have not yet initiated clinical trials for CHS-3351, CHS-2020, or CHS-131 in NASH patients. It may be some time before we file for market approval with the relevant regulatory agencies for these 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. For example, in June 2017, we received a CRL from the FDA in response to our 351(k) BLA for UDENYCA®, identifying certain issues, including a request for reanalysis of a subset of subject samples with a revised immunogenicity assay and requests for certain additional manufacturing related process information, which must be addressed before approval can be granted. If we and our existing or future 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 U.S., the E.U., and 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 and biosimilar products are subject to extensive regulation by the FDA and other regulatory authorities in the U.S., by the EMA and EEA Competent Authorities in the European

Economic Area ("EEA"), and by other regulatory authorities in other countries, where regulations differ from country to country. Neither we nor any existing or future collaboration partners are permitted to market our product candidates in the U.S. until we and our collaboration partners receive approval from the FDA, or in the EEA until we and our collaboration partners receive EC 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, other than UDENYCA®, and it is possible that none of our other 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 an original BLA, an NDA, a biosimilar product application under the 351(k) pathway of the Public Health Service Act ("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 U.S., 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 U.S. for the full originator label but received a much narrower originator label when initially approved in Canada. That infliximab biosimilar only received full label extension in Canada in 2016 after providing additional clinical data. A similar outcome could occur with respect to one or more

of our product candidates and there is no guarantee that our product candidates will receive a full originator label even after the provision of additional clinical data.

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.

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 for our product candidates will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval. Furthermore, biosimilar clinical studies must use originator products as comparators, and such supplies may not be available on a timely basis to support such trials.

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 (“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 (“IRB”), approval at each clinical study site;
- imposition of a clinical hold by regulatory agencies, after review of an investigational new drug (“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 patients completing 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-1420 and CHS-0214 and will need to provide data to the FDA and foreign regulatory authorities demonstrating that the change in manufacturing process has not changed the product candidate. If we are unable to make that demonstration to the FDA or comparable foreign regulatory authorities, we could face significant delays or fail to obtain regulatory approval to market the product, which could significantly harm our business. In March 2017, we completed a clinical PK bioequivalence study comparing CHS-1420 to U.S. manufactured Humira. In August 2017, we completed a clinical PK bioequivalence study comparing CHS-1420 to European manufactured Humira.

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

We and our collaboration partners intend to pursue market authorization globally. In the U.S., an abbreviated pathway for approval of biosimilar products was established by the Biologics Price Competition and Innovation Act of 2009 ("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 ("PHSA"). Subsequent to the enactment of the BPCIA, the FDA issued guidance documents regarding the demonstration of biosimilarity and interchangeability as well as the submission and review of biosimilar applications. Moreover, market acceptance of biosimilar products in the U.S. 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, payers 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 originator-controlled patent portfolios 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 continues to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are evolving and remain 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. Moreover, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these Executive Orders will be interpreted and implemented, and the extent to which they will impact the FDA's ability to continue implementing the BPCIA and engage in its other regulatory authorities under the FDCA. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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 E.U. regulations, an application for regulatory approval of a biosimilar drug cannot be submitted in the E.U. 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 E.U. 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 EC. 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 U.S. 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), adalimumab (Humira), etanercept (Enbrel), ranibizumab (Lucentis) or aflibercept (Eylea) 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 U.S. 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 a 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 are marketing UDENYCA® in the United States, and subject to product approvals and relevant patent expirations, we intend to market our other biosimilar products in the U.S. and outside the U.S. on our own or with future collaboration partners. We entered into a distribution agreement with our licensee Orox for the commercialization of biosimilar versions of etanercept (Enbrel), rituximab (Rituxan), adalimumab (Humira) and pegfilgrastim (Neulasta) in certain Caribbean and Latin American countries. We intend to market our biosimilar product candidates in the U.S. and may seek to partner commercially all biosimilars outside the U.S.

In order to market our products in the E.U., the U.S. 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 U.S. or in any market outside the U.S. Failure to obtain these approvals would materially and adversely affect our business, financial condition and results of 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.

Risks Related to Our Compliance with Applicable Laws

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 (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 have increased our legal and financial compliance costs and make some activities more time consuming and costly. Any changes we have made, and may make in the future 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 ("Section 404"), and the related rules of the Securities and Exchange Commission ("SEC"), which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Market or other adverse consequences that would materially harm our business.

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.

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

In the U.S., 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, (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. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future, particularly in light of the current presidential administration and U.S. Congress. In addition, Congress could consider subsequent legislation to replace or repeal and replace elements of the PPACA. At the end of 2017, the Tax Cuts and Jobs Act (the "Tax Act") was enacted, which, among other things, removes penalties for not complying with PPACA's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the PPACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the PPACA are invalid as well. While the Trump Administration and the CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, will impact the law. At this time, the full effect that the PPACA and any subsequent legislation would have on our business remains unclear.

In addition, other legislative changes have been proposed and adopted in the U.S. since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to certain providers, including physicians, hospitals and cancer treatment centers. Recently there has also been heightened government scrutiny over the manner in which manufacturers set prices for their approved products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, reform government program reimbursement methodologies. Individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

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.

Our operations are 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 impact, among other things, 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. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, 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;
- federal civil and criminal false claims 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 payers that are false or fraudulent and which may apply to entities that provide coding and billing advice to customers;
- federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the federal Health Insurance Portability and Accountability Act of 1996 ("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. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- 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 (including their immediate family members), certain other healthcare professionals as of 2022, and teaching hospitals and ownership and investment interests held by physicians and their immediate family members and applicable GPOs; 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 payer, 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 pricing information; 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.

Efforts to ensure that our operations and business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If we 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, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws 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. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

If we participate in and then fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

With the approval of UDENYCA®, we anticipate that we will need to participate in the Medicaid Drug Rebate Program, Medicare Coverage Gap Discount Program and a number of other federal and state government pricing programs in the U.S. in order to obtain coverage for the product by certain government healthcare programs. These programs would generally require us to pay rebates or provide discounts to certain private purchasers or government payers in connection with our products when dispensed to beneficiaries of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing and rebate calculations that we report on a monthly and quarterly basis to the government agencies that administer the programs. The terms, scope and complexity of these government pricing programs change frequently. We may also have reimbursement obligations or be subject to penalties if we fail to provide timely and accurate information to the government, pay the correct rebates or offer the correct discounted pricing. Changes to the price reporting or rebate requirements of these programs would affect our obligations to pay rebates or offer discounts. Responding to current and future changes may increase our costs and the complexity of compliance, will be time-consuming, and could have a material adverse effect on our results of operations.

We are subject to governmental regulation and other legal obligations related to privacy, data protection and information security. Compliance with these requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data, and the failure to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations.

Privacy and data security have become significant issues in the U.S., E.U. and in many other jurisdictions where we may in the future conduct our operations. As we receive, collect, process, use and store personal and confidential data, we are subject to diverse laws and regulations relating to data privacy and security, including, in the U.S., HIPAA, and, in the E.U., and shortly in the EEA, Regulation 2016/679, known as the General Data Protection Regulation ("GDPR"). Compliance with these privacy and data security requirements is rigorous and time-intensive and may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm, which could materially and adversely affect our business, financial condition and results of operations.

In addition, the regulatory framework for the receipt, collection, processing, use, safeguarding, sharing and transfer of personal and confidential data is rapidly evolving and is likely to remain uncertain for the foreseeable future as new global privacy rules are being enacted and existing ones are being updated and strengthened. For example, on May 25, 2018, the GDPR took effect in the E.U. The GDPR is directly applicable in each E.U. member state and applies to companies established in the E.U. as well as companies that collect and use personal data to offer goods or services to, or monitor the behavior of, individuals in the E.U., including, for example, through the conduct of clinical trials. GDPR introduces more stringent data protection obligations for processors and controllers of personal data, and penalties and fines for failure to comply with GDPR are significant, including fines of up to €20 million or 4% of total worldwide annual turnover, whichever is higher.

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

We currently have limited international operations of our own and have and may have in the future 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 payer reimbursement regimes, government payers 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 military intervention in Ukraine in March 2014, the U.S. and the E.U. imposed sanctions on Russia, including sanctions on certain individuals and other entities. In response, Russia has imposed entry bans on certain U.S. lawmakers and officials, and trading sanctions against nations that implemented or supported the anti-Russia sanctions, including the U.S. and the E.U. Our wholly-owned subsidiary, InteKrin Therapeutics, Inc. ("InteKrin"), which we acquired in February 2014, wholly-owns InteKrin Russia, a pharmaceutical development entity in Russia, which holds an immaterial amount of cash in Russian banks as of June 30, 2019. 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 ("PPAR"), gamma modulator that may hold promise in treatment of multiple sclerosis and NASH. While not a biosimilar, this PPAR gamma modulator compound may be complementary to biosimilar business. If the U.S. and the E.U. were to impose broader sanctions on Russia, including sanctions on Russian businesses such as InteKrin, 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 modulator 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.

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 $8.05 to $38.10 per share during the period from November 6, 2014 through July 31, 2019 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 the "Risk Factors" section of this Annual Report on Form 10-K and others such as:

- adverse results or delays in preclinical or clinical studies;
- any inability to obtain additional funding;
- any delay in filing an IND, NDA, original BLA, 351(k) 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, original BLA, 351(k) 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 citizen 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 June 30, 2019, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 49% of our voting stock (assuming no exercise of outstanding options or conversion of our outstanding convertible notes). 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 June 30, 2019, there were 69,627,148 shares of common stock outstanding. Of these shares, the shares of our common stock sold in our IPO, our underwritten follow-on offering, pursuant to our at-the-market equity offering program and in private placement transactions (subject to certain lock-up periods) are currently freely tradable, without restriction (except as otherwise applicable), in the public market.

In addition, as of June 30, 2019, approximately 21.1 million shares of common stock that are either subject to outstanding options and restricted stock units 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 have needed and anticipate we will need additional capital in the future to continue our planned operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. Similar to prior financing transactions, 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. Any future debt financing may involve covenants that restrict our operations, including, among other restrictions, limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. In addition, if we raise additional funds through licensing arrangements, it may be necessary to grant potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

Pursuant to our 2014 Equity Incentive Award Plan (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 (“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 (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. As of December 31, 2018, we reserved for future issuance under the 2016 Plan a total of 2,300,000 share of common stock for new employees. In January 2019, we increased the reserve for future issuance under the 2016 Plan to 2,800,000 shares of common stock for new employees. In April 2019, we increased the reserve for future issuance under the 2016 Plan to 3,450,000 shares 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.

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.

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	11/13/2014	
3.2	Amended and Restated Bylaws.	8-K	3.2	11/13/2014	
10.1†	Confidential Litigation Settlement Agreement and Release, dated as of April 30, 2019 between Amgen Inc. and Amgen USA Inc. (collectively "Amgen"), and Coherus BioSciences Inc.				X
31.1	Certification of Principal Executive Officer Required under Securities Exchange Act Rule 13a-14(a) and 15d-14(a).				X
31.2	Certification of Principal Financial Officer under Securities Exchange Act Rule 13a-14(a) and 15d-14(a).				X
32.1	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350 and Securities Exchange Act Rule 13a-14(b).				X
101	The following materials from Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 formatted in eXtensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at June 30, 2019 (unaudited) and December 31, 2018, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2019 and 2018, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and six months ended June 30, 2019 and 2018, (iv) Condensed Consolidated Statements of Stockholders' Deficit (unaudited) for the three and six months ended June 30, 2019 and 2018, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2019 and 2018, and (vi) Notes to the Condensed Consolidated Financial Statements.				X

† Certain portions of this exhibit (indicated by asterisks) have been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

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: August 5, 2019

/s/ Dennis M. Lanfear

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

Date: August 5, 2019

/s/ Jean-Frédéric Viret

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

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

Exhibit 10.1

CONFIDENTIAL LITIGATION SETTLEMENT AGREEMENT AND RELEASE

This Confidential Litigation Settlement Agreement and Release ("**Settlement Agreement**"), signed on the 30th day of April, 2019, is between Amgen Inc. and Amgen USA Inc. (collectively "**Amgen**"), and Coherus BioSciences Inc. ("**Coherus**") and resolves the litigation involving Amgen and Coherus pending in the Superior Court of California County of Ventura, (the "**Court**") Case No. 56-2017-00493553-CU-BT-VTA (the "**Action**"). Amgen and Coherus may each be referred to herein individually as "**Party**" or collectively as "**Parties**."

WHEREAS Amgen is a Delaware corporation, having a principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799;

WHEREAS Coherus is a Delaware corporation, having a principal place of business at 333 Twin Dolphin Drive, Suite 600, Redwood City, California 94065;

WHEREAS Amgen developed and obtained regulatory approval to sell both a filgrastim and a pegylated filgrastim product ("**pegfilgrastim**") in the United States and in many other countries around the world;

WHEREAS beginning in 2002, Amgen has sold and continues to sell pegfilgrastim in the United States and many countries under the tradename Neulasta®;

WHEREAS Coherus developed and obtained regulatory approval to sell a biosimilar pegfilgrastim product, designated UDENYCA® or pegfilgrastim-cbqv, in the United States and Europe;

WHEREAS Coherus has launched its biosimilar pegfilgrastim in the United States;

WHEREAS beginning in 2019, Coherus has sold and continues to sell its pegfilgrastim product in the United States under the trade name UDENYCA®;

WHEREAS on March 3, 2017, Amgen filed a lawsuit against Coherus and others alleging unfair competition, misappropriation of trade secrets, and tortious interference, among other claims, relating to the development, manufacture, and marketing of Coherus' pegfilgrastim biosimilar product. On April 21, 2017, Amgen filed a First Amended Complaint and on June 1, 2017, Amgen filed a Second Amended Complaint with the same and additional causes of action against Coherus and others. Amgen alleged, among other things, that Coherus had misappropriated confidential and trade secret information from Amgen relating to particular components of Amgen's pegfilgrastim product, certain steps in the manufacturing process to make such product, and certain information relating to Amgen's marketing and pricing of its pegfilgrastim product. In this Action, Amgen alleged that Coherus has used and continues to use Amgen's trade secrets and confidential business information in the manufacture and marketing of Coherus' biosimilar pegfilgrastim all to Amgen's detriment. Amgen sought injunctive and other relief, including damages, from Coherus as compensation for its actions;

WHEREAS Coherus denied Amgen's allegations and raised certain defenses;

WHEREAS the Parties, having a full and fair opportunity to litigate their claims and defenses, now seek to resolve by settlement the Action and all claims and defenses raised, and those that could have been raised therein, and to avoid further litigation and expenditure of attorney fees or other resources;

NOW, THEREFORE, for good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties intending to be legally bound do hereby agree as follows:

1. DEFINITIONS

1.1 The term "**Affiliate**" shall mean, with respect to a Party, any entity or person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Party. For purposes of this definition, "control" means (a) ownership, directly or through one or more intermediaries, of (i) more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or (ii) more than fifty percent (50%) of the equity interests in the case of any other type of legal entity or status as a general partner in any partnership, or (b) any other arrangement whereby an entity or person has the right to elect a majority of the board of directors or equivalent governing body of a corporation or other entity or the right to direct the management and policies of a corporation or other entity.

1.2 The term "**Coherus Product**" shall mean any product that includes pegfilgrastim or its equivalent, including pegfilgrastim-cbqv or UDENYCA®, that is manufactured by or for, sold, offered for sale, or distributed by or on behalf of Coherus or by a Third Party to whom Coherus transfers its interest in pegfilgrastim-cbqv or its equivalent as permitted by the provisions of this Settlement Agreement.

1.3 "**Calendar Quarter**" means a three-month period beginning on January, April, July or October 1st.

1.4 "**Calendar Year**" means a one-year period beginning on January 1st and ending on December 31st.

1.5 "**Contract Interest Rate**" shall mean [***] percent ([***]%) plus the [***] day U.S. Dollar LIBOR rate effective for the date that payment was due, as published by Reuters, on the date such payment was due (or, if unavailable on such date, the first date thereafter on which such rate is available), or, if lower, the maximum rate permitted by applicable law.

1.6 "**Net Sales**" means the actual gross retail or wholesale amounts (as the case may be) invoiced by Coherus, its Affiliates or distribution partners from the sale of the Coherus Product to Third Parties in the Territory in a given period, less allowances for the following without duplication:

a) sales and excise taxes, value added taxes, and duties which fall due and are paid by the purchaser as a direct consequence of such sales and any other governmental charges imposed upon the importation, use or sale of such product, but only to the extent that such taxes and duties are (i) actually included and itemized in the gross amounts invoiced to and specifically paid by the purchaser over and above the usual selling price of such product, (ii) customarily included and itemized in the gross amounts invoiced to and specifically paid by the purchaser over and above the usual selling price of all comparable products in the relevant market and (iii) are not recovered or recoverable;

b) Third Party distribution fees and trade, quantity and cash discounts, including prompt pay discounts, that are customary in the industry in the United States and that are actually allowed on such product;

c) allowances or credits to customers on account of rejection, withdrawal, recall (only for the purchase price of such product; Coherus shall be responsible for any other costs associated with a recall), return of Coherus Product, on account of retroactive price reductions, reprocurement charges, price protection and shelf stock adjustments, slotting allowances, allowances, discounts or inventory management fees, to the extent that

such allowances, credits or charges are customary in the generic pharmaceutical industry in the United States;

d) rebates and chargebacks specifically related to such product on an accrual basis, which shall be trued up and reconciled in the ordinary course of business, including, but not limited to, those granted to government agencies (i.e. payments made under the "Medicare Part D Coverage Gap Discount Program");

e) freight, insurance and other transportation charges to the extent that Coherus or an Affiliate is responsible for payment of such charges;

provided, however, where any such discount (or similar adjustment to Net Sales) is based on sales of a bundled set of products in which such product is included, the discount (or similar adjustment to Net Sales) shall be allocated to such product on a pro rata basis based upon the sales value (i.e., the unit average selling price of a bundled set of products in which such product is included multiplied by the unit volume of such product within the bundled set of products) of such product relative to the sales value contributed by the other constituent products in the bundled set, with respect to such sale. Net Sales are to be ascertained from books and records maintained by or on behalf of Coherus in accordance with generally accepted accounting principles, as consistently applied by it with respect to sales of all its drug products.

1.7 The **"Royalty Period"** shall be July 1, 2019 to July 1, 2024.

1.8 The term "**Third Party**" shall mean any entity or person that is not a Party or an Affiliate of a Party.

1.9 The term "**Territory**" shall include all countries in the world.

2. JOINT REQUEST FOR DISMISSAL

2.1 Within [***] business days after the date of signature of the last Party to sign this Settlement Agreement (the "**Signing Date**"), the Parties, through their respective counsel, will dismiss the entire Action with Prejudice. Counsel for Amgen shall lodge (and shall be authorized by this Settlement Agreement to lodge) with the Court the Joint Request Regarding Settlement and [Proposed] Order for Dismissal of Defendant Coherus Biosciences Inc. from Action (the "**Joint Request and Order Re: Dismissal**"), in the form attached hereto as Exhibit A. If for any reason the Court raises an objection to the Joint Request and Order Re: Dismissal as drafted or requires that the Parties modify the Proposed Order before it will enter it as an order of the Court, the Parties agree to confer promptly and in good faith and revise that document consistent with the requirements of the Court. Coherus will cause its counsel to execute the Joint Request and Order Re: Dismissal prior to or contemporaneously with the execution of this Settlement Agreement, and Coherus hereby consents to the filing of the document with the Court by counsel for Amgen.

2.2 The date on which the Joint Request and Order Re: Dismissal is entered by the Court shall be the "**Effective Date**" of this Settlement Agreement.

3. OBLIGATIONS AND MUTUAL RELEASES

3.1 In marketing the Coherus Product, Coherus agrees that it will not reference Amgen's manufacturing process for pegfilgrastim or any similarity of Coherus' manufacturing process to Amgen's process. This provision does not preclude Coherus from discussing the attributes or characteristics of the Coherus Product or the fact that it is a biosimilar to Amgen's Neulasta®. Coherus agrees that it will destroy any Amgen document found in the possession of a Coherus employee in the course of this Action. In addition, if Coherus discovers any Amgen

document not previously discovered, Coherus agrees to destroy or return such document to Amgen. For sake of clarity, this provision does not impose any obligation on Coherus to search for such Amgen documents.

3.2 As of the Effective Date, in settlement of the disputed claims in the Action, and in consideration of the promise of payment of future royalties by Coherus, and the representations, warranties and covenants contained in this Settlement Agreement, Amgen and its subsidiaries, successors, and assigns, on behalf of themselves and their successors, administrators and attorneys, Affiliates, assigns, agents, officers, employees, directors, representatives, and all other Persons claiming by, through and under them (the "***Amgen Releasors***") hereby fully, finally and forever release, relinquish, acquit, and discharge Coherus and its respective administrators, attorneys, agents, stockholders, directors, officers, employees, representatives, insurers, predecessors, successors, assigns and customers, distributors and suppliers of the Coherus Product, (the "***Coherus Releasees***") from any and all claims, demands, damages, lawsuits, liabilities, obligations, causes of action, and controversies, whether known or unknown, that Amgen could assert at common law or by any statute, rule, regulation, ordinance or law, whether federal, state or local, or on any other grounds whatsoever that arise out of the allegations, claims, or defenses made in this Action or the filing of the Action, including but not limited to, costs, expenses and attorneys' fees arising before the Effective Date of this Settlement Agreement. For sake of clarity, this release does not extend to any breach of contract claims that Amgen may have against any Third Party.

3.3 As of the Effective Date, in settlement of the disputed claims in the Action, and in consideration of the representations, warranties and covenants contained in this Settlement Agreement, Coherus and its subsidiaries, successors, and assigns, on behalf of themselves and

their successors, administrators and attorneys, Affiliates, assigns, agents, officers, employees, directors, representatives, and all other Persons claiming by, through and under them (the ***"Coherus Releasors"***) hereby fully, finally and forever release, relinquish, acquit, and discharge Amgen and its respective administrators, attorneys, agents, stockholders, directors, officers, employees, representatives, insurers, predecessors, successors, assigns and customers, distributors and suppliers of Neulasta® (the "***Amgen Releasees***") from any and all claims, demands, damages, lawsuits, liabilities, obligations, causes of action, and controversies, whether known or unknown, that Coherus could assert at common law or by any statute, rule, regulation, ordinance or law, whether federal, state or local, or on any other grounds whatsoever that arise out of the allegations, claims, or defenses made in this Action or the filing of the Action, including but not limited to, costs, expenses and attorneys' fees arising before the Effective Date of this Settlement Agreement. For the sake of clarity, this release does not extend to any breach of contract claims that Coherus may have against any Third Party.

3.4 In connection with this Settlement Agreement, the Parties and their respective Affiliates expressly waive and relinquish all rights and benefits afforded by Section 1542 of the California Civil Code ("**Section 1542**"), which provides as follows:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN TO HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

Further, the Parties and their respective Affiliates expressly waive and relinquish all rights and benefits afforded by any law in any other jurisdiction similar to Section 1542.

3.5 For the avoidance of doubt, the releases in this Article 3 do not apply to the obligations and responsibilities agreed to herein or to the enforcement of compliance with this Settlement Agreement.

3.6 The Amgen Releasors covenant that no Amgen Releasor will commence or cause to be commenced against any of the Coherus Releasees any action or other proceeding based upon any claim which has been released in this Article 3 and will not challenge or seek to challenge the validity or enforceability of any portion of the release contained in this Article 3.

3.7 The Coherus Releasors covenant that no Coherus Releasor will commence or cause to be commenced against any of the Amgen Releasees any action or other proceeding based upon any claim which has been released in this Article 3 and will not challenge or seek to challenge the validity or enforceability of any portion of the release contained in this Article 3.

4. ROYALTIES, REPORTS AND PAYMENTS

4.1 As compensation to Amgen, Coherus shall pay a [***] percent ([***]%) royalty on Net Sales of the Coherus Product in the Territory for the Royalty Period.

4.2 Beginning with the first Calendar Quarter in the Royalty Period and thereafter for each Calendar Quarter until the expiration of the Royalty Period, Coherus shall deliver a report of the sale of the Coherus Product for each Calendar Quarter to Amgen within [***] days after the end of each Calendar Quarter. Such report shall state: (i) Net Sales of each such Coherus Product by or on behalf of Coherus or its Affiliates by country or region during the applicable Calendar Quarter; and (ii) a calculation of the royalty payment due from Coherus hereunder for such Calendar Quarter.

4.3 Based on the royalty report, Coherus shall pay the amount of royalty payment due within [***] days after the end of each Calendar Quarter to an account designated by Amgen. All payments made hereunder shall be made in U.S. Dollars. Coherus shall pay all sums due hereunder by check, wire transfer, or electronic funds transfer in immediately available funds. Amgen will promptly notify the other Party of the appropriate account information to facilitate any such payments. All amounts owing under this Settlement Agreement shall be paid in full.

4.4 Coherus shall keep complete and accurate records pertaining to the underlying revenue and expenses data relating to the calculation of Net Sales for the Coherus Product in sufficient detail to permit Amgen to confirm the accuracy of all payments due hereunder. Coherus will retain their books and records pertaining to the Net Sales for the Coherus Product for each Calendar Quarter for at least [***] years from the end of such Calendar Quarter. Until [***] years after the expiration of the Royalty Period, Amgen may provide Coherus with reasonable notice of its request to have an independent public accounting firm licensed to practice in the United States audit records required to determine the Net Sales of the Coherus Product and the royalty due under this Agreement. Coherus will accommodate such an audit and use reasonable efforts to accommodate such request within [***] days of Amgen's request; provided however, any audit under this Article 4.4 shall be conducted during normal business hours of Coherus. The audit will be at Amgen's sole expense unless the audit shows an underpayment in the royalties due to Amgen of [***] percent ([***]%) or more in any Calendar Quarter in which case Coherus will pay for the audit. In the event that an audit reveals any underpayment in royalties due to Amgen, Coherus shall promptly, but in no event later than [***] days after receipt of written notice thereof, pay such underpayment to Amgen. Amgen's audit rights may only be exercised [***] and any such audit shall be limited to those necessary books and records for a period no greater than [***] years prior to the quarter in which such audit takes place. No set of books and records for any given period shall be audited more than once and cannot cover any period outside of the Royalty Period.

4.5 Each Party will be responsible for its own taxes, fees, or duties payable on account of any payments made under this Settlement Agreement.

4.6 Any payments or portions thereof due hereunder which are not paid when due shall bear interest at the Contract Interest Rate calculated on the number of days such payment is delinquent. The provisions of this Section shall in no way limit any other remedies available to Amgen.

5. REPRESENTATIONS, WARRANTIES AND ASSIGNMENT

5.1 Each Party represents and warrants to the other Party that: (a) it has the power and authority to enter into this Settlement Agreement and to perform its obligations hereunder, (b) its execution, delivery and performance of this Settlement Agreement have been duly authorized by all necessary corporate or other organizational actions of it and its Affiliates, and (c) that entering into this Settlement Agreement does not and will not conflict with or result in a breach of any other agreement to which it or any of its Affiliates is a party, any judgment of any court or governmental body applicable to the Party or its properties, or, to the Party's knowledge, any statute, decree, order, rule or regulation of any court or governmental authority applicable to the Party or its properties.

5.2 Upon execution and delivery of this Settlement Agreement by both Parties, this Settlement Agreement is a valid obligation binding upon such Party and enforceable in accordance with its terms.

5.3 Coherus represents that it is the sole owner of the Coherus Product and holds all the rights to commercialize the Coherus Product in the Territory. Coherus agrees that it will not transfer the rights to commercialize the Coherus Product to any Third Party during the term of the Royalty Period unless, first, such Third Party provides a written acceptance of the Coherus obligations under this Settlement Agreement and agrees to be bound by the terms of this Settlement Agreement as Coherus is bound, second, provides such written acceptance to Amgen, and third, Amgen shall then have [***] business days to approve such transfer and such approval

may not be unreasonably withheld. In the event of a transfer, Coherus will guarantee the payment of royalties pursuant to the terms of this Settlement Agreement.

5.4 Any such purported assignment, transfer or attempt by Coherus to assign or transfer the commercialization rights to the Coherus Product without Amgen's consent as required in 5.3 shall be void and of no effect, except that Coherus may, after providing notice pursuant to Section 5.3 to Amgen, transfer this Settlement Agreement to an Affiliate or a Third Party without prior written consent of Amgen upon the sale to such Third Party of all or substantially all Coherus' business. Upon any permitted assignment, this Settlement Agreement, including the obligations of the Parties, shall be binding upon and shall inure to the benefit of each Party hereto, and each of its Affiliates, successors and permitted assigns, and any Third Party to which any rights are transferred.

6. GENERAL PROVISIONS

6.1 **Confidentiality**. The Parties shall keep the terms of this Agreement and the underlying settlement terms confidential using at least the level of care they use for their own proprietary information. Except as (a) required by statute, ordinance or regulation, (b) required pursuant to compulsory legal process, (c) necessary for the exercise of the rights granted to the Parties under this Settlement Agreement, or (d) as expressly permitted under this Section 6.1, neither the Parties nor their Affiliates shall publicly announce or otherwise disclose to Third Parties any of the confidential terms of this Settlement Agreement without the prior written approval of the other Party, not to be unreasonably withheld or delayed. Except as otherwise provided in this Section 6.1, the Parties shall only release public announcements of the execution of this Settlement Agreement in the following form:

Amgen and Coherus have settled the trade secret action brought by Amgen against Coherus that was pending in the Superior Court of California County of Ventura. The details of the settlement are confidential but Coherus will continue to market UDENYCA and will pay a mid-single digit royalty to Amgen.

If a Party intends to disclose more details relating to this Settlement Agreement because it is required to do so in order to comply with a statute, ordinance, regulation, or compulsory legal process, including, without limitation, its reporting requirements under the Securities Exchange Act of 1934, as amended, such Party shall give the other Party at least [***] business days' prior notice in writing of the text of the intended disclosure, unless such statute, ordinance, regulation, or compulsory legal process requires earlier disclosure, in which event the notice shall be provided as early as practicable. A Party that determines that it is required to file this Settlement Agreement with the Securities and Exchange Commission or any other governmental authority shall request confidential treatment with respect to the terms of this Settlement Agreement, shall consult in good faith with the other Party regarding such confidential treatment and shall use commercially reasonable efforts to have redacted from any publicly available version such provisions as the Parties may agree.

6.2 **Governing Law.** This Settlement Agreement and the rights and obligations of the Parties under this Settlement Agreement shall be governed and construed in accordance with the laws of the State of California, without regard to its choice-of-law or conflicts-of-law principles that might otherwise refer construction or interpretation of this Settlement Agreement to the substantive law of another jurisdiction. Amgen and Coherus agree that venue is proper in the Superior Court of California County of Ventura.

6.3 **Waiver**. No waiver of a breach, failure of any condition, or any right or remedy, contained in or granted by the provisions of this Settlement Agreement shall be effective unless it is in writing and signed by the Party waiving the breach, failure, right or remedy. No waiver of any breach, failure, right or remedy shall be deemed a waiver of any other breach, failure, right or remedy, whether or not similar, nor shall any waiver constitute a continuing waiver unless the writing so specifies.

6.4 **Entire Agreement**. This Settlement Agreement, including Exhibit A, represents the entire understanding and agreement of the Parties with regards to the matters addressed herein. No terms or conditions of this Settlement Agreement will be varied or modified by any prior or subsequent statement, conduct or act of either Party, except that the Parties may supplement, amend, or modify this Settlement Agreement by a subsequent written agreement executed by all of the Parties through their authorized representatives. Each Party and its counsel have participated fully in the review and revision of this Settlement Agreement. Any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not apply in interpreting this Settlement Agreement.

6.5 **Notice**. Any notice required or permitted to be given or sent under this Settlement Agreement shall be hand delivered, sent by an express delivery service that provides proof of delivery, or sent by certified or registered mail, postage prepaid, to the Parties at the addresses indicated below.

If to Amgen, to:

Jonathan Graham
Senior Vice President, General Counsel & Secretary
One Amgen Center Drive

Building 28-1E
Thousand Oaks, CA 91320

If to Coherus, to:

Thomas Fitzpatrick
Chief Legal Officer
333 Twin Dolphin Drive, Suite 600
Redwood City, CA 94065

These addresses may be changed by notice given pursuant to this Section.

6.6 **Counterparts**. This Settlement Agreement may be executed in any number of counterparts, and through pdf, facsimile or photocopy signatures. Each counterpart shall be deemed an original instrument, but all counterparts together shall constitute but one agreement.

6.7 **Headings**. The descriptive headings contained in this Agreement are for convenience of reference only and shall not in any way affect the meaning or interpretation of this Agreement.

6.8 **Evidence**. This Agreement and all of the terms herein constitute compromises and offers to compromise covered by California Evidence Code Section 1152. Nothing in this Agreement may be used as evidence in any action or proceeding between the Parties hereto, except in connection with any action or proceeding relating to enforcement of this Agreement.

6.9 **No Admission of Liability**. The Parties hereby acknowledge and agree that neither the execution of this Agreement, nor the performance of any act pursuant to the Agreement, constitutes an admission of liability, express or implied, of any Party with respect to any fact or matter which may have arisen in connection with the Action. This Agreement is

entered into for the purpose of resolving the disputes that have arisen between the Parties without further expenditure of attorney fees or other resources.

[*remainder of this page left blank intentionally*]

IN WITNESS WHEREOF, the Parties, through their authorized officers, have executed this Settlement Agreement as of the Signing Date.

Amgen Inc. and Amgen USA Inc.
By: /s/ STUART L. WATT
Name: Stuart L. Watt
Title: VP Law & Intellectual Property Officer
Date: May 1, 2019

Coherus BioSciences Inc.

By: /s/ DENNIS M. LANFEAR
Name: Dennis M. Lanfear
Title: Chief Executive Officer
Date: May 1, 2019

EXHIBIT A

Proposed Order of Dismissal

Omitted pursuant to Regulation S-K, Item 601(a)(5)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dennis M. Lanfear, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Coherus BioSciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2019

/s/ Dennis M. Lanfear
Dennis M. Lanfear
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jean-Frédéric Viret, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Coherus BioSciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2019

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

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officers of Coherus BioSciences, Inc. (the "Registrant") certify that the Quarterly Report of Coherus BioSciences, Inc. on Form 10-Q for the quarterly period ended June 30, 2019 (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: August 5, 2019

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

Date: August 5, 2019

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.