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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, 2021

☐ **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 30, 2021, 76,480,152 shares of the registrant's common stock were outstanding.

COHERUS BIOSCIENCES, INC.
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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements 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 maintain or increase sales for UDENYCA® (pegfilgrastim-cbqv) in the United States;
- our expectations regarding our ability to develop and commercialize our toripalimab drug candidates in the United States and Canada and whether the trial results, data package or biologics license application (“BLA”) will be sufficient to support the regulatory approvals;
- our expectations regarding our ability to develop and commercialize our bevacizumab (Avastin®) biosimilar candidate in the United States and Canada, including the anticipated three-way pharmacokinetic study, the planned additional analytical similarity characterizations and our plans to submit a 351(k) BLA to the U.S. Food and Drug Administration (“FDA”);
- whether our CHS-1420 (our adalimumab (Humira®) biosimilar candidate) trial results, data package or BLA will be sufficient to support domestic or global regulatory approvals;
- whether our ranibizumab (Lucentis®) biosimilar candidate partner, Bioeq AG (“Bioeq”), will be able to obtain regulatory approval in the United States or if we will be able successfully initiate sales of Bioeq’s biosimilar candidate upon such approval;
- our ability to maintain regulatory approval for UDENYCA® and our ability to obtain and maintain regulatory approval of our 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 financial performance, including, but not limited to, future performance of our gross margins, research and development expenses and selling and general administrative expenses;
- the implementation of strategic plans for our business and products;

- 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 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®, Avastin®, Humira® and Lucentis®;
- developments and projections relating to our competitors and our industry; and
- the potential impact of COVID-19 on our business and prospects.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. Risk Factors and discussed elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

PART I. FINANCIAL INFORMATION

ITEM 1. Unaudited Condensed Consolidated Financial Statements

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

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 329,738	$ 541,158
Investments in marketable securities	124,683	—
Trade receivables, net	141,825	157,046
Inventory	39,668	44,233
Prepaid manufacturing	15,159	19,429
Other prepaid and other assets	8,940	5,613
Total current assets	660,013	767,479
Property and equipment, net	9,130	10,108
Inventory, non-current	56,413	47,956
Intangible assets	2,620	2,620
Goodwill	943	943
Other assets, non-current	10,423	12,543
Total assets	$ 739,542	$ 841,649
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 14,568	$ 15,201
Accrued rebates, fees and reserves	83,758	81,529
Accrued compensation	14,816	22,244
Accrued and other current liabilities	54,899	26,679
Convertible notes due 2022 - current	80,605	—
Convertible notes due 2022 - related parties, current	26,868	—
Term Loan - current portion	11,538	—
Total current liabilities	287,052	145,653
Convertible notes due 2022	—	79,885
Convertible notes due 2022 - related parties	—	26,628
Convertible notes due 2026	223,655	223,029
Term loan - non-current portion	63,420	74,481
Lease liabilities, non-current	8,444	9,948
Other liabilities, non-current	751	1,051
Total liabilities	583,322	560,675
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock ($0.0001 par value; Shares authorized: 5,000,000; No shares issued and outstanding as of June 30, 2021 and December 31, 2020)	—	—
Common stock ($0.0001 par value; shares authorized: 300,000,000; shares issued and outstanding: 76,464,700 and 72,513,348 at June 30, 2021 and December 31, 2020, respectively)	7	7
Additional paid-in capital	1,122,081	1,043,991
Accumulated other comprehensive loss	(267)	(270)
Accumulated deficit	(965,601)	(762,754)
Total stockholders' equity	156,220	280,974
Total liabilities and stockholders' equity	$ 739,542	$ 841,649

See accompanying notes.

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,	
	2021	2020	2021	2020
Revenue:				
Net product revenue	$ 87,643	$ 135,674	$ 170,677	$ 251,854
Operating expenses:				
Cost of goods sold	16,696	10,139	24,207	16,994
Research and development	54,766	26,173	258,258	59,280
Selling, general and administrative	40,345	34,052	79,736	69,402
Total operating expenses	111,807	70,364	362,201	145,676
(Loss) income from operations	(24,164)	65,310	(191,524)	106,178
Interest expense (includes related party expense of $634 and $622 for the three months ended June 30, 2021 and 2020, respectively; and $1,265 and $1,242 for the six months ended June 30, 2021 and 2020, respectively)	(5,747)	(5,408)	(11,395)	(9,839)
Other income, net	11	423	72	491
Net (loss) income before income taxes	(29,900)	60,325	(202,847)	96,830
Income tax provision	—	1,294	—	2,227
Net (loss) income	$ (29,900)	$ 59,031	$ (202,847)	$ 94,603
Net (loss) income per share:				
Basic	$ (0.40)	$ 0.83	$ (2.73)	$ 1.33
Diluted	$ (0.40)	$ 0.70	$ (2.73)	$ 1.20
Weighted-average number of shares used in computing net (loss) income per share:				
Basic	75,559,697	71,099,773	74,203,858	70,880,979
Diluted	75,559,697	88,660,280	74,203,858	83,775,353

See accompanying notes.

Coherus BioSciences, Inc.
Condensed Consolidated Statements of Comprehensive (Loss) Income
(in thousands)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net (loss) income	$(29,900)	$59,031	$(202,847)	$94,603
Other comprehensive (loss) income:				
Unrealized gain on available-for-sale securities, net of tax	40	12	3	12
Foreign currency translation adjustments, net of tax	—	(319)	—	289
Comprehensive (loss) income	$(29,860)	$58,724	$(202,844)	$94,904

See accompanying notes.

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2020	72,513,348	$ 7	$1,043,991	$ (270)	$ (762,754)	$ 280,974
Issuance of common stock upon exercise of stock options	451,883	—	4,429	—	—	4,429
Issuance of common stock upon vesting of restricted stock units (RSUs)	252,846	—	—	—	—	—
Taxes paid related to net share settlement of RSUs	(95,169)	—	(1,730)	—	—	(1,730)
Stock-based compensation expense	—	—	16,982	—	—	16,982
Unrealized loss on marketable securities	—	—	—	(37)	—	(37)
Cumulative translation adjustment	—	—	—	—	—	—
Net loss	—	—	—	—	(172,947)	(172,947)
Balances at March 31, 2021	73,122,908	7	1,063,672	(307)	(935,701)	127,671
Issuance of common stock upon exercise of stock options	686,145	—	4,009	—	—	4,009
Issuance of common stock upon vesting of restricted stock units (RSUs)	9,334	—	—	—	—	—
Issuance of common stock to Shanghai Junshi Biosciences Ltd. ("Junshi Biosciences"), net of issuance costs	2,491,988	—	40,903	—	—	40,903
Issuance of common stock under the employee stock purchase plan ("ESPP")	154,325	—	1,985	—	—	1,985
Stock-based compensation expense	—	—	11,512	—	—	11,512
Unrealized gain in marketable securities	—	—	—	40	—	40
Cumulative translation adjustment	—	—	—	—	—	—
Net loss	—	—	—	—	(29,900)	(29,900)
Balances at June 30, 2021	76,464,700	$ 7	$1,122,081	$ (267)	$ (965,601)	$ 156,220

See accompanying notes.

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2019	70,366,661	$ 7	$1,000,763	$ (558)	$ (894,998)	$ 105,214
Issuance of common stock upon exercise of stock options	421,850	—	4,438	—	—	4,438
Issuance of common stock upon vesting of RSUs	10,000	—	—	—	—	—
Issuance of common stock upon 2019 bonus payout	134,099	—	2,378	—	—	2,378
Taxes paid related to net share settlement of bonus payout in RSUs	(49,616)	—	(880)	—	—	(880)
Stock-based compensation expense	—	—	9,945	—	—	9,945
Cumulative translation adjustment	—	—	—	608	—	608
Net income	—	—	—	—	35,572	35,572
Balances at March 31, 2020	70,882,994	7	1,016,644	50	(859,426)	157,275
Issuance of common stock upon exercise of stock options	289,241	—	3,305	—	—	3,305
Issuance of common stock under the ESPP	180,970	—	2,557	—	—	2,557
Stock-based compensation expense	—	—	9,686	—	—	9,686
Purchase of capped call options related to convertible notes due 2026	—	—	(18,170)	—	—	(18,170)
Unrealized gain in marketable securities	—	—	—	12	—	12
Cumulative translation adjustment	—	—	—	(319)	—	(319)
Net income	—	—	—	—	59,031	59,031
Balances at June 30, 2020	71,353,205	$ 7	$1,014,022	$ (257)	$ (800,395)	$ 213,377

See accompanying notes.

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

	Six Months Ended June 30,	
	2021	**2020**
Operating activities		
Net (loss) income	$ (202,847)	$ 94,603
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	1,726	1,355
Stock-based compensation expense	28,479	18,980
Write-off of prepaid manufacturing services related to the termination of CHS-2020	3,210	—
Non-cash accretion of discount on marketable securities	649	—
Non-cash interest expense from amortization of debt discount	2,064	1,523
Non-cash operating lease expense	1,066	1,038
Upfront license fee payment to Junshi Biosciences	136,000	—
Upfront license fee payment to Innovent	—	5,000
Other non-cash adjustments	181	326
Changes in operating assets and liabilities:		
Trade receivables, net	15,243	(30,677)
Inventory	(3,860)	(25,236)
Prepaid manufacturing	2,335	(5,577)
Other prepaid, current and non-current assets	(3,556)	(2,222)
Accounts payable	(773)	(5,132)
Accrued rebates, fees and reserves	2,229	15,109
Accrued compensation	(7,428)	(2,863)
Accrued and other current and non-current liabilities	26,461	7,441
Net cash provided by operating activities	1,179	73,668
Investing activities		
Purchases of property and equipment	(560)	(4,167)
Proceeds from disposal of property and equipment	—	167
Purchases of investments in marketable securities	(140,330)	(231,864)
Proceeds from maturities of investments in marketable securities	15,000	—
Upfront license fee payment to Junshi Biosciences	(136,000)	—
Upfront license fee payment to Innovent	—	(5,000)
Net cash used in investing activities	(261,890)	(240,864)
Financing activities		
Proceeds from issuance of Convertible Notes due 2026, net of issuance costs	—	222,830
Purchase of capped call options related to Convertible Notes due 2026	—	(18,170)
Proceeds from issuance of common stock to Junshi Biosciences, net of issuance costs	40,903	—
Proceeds from issuance of common stock upon exercise of stock options	8,446	8,105
Proceeds from purchase under the employee stock purchase plan	1,985	2,557
Taxes paid related to net share settlement of RSUs	(1,730)	(880)
Other immaterial financing activities	(313)	(97)
Net cash provided by financing activities	49,291	214,345
Net (decrease) increase in cash, cash equivalents and restricted cash	(211,420)	47,149
Cash, cash equivalents and restricted cash at beginning of period	541,598	177,908
Cash, cash equivalents and restricted cash at end of period	$ 330,178	$ 225,057
Supplemental disclosure of cash flow information		
Non-cash bonus payment settled in common stock	$ —	$ 1,498
Right-of-use assets obtained in exchange for lease obligations related to operating leases	$ —	$ 1,388
Right-of-use assets obtained in exchange for lease obligations related to finance leases	$ 342	$ 1,528

See accompanying notes.

Coherus BioSciences, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Organization and Summary of Significant Accounting Policies

Organization

Coherus BioSciences, Inc. (the "Company" or "Coherus") is a commercial-stage biotherapeutics company focused on the biosimilar and immuno-oncology market primarily in the United States. The Company's headquarters and laboratories are located in Redwood City, California and in Camarillo, California, respectively. The Company's product pipeline comprises four drugs, CHS-1420 (an adalimumab (Humira) biosimilar), a ranibizumab (Lucentis) biosimilar in-licensed for U.S. and Canadian commercial rights from Bioeq AG, a bevacizumab (Avastin) biosimilar in-licensed for U.S. commercial rights from Innovent Biologics (Suzhou) Co., Ltd. and toripalimab, an anti-PD-1 antibody being developed in collaboration with Shanghai Junshi Biosciences Co., Ltd.

The Company commercializes UDENYCA® (pegfilgrastim-cbqv), a biosimilar to Neulasta, a long-acting granulocyte-colony stimulating factor, in the United States.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of Coherus and its wholly-owned subsidiaries. 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 unaudited 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 Securities and Exchange Commission ("SEC") on February 25, 2021.

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, 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. These estimates form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources. Accounting estimates and judgements are inherently uncertain and the actual results could differ from these estimates.

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 which, in aggregate, represent the amount reported in the condensed consolidated statements of cash flows (in thousands):

	Six Months Ended June 30,	
	2021	2020
At beginning of period:		
Cash and cash equivalents	$ 541,158	$ 177,668
Restricted cash - non-current	440	240
Total cash, cash equivalents and restricted cash	$ 541,598	$ 177,908
At end of period:		
Cash and cash equivalents	$ 329,738	$ 224,617
Restricted cash - non-current	440	440
Total cash, cash equivalents and restricted cash	$ 330,178	$ 225,057

Restricted cash – non-current consists of deposits for letter of credits that the Company has provided to secure its obligations under certain facility and other leases.

Investments in Marketable Securities

Investments in marketable securities primarily consist of corporate debt obligations and commercial paper. Management determines the appropriate classification of investments in marketable securities at the time of purchase based upon management's intent with regards to such investment and reevaluates such designation as of each balance sheet date. The Company's investment policy requires that it only invests in highly rated securities and limit its exposure to any single issuer. All investments in debt 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 on available-for-sale securities are reported as a component of accumulated comprehensive income (loss), with the exception of unrealized losses believed to be related to credit losses, if any, which are recognized in earnings in the period the impairment occurs. Impairment assessments are made at the individual security level each reporting period. When the fair value of an investment is less than its cost at the balance sheet date, a determination is made as to whether the impairment is related to a credit loss and, if it is, the portion of the impairment relating to credit loss is recorded as an allowance through net income. Realized gains and losses and declines in value, if any, on available-for-sale securities are included in other income, net, based on the specific identification method.

Trade Receivables

Trade receivables are recorded net of allowances for chargebacks, chargeback prepayments, cash discounts for prompt payment and credit losses. The Company estimates an allowance for expected credit losses by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. The corresponding expense for the credit loss allowance is reflected in selling, general and administrative expenses. The credit loss allowance was immaterial as of June 30, 2021.

Recent Accounting Pronouncements

The following are the recent accounting pronouncements adopted by the Company in 2021:

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The new guidance removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. It also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. The Company adopted this guidance as of January 1, 2021. The adoption did not have a material impact on the Company's condensed consolidated financial statements.

In October 2020, the FASB issued ASU 2020-10, *Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC's regulations. The Company adopted this guidance as of January 1, 2021. The adoption did not have a material impact on the Company's condensed consolidated financial statements.

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

2. 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, 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 that are included in cash and cash equivalents, and restricted cash. The unrealized gains and losses in the Company's investments in these money market funds were immaterial.

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.

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 were as follows (in thousands):

	Fair Value Measurements June 30, 2021			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Money market funds	$ 326,911	$ 326,911	$ —	$ —
Restricted cash (money market funds)	440	440	—	—
Corporate notes and Commercial paper	124,683	—	124,683	—
Total financial assets	$ 452,034	$ 327,351	$ 124,683	$ —
Financial Liabilities:				
Contingent consideration	$ 102	$ —	$ —	$ 102

	Fair Value Measurements December 31, 2020			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Money market funds	$ 538,673	$ 538,673	$ —	$ —
Restricted cash (money market funds)	440	440	—	—
Total financial assets	$ 539,113	$ 539,113	$ —	$ —
Financial Liabilities:				
Contingent consideration	$ 102	$ —	$ —	$ 102

Cash equivalents, marketable securities and restricted cash, consisted of the following (in thousands):

	June 30, 2021			
	Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Money market funds	$ 326,911	$ —	$ —	$ 326,911
Classified as cash equivalents	$ 326,911	$ —	$ —	$ 326,911
Corporate notes and Commercial paper	$ 124,680	$ 3	$ —	$ 124,683
Classified as marketable securities	$ 124,680	$ 3	$ —	$ 124,683
Money market funds	$ 440	$ —	$ —	$ 440
Classified as restricted cash	$ 440	$ —	$ —	$ 440

	December 31, 2020			
	Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Money market funds	$ 538,673	$ —	$ —	$ 538,673
Classified as cash equivalents	$ 538,673	$ —	$ —	$ 538,673
Money market funds	$ 440	$ —	$ —	$ 440
Classified as restricted cash	$ 440	$ —	$ —	$ 440

As of June 30, 2021, the remaining contractual maturities of available-for-sale securities were less than one year, and the average maturity of investments upon acquisition was approximately 10 months. The realized gains or losses on marketable securities for the periods presented were immaterial. None of the Company's investments in marketable securities has been in an unrealized loss position for more than one year. The Company determined that it has the ability and intent to hold all marketable securities that have been in a continuous loss position until maturity or recovery and there is no indication of default on interest or principal payments for any of its debt securities, thus no credit losses have been recognized in the three and six months ended June 30, 2021 and 2020.

1.5% Convertible Notes due 2026

The estimated fair values of the 1.5% Convertible Notes due 2026 issued by the Company in April 2020 (see Note 7) for the periods presented were determined by prices observed in markets that were not active and thus considered to be level 2 inputs. Among other factors, these market prices are influenced by interest rates, the Company's stock price and price volatility. The estimated fair value of the Convertible Notes due 2026 was approximately $237.0 million and $269.1 million (par value $230.0 million) as of June 30, 2021 and December 31, 2020, respectively.

8.2% Convertible Notes due 2022

The estimated fair values of the 8.2% Convertible Senior Notes due 2022 issued by the Company in February 2016 (see Note 7) for the periods presented were determined using an income approach that incorporates a single factor binomial lattice model, and is therefore considered to be Level 3 inputs. This lattice model incorporates the terms and conditions of the convertible notes and market-based risk measurements that are indirectly observable, such as credit risk. The estimated fair value is based on changes in the price of the underlying common shares over successive periods of time. An estimated yield based on market data is used to discount straight-debt cash flows. The estimated fair value of the 8.2% Convertible Senior Notes due 2022 was approximately $109.0 million and $113.7 million (par value $100.0 million) as of June 30, 2021 and December 31, 2020, respectively.

Term Loan

The principal amount outstanding under the Company's Term Loan (see Note 7) of $75 million as of June 30, 2021 is subject to variable interest rate, which is based on a fixed percentage plus three month LIBOR ("LIBOR"), and as such, the Company believes the carrying amount of these obligations approximates fair value.

3. Inventory

Inventory consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Raw Materials	$ 4,922	$ 5,205
Work in process	47,086	43,952
Finished goods	44,073	43,032
Total	$ 96,081	$ 92,189

Inventory expected to be sold more than twelve months from the balance sheet date is classified as inventory, non-current on the condensed consolidated balance sheets. As of June 30, 2021 and December 31, 2020, the non-current portion of inventory consisted of raw materials, work in process and a portion of finished goods. The following tables presents the inventory balance sheet classifications (in thousands):

	June 30, 2021	December 31, 2020
Inventory	$ 39,668	$ 44,233
Inventory, non-current	56,413	47,956
Total	$ 96,081	$ 92,189

Prepaid manufacturing of $15.2 million as of June 30, 2021 includes prepayments of $11.3 million to a contract manufacturing organization (“CMO”) for manufacturing services for UDENYCA®, which the Company expects to be converted into inventory within the next twelve months; and prepayments of $3.9 million to various CMOs for other research and development pipeline programs. Prepaid manufacturing of $19.4 million as of December 31, 2020 included prepayments of $8.9 million to a CMO for manufacturing services for UDENYCA®; and prepayments of $10.5 million to various CMOs for other research and development pipeline programs.

Other Assets, non-current of $10.4 million on the condensed consolidated balance sheet as of June 30, 2021 primarily include $8.9 million of operating lease right-of-use assets. Other Assets, non-current of $12.5 million on the consolidated balance sheet as of December 31, 2020 primarily includes $10.0 million of operating lease right-of-use assets and prepayments of $1.3 million made to a CMO for manufacturing services for UDENYCA®.

In February 2021, the Company announced the discontinuation of the development of CHS-2020, a biosimilar of Eylea® as part of a realignment of research and development resources toward other development programs. As part of the discontinuation, the Company wrote-off prepaid manufacturing services not deemed to have any probable future benefits resulting in the recognition of an impairment charge of $3.2 million within research and development expenses on the Company’s first quarter condensed consolidated statement of operations. Also during the first quarter of 2021, the Company recognized an expense of $8.3 million within research and development expenses on its condensed consolidated statement of operations in connection with the cancellation of open purchase orders with various vendors related to CHS-2020 development. No expense relating to the discontinuation of CHS-2020 was recognized in the second quarter of 2021.

4. Balance Sheet Components

Property and Equipment, Net

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

	June 30, 2021	December 31, 2020
Machinery and equipment	$ 13,876	$ 13,301
Computer equipment and software	4,029	3,996
Furniture and fixtures	1,274	1,268
Leasehold improvements	5,942	5,830
Finance lease right of use assets	2,160	1,451
Construction in progress	—	312
Total property and equipment	27,281	26,158
Accumulated depreciation and amortization	(18,151)	(16,050)
Property and equipment, net	$ 9,130	$ 10,108

Depreciation and amortization expense was $0.9 million and $1.7 million for the three and six months ended June 30, 2021, respectively, and $0.7 million and $1.4 million for the three and six months ended June 30, 2020, respectively.

Accrued and Other Current Liabilities

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

	June 30, 2021	December 31, 2020
Accrued clinical and manufacturing	$ 25,927	$ 11,365
Accrued co-development costs for toripalimab	15,452	—
Accrued other	10,108	12,182
Lease liabilities, current	3,412	3,132
Total Accrued and other current liabilities	$ 54,899	$ 26,679

5. Revenue

The Company recorded net product revenue of $87.6 million and $170.7 million during the three and six months ended June 30, 2021, respectively, and $135.7 million and $251.9 million during the three and six months ended June 30, 2020, respectively.

Revenue by significant customer was as follows:

	Three Months Ended		Six Months Ended	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
McKesson Corporation	39 %	37 %	39 %	39 %
AmeriSource-Bergen Corporation	38 %	38 %	38 %	37 %
Cardinal Health, Inc.	22 %	23 %	21 %	22 %
Others	1 %	2 %	2 %	2 %
Total revenue	100 %	100 %	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):

	Six Months Ended June 30, 2021			
	Chargebacks and Discounts for Prompt Payment	Rebates	Other Fees, Co-pay Assistance and Returns	Total
Balance at December 31, 2020	$ 40,580	$ 54,058	$ 28,760	$ 123,398
Provision related to sales made in:				
Current period	237,745	61,190	50,039	348,974
Prior period	(2,850)	(1,890)	(2,818)	(7,558)
Payments and customer credits issued	(247,641)	(52,213)	(50,726)	(350,580)
Balance at June 30, 2021	$ 27,834	$ 61,145	$ 25,255	$ 114,234

	Six Months Ended June 30, 2020			
	Chargebacks and Discounts for Prompt Payment	Rebates	Other Fees, Co-pay Assistance and Returns	Total
Balance at December 31, 2019	$ 35,159	$ 27,494	$ 24,494	$ 87,147
Provision related to sales made in:				
Current period	208,917	49,245	58,645	316,807
Prior period	(159)	(3,287)	(6,108)	(9,554)
Payments and customer credits issued	(219,040)	(31,732)	(51,403)	(302,175)
Balance at June 30, 2020	$ 24,877	$ 41,720	$ 25,628	$ 92,225

Government and other chargebacks payable to our direct customers and discounts for prompt payment are recorded as a reduction in trade receivables, and the remaining reserve balances are classified as current liabilities on the accompanying unaudited condensed consolidated balance sheets.

6. License Agreements

Shanghai Junshi Biosciences, Co., Ltd.

On February 1, 2021, the Company entered into an Exclusive License and Commercialization Agreement (the “Collaboration Agreement”) with Junshi Biosciences for the co-development and commercialization of toripalimab, Junshi Biosciences’ anti-PD-1 antibody, in the United States and Canada.

Under the terms of the Collaboration Agreement, the Company paid $150.0 million upfront for exclusive rights to toripalimab in the United States and Canada, options in these territories to Junshi Biosciences’ anti-TIGIT antibody and next-generation engineered IL-2 cytokine, and certain negotiation rights to two undisclosed preclinical immuno-oncology drug candidates. The Company will have the right to conduct all commercial activities of toripalimab in the United States and Canada. The Company will be obligated to pay Junshi Biosciences a 20% royalty on net sales of toripalimab and up to an aggregate $380.0 million in one-time payments for the achievement of various regulatory and sales milestones. If the Company exercises its options, it will be obligated to pay an option exercise fee for each of the anti-TIGIT antibody and the IL-2 cytokine of $35.0 million per program. Additionally, for each exercised option, the Company will be obligated to pay Junshi Biosciences an 18% royalty on net sales and up to an aggregate $255.0 million for the achievement of various regulatory and sales milestones. Under the Collaboration Agreement, the Company retains the right to collaborate in the development of toripalimab and the other licensed compounds and will pay for a portion of these co-

development activities up to a maximum of $25.0 million per licensed compound per year. The Company is responsible for certain associated regulatory and technology transfer costs for toripalimab and other licensed compounds and will reimburse such costs reasonably incurred by Junshi Biosciences. The Company recognized research and development expense of $15.5 million and $22.2 million in the condensed consolidated statement of operations for the three and six months ended June 30, 2021, respectively, and recognized $15.5 million in accrued and other current liabilities on the condensed consolidated balance sheet as of June 30, 2021 related to the co-development activities. The Company accounted for the licensing transaction as an asset acquisition under the relevant accounting rules. The Company recorded research and development expense of $145.0 million during the first quarter of 2021, related to the upfront payment for exclusive rights to toripalimab in the United States and Canada. The Company had entered into a Right of First Negotiation agreement with Junshi Biosciences and paid a fee of $5.0 million which was fully expensed as research and development expense in the fourth quarter of 2020. The Right of First Negotiation fee was fully credited against the total upfront license fee obligation under the collaboration agreement. As of June 30, 2021, the Company did not have any outstanding milestone or royalty payment obligations to Junshi Biosciences.

The additional milestone payments, option fees for additional anti-TIGIT antibodies and the IL-2 cytokines and royalties are contingent upon future events and, therefore, will be recorded when it is probable that a milestone will be achieved, option fees will be incurred or when royalties are due.

In connection with the Collaboration Agreement, the Company entered into a stock purchase agreement (the “Stock Purchase Agreement”) with Junshi Biosciences agreeing, subject to customary conditions, to acquire certain equity interests in the Company. Pursuant to the Stock Purchase Agreement, on April 16, 2021, the Company issued 2,491,988 unregistered shares of its common stock to Junshi Biosciences, at a price per share of $20.0643, for an aggregate value of approximately $50.0 million cash. Under the terms of the Stock Purchase Agreement, Junshi Biosciences is not permitted to sell, transfer, make any short sale of, or grant any option for the sale of the common stock for the two-year period following its effective date. The Collaboration Agreement and the Stock Purchase Agreement were negotiated concurrently and were therefore evaluated as a single agreement. The Company used the “Finnerty” and “Asian put” valuation models and determined the fair value for the discount for lack of marketability (“DLOM”) was $9.0 million. The fair value of the DLOM was included as an offset against the research and development expense in the condensed consolidated statement of operations for the three and six months ending June 30, 2021.

Innovent Biologics (Suzhou) Co., Ltd.

On January 13, 2020, the Company entered into a license agreement (the “License Agreement”) with Innovent Biologics (Suzhou) Co., Ltd. (“Innovent”) for the development and commercialization of a biosimilar version of bevacizumab (Avastin®) in any dosage form and presentations (“bevacizumab Licensed Product”) in the United States and Canada (the “Territory”). Under the License Agreement, Innovent granted to the Company an exclusive, royalty-bearing license to develop and commercialize the bevacizumab Licensed Product in the field of treatment, prevention or amelioration of any human diseases and conditions as included in the label of Avastin®. Under the License Agreement, the Company also acquired an option to develop and commercialize Innovent’s biosimilar version of rituximab (Rituxan®) in any dosage form and presentations (the “rituximab Licensed Product” and together with the bevacizumab Licensed Product, the “Innovent Licensed Products”) in the Territory. Subject to the terms of the License Agreement, the Company may exercise its option within 12 months of its receipt of certain regulatory materials from Innovent. Following the Company’s option exercise, Innovent’s biosimilar version of rituximab would be deemed an Innovent Licensed Product for all purposes of the License Agreement and Innovent would grant to the Company an exclusive, royalty-bearing license to develop and commercialize Innovent’s biosimilar version of rituximab in the field of treatment, prevention or amelioration of any human diseases and conditions as included in the label of Rituxan®.

Innovent will supply the Innovent Licensed Products to the Company in accordance with a manufacturing and supply agreement to be executed by the parties. Under the License Agreement, the Company acquired the right to require Innovent to perform technology transfer for the manufacturing of the Innovent Licensed Products in the Territory and, upon completion of such technology transfer, the Company will have the exclusive right to manufacture the Innovent Licensed Products in the Territory.

Under the License Agreement, the Company committed to pay Innovent a $5.0 million upfront payment and an aggregate of up to $40.0 million in milestone payments in connection with the achievement of certain development, regulatory and sales milestones with respect to the bevacizumab Licensed Product and, if the Company's option is exercised, an aggregate of up to $40.0 million in milestone payments in connection with the achievement of certain development, regulatory and sales milestones with respect to the rituximab Licensed Product. The Company will share a percentage of net sales of Innovent Licensed Products with Innovent in the mid-teens to low twenty percent range. If the Company exercises its option to acquire Innovent's biosimilar version of rituximab (Rituxan®), it would be required to pay a fee of $5.0 million. Subject to the terms of the License Agreement, if the Company requests Innovent to perform technology transfer for the manufacturing of the Innovent Licensed Products, it would be required to pay up to $10.0 million for fees related thereto. The Company accounted for the licensing transaction as an asset acquisition under the relevant accounting rules. The Company recorded research and development expense of $5.0 million during the first quarter of 2020, related to an upfront payment for the bevacizumab Licensed Product. During the three and six months ended June 30, 2021, the Company recognized research and development expense of $3.3 million and $6.6 million, respectively, related to bevacizumab Licensed Product development activities. The expense for bevacizumab Licensed Product development activities was immaterial for the three and six months ended June 30, 2020. As of June 30, 2021, the Company did not have any outstanding milestone or royalty payment obligations to Innovent.

The additional milestone payments, option fee for licensing of rituximab (Rituxan®), manufacturing technology transfer fee and royalties are contingent upon future events and, therefore, will be recorded when such payments become probable.

7. Convertible Notes and Term Loan

1.5% Convertible Senior Subordinated Notes due 2026

In April 2020, the Company issued and sold $230.0 million aggregate principal amount of its 1.5% Convertible Senior Subordinated notes due 2026 (the "2026 Convertible Notes") in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act. The net proceeds from the offering were $222.2 million after deducting initial purchasers' fees and offering expenses. The 2026 Convertible Notes are general unsecured obligations and will be subordinated to the Company's designated senior indebtedness (as defined in the indenture for the 2026 Convertible Notes) and structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables. The 2026 Convertible Notes accrue interest at a rate of 1.5% per annum, payable semi-annually in arrears on April 15 and October 15 of each year, beginning on October 15, 2020, and will mature on April 15, 2026, unless earlier repurchased or converted.

At any time before the close of business on the second scheduled trading day immediately before the maturity date, noteholders may convert their 2026 Convertible Notes at their option into shares of the Company's common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 51.9224 shares of common stock per $1,000 principal amount of the 2026 Convertible Notes, which represents an initial conversion price of approximately $19.26 per share of common stock. The initial conversion price represents a premium of approximately 30.0% over the last reported sale of $14.815 per share of the Company's common stock on the Nasdaq Global Market on April 14, 2020, the date the 2026 Convertible Notes were issued. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. If a "make-whole fundamental change" (as defined in the indenture for the 2026 Convertible Notes) occurs, the Company will, in certain circumstances, increase the conversion rate for a specified period of time for noteholders who convert their 2026 Convertible Notes in connection with that make-whole fundamental change. The 2026 Convertible Notes are not redeemable at the Company's election before maturity. If a "fundamental change" (as defined in the indenture for the 2026 Convertible Notes) occurs, then, subject to a limited exception, noteholders may require the Company to repurchase their 2026 Convertible Notes for cash. The repurchase price will be equal to the principal amount of the 2026

Convertible Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable repurchase date.

The 2026 Convertible Notes have customary provisions relating to the occurrence of "events of default" (as defined in the indenture for the 2026 Convertible Notes). The occurrence of such events of default could result in the acceleration of all amounts due under the 2026 Convertible Notes.

As of June 30, 2021, the Company was in full compliance with these covenants and there were no events of default under the 2026 Convertible Notes.

The 2026 Convertible Notes are accounted for in accordance with ASC 470-20, *Debt with Conversion and Other Options* ("ASC 470-20") and ASC 815-40, *Contracts in Entity's Own Equity* ("ASC 815-40"). Under ASC 815-40, to qualify for equity classification (or non-bifurcation, if embedded) the instrument (or embedded feature) must be both (1) indexed to the issuer's stock and (2) meet the requirements of the equity classification guidance. The Company determined that the 2026 Convertible Notes do contain embedded features indexed to its own stock, but do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component. Since the embedded conversion feature meets the equity scope exception from derivative accounting, and since the embedded conversion option does not need to be separately accounted for as an equity component under ASC 470-20, the proceeds received from the issuance of the convertible debt were recorded as a liability on the condensed consolidated balance sheets.

Capped Call Transactions

In connection with the pricing of the 2026 Convertible Notes, the Company also paid $18.2 million to enter into privately negotiated capped call transactions with one or a combination of the initial purchasers, their respective affiliates and other financial institutions (the "option counterparties"). The capped call transactions are generally expected to reduce the potential dilution upon conversion of the 2026 Convertible Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the 2026 Convertible Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the 2026 Convertible Notes. The cap price of the capped call transactions will initially be $25.9263 per share, which represents a premium of approximately 75.0% over the last reported sale price of the Company's common stock of $14.815 per share on April 14, 2020, and is subject to certain adjustments under the terms of the capped call transactions.

The capped call transactions are accounted for as separate transactions from the 2026 Convertible Notes and classified as equity instruments. Therefore, the total $18.2 million capped call premium paid was recorded as a reduction to additional paid-in capital on the condensed consolidated balance sheets. The capped calls will not be subsequently re-measured as long as the conditions for equity classification continue to be met.

The Company incurred $0.9 million of debt issuance costs relating to the issuance of the 2026 Convertible Notes, which were recorded as a reduction to the notes on the condensed consolidated balance sheets. The debt issuance costs are being amortized and recognized as additional interest expense over the six-year contractual term of the notes using the effective interest rate method.

The following table summarizes components of the 2026 Convertible Notes (in thousands):

	June 30, 2021	December 31, 2020
Principal amount of the 2026 Convertible Notes	$ 230,000	$ 230,000
Unamortized debt discount and debt issuance costs	(6,345)	(6,971)
Total 2026 Convertible Notes	$ 223,655	$ 223,029

If the 2026 Convertible Notes were to be converted on June 30, 2021, the holders of the 2026 Convertible Notes would receive common shares with an aggregate value of $165.2 million based on the Company's closing stock price of $13.83 as of June 30, 2021.

The following table presents the components of interest expense related to 2026 Convertible Notes (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Stated coupon interest	$ 862	$ 709	$ 1,725	$ 709
Accretion of debt discount and debt issuance costs	314	253	626	253
Total interest expense	$ 1,176	$ 962	$ 2,351	$ 962

The remaining unamortized debt discount and debt offering costs related to the Company's 2026 Convertible Notes of approximately $6.3 million as of June 30, 2021, will be amortized using the effective interest rate over the remaining term of the 2026 Convertible Notes of 4.8 years. The annual effective interest rate is 2.11% for the 2026 Convertible Notes.

Future payments on the 2026 Convertible Notes as of June 30, 2021 are as follows (in thousands):

Year ending December 31,	
Remainder of 2021	$ 1,725
2022	3,450
2023	3,450
2024	3,450
2025 and beyond	235,175
Total minimum payments	247,250
Less amount representing interest	(17,250)
2026 Convertible Notes, principal amount	230,000
Less debt discount and debt issuance costs on 2026 Convertible Notes	(6,345)
Net carrying amount of 2026 Convertible Notes	$ 223,655

8.2% Convertible Notes due 2022

On February 29, 2016, the Company issued and sold $100.0 million aggregate principal amount of its 8.2% Convertible Senior Notes (the "2022 Convertible Notes"). The 2022 Convertible Notes constitute general, senior unsubordinated obligations of the Company and are guaranteed by certain subsidiaries of the Company. The 2022 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, beginning on March 31, 2016, and will mature on March 31, 2022, unless earlier converted, redeemed or repurchased. The 2022 Convertible Notes also bear a premium of 9% of their principal amount, which is payable when the 2022 Convertible Notes mature or are repurchased or redeemed by the Company.

The 2022 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.

At any time before the close of business on the business day immediately preceding March 31, 2022, the 2022 Convertible Note noteholders may convert their 2022 Convertible Notes at their option into shares of the Company's common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 44.7387 shares of common stock per $1,000 principal amount of the 2022 Convertible Notes, which represents an initial conversion price of approximately $22.35 per share of common stock. The initial conversion price represents a 60% premium over the average last reported sale price of our common stock over the 15 trading days preceding the date the 2022 Convertible Notes were issued. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. The 2022 Convertible Notes are redeemable in whole, and not in part, at the Company's option with effect from 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 2022 Convertible Notes. At maturity or redemption, if not earlier converted, the Company will pay 109% of the principal amount of the 2022 Convertible Notes maturing or being redeemed, together with accrued and unpaid interest, in cash.

The 2022 Convertible Notes contain customary negative covenants and events of default, the occurrence of which could result in the acceleration of all amounts due under the 2022 Convertible Note. As of June 30, 2021, the Company was in full compliance with these covenants and there were no events of default under the 2022 Convertible Notes.

The 2022 Convertible Notes are accounted for in accordance with ASC 470-20. Pursuant to ASC 470-20, the Company evaluated the features embedded in the 2022 Convertible Notes and concluded that the embedded features do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component.

The following table summarizes components of the 2022 Convertible Notes (in thousands):

	June 30, 2021	December 31, 2020
Principal amount of the 2022 Convertible Notes	$ 81,750	$ 81,750
Unamortized debt discount and debt issuance costs	(1,145)	(1,865)
2022 Convertible Notes	$ 80,605	$ 79,885
Principal amount of the 2022 Convertible Notes - related parties	$ 27,250	$ 27,250
Unamortized debt discount and debt issuance costs - related parties	(382)	(622)
2022 Convertible Notes - related parties	$ 26,868	$ 26,628
Total 2022 Convertible Notes	$ 107,473	$ 106,513

The 2022 Convertible Notes and the 2022 Convertible Notes – related parties were classified in current liabilities as of June 30, 2021 and in non-current liabilities as of December 31, 2020 on the condensed consolidated balance sheets. If the 2022 Convertible Notes were to be converted on June 30, 2021, the holders of the 2022 Convertible Notes would receive common shares with an aggregate value of $61.9 million based on the Company's closing stock price of $13.83 as of June 30, 2021.

The following table presents the components of interest expense related to 2022 Convertible Notes (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Stated coupon interest	$ 1,537	$ 1,538	$ 3,075	$ 3,076
Accretion of debt discount and debt issuance costs	364	332	720	656
Interest expense	$ 1,901	$ 1,870	$ 3,795	$ 3,732
Stated coupon interest - related parties	$ 513	$ 512	$ 1,025	$ 1,024
Accretion of debt discount and debt issuance costs - related parties	121	110	240	218
Interest expense - related parties	$ 634	$ 622	$ 1,265	$ 1,242
Total interest expense	$ 2,535	$ 2,492	$ 5,060	$ 4,974

The remaining unamortized debt discount and debt offering costs related to the 2022 Convertible Notes of approximately $1.5 million as of June 30, 2021, will be amortized using the effective interest rate over the remaining term of the 2022 Convertible Notes of nine months. The annual effective interest rate is 9.48% for the 2022 Convertible Notes.

Future payments on the 2022 Convertible Notes as of June 30, 2021 are as follows (in thousands):

Year ending December 31,	
Remainder of 2021	$ 4,100
2022	111,050
Total minimum payments	115,150
Less amount representing interest	(6,150)
2022 Convertible Notes, principal amount	109,000
Less debt discount and debt issuance costs on 2022 Convertible Notes	(1,527)
Net carrying amount of 2022 Convertible Notes	$ 107,473

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 6.75% per annum plus three-month LIBOR. Interest is payable quarterly in arrears. 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, 2021, the effective interest rate is 10.68%.

The Company is required to pay principal on the Borrowings in equal quarterly installments beginning on the third anniversary of the Term Loan Closing Date (or, if consolidated net sales of UDENYCA® in the fiscal year ending December 31, 2021 exceed $375.0 million, beginning on the fourth anniversary of the Term Loan Closing Date), with the outstanding balance to be repaid on January 7, 2025, the maturity date. As of June 30, 2021, $11.5 million of the carrying value was reclassified to current liabilities on our condensed consolidated balance sheets based upon our expectation that principal payments will commence within twelve months of June 30, 2021.

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 third 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 fourth anniversary of the term loan closing date but on or prior to the fifth 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 $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, or in asset sales, and declare dividends or redeem or repurchase capital stock. Additionally, the consolidated net sales for UDENYCA® must not be lower than $150.0 million for each fiscal year after the fiscal year ending December 31, 2020. 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.

On April 13, 2020, the Company entered into an amendment to the Term Loan, which amended the Term Loan's indebtedness covenant such that the Company could incur Convertible Bond Indebtedness (as defined in the credit agreement governing the Term Loan) in an amount not to exceed the greater of $230.0 million or 20% of the Company's market capitalization.

As of June 30, 2021, the Company was in full compliance with these covenants and there were no events of default under the Term Loan.

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

	June 30, 2021	December 31, 2020
Principal amount of the Term Loan	$ 75,000	$ 75,000
Unamortized debt discount and debt issuance costs	(42)	(519)
Term Loan	$ 74,958	$ 74,481

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Stated coupon interest	$ 1,754	$ 1,754	$ 3,488	$ 3,507
Accretion of debt discount and debt issuance costs	263	200	478	396
Interest expense	$ 2,017	$ 1,954	$ 3,966	$ 3,903

The remaining unamortized debt discount and debt offering costs related to the Term Loan of approximately $42,000 as of June 30, 2021, will be amortized using the effective rate over the remaining term of the Term Loan of 3.5 years.

Future payments on the Term Loan as of June 30, 2021 are as follows (in thousands):

Year ending December 31,	
Remainder of 2021	$ 3,546
2022	29,294
2023	27,130
2024	24,972
2025	8,780
Total minimum payments	93,722
Less amount representing interest	(15,722)
Term Loan, gross	78,000
Less debt discount and debt issuance costs on Term Loan	(3,042)
Net carrying amount of Term Loan	$ 74,958

8. Commitments and Contingencies

Purchase Commitments

The Company entered into agreements with a vendor to secure raw materials and a CMO to manufacture its commercial supply of UDENYCA®. As of June 30, 2021, the Company's contractual obligations under the terms of the agreements are as follows (in thousands):

Years ending December 31,	
Remainder of 2021	$ 30,257
2022	30,512
2023	9,753
2024	3,441
Total obligations	$ 73,963

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.

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. Stock-Based Compensation

The following table summarizes the classification of stock-based compensation expense in our condensed consolidated statements of income related to options and restricted stock units granted to employees and nonemployees (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Cost of goods sold [1]	$ 311	$ 176	$ 502	$ 221
Research and development	4,084	3,495	10,516	7,085
Selling, general and administrative	7,200	5,754	17,461	11,674
Stock-based compensation expense	$11,595	$ 9,425	$28,479	$18,980
Capitalized stock-based compensation expense into inventory	$ 228	$ 438	$ 517	$ 872

(1) Stock-based compensation capitalized into inventory is recognized as cost of goods sold when the related product is sold.

10. Net Income (loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive common shares. Diluted net income per share is computed by dividing the net income 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. Since the Company was in a net loss position for the three and six months ended June 30, 2021, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential dilutive common shares would have been anti-dilutive for that period.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Basic net (loss) income per share				
Numerator:				
Net (loss) income	$ (29,900)	$ 59,031	$ (202,847)	$ 94,603
Denominator:				
Weighted-average common shares outstanding	75,559,697	71,099,773	74,203,858	70,880,979
Basic net (loss) income per share	$ (0.40)	$ 0.83	$ (2.73)	$ 1.33
Diluted net income (loss) per share				
Numerator:				
Net (loss) income	$ (29,900)	$ 59,031	$ (202,847)	$ 94,603
Add interest expense on 2026 convertible notes, net of tax	—	3,454	—	5,936
Numerator for diluted (loss) net income per share	$ (29,900)	$ 62,485	$ (202,847)	$ 100,539
Denominator:				
Denominator for basic net (loss) income per share	75,559,697	71,099,773	74,203,858	70,880,979
Add effect of potential dilutive securities:				
Stock options, including shares subject to ESPP	—	3,208,580	—	3,437,358
Restricted stock units	—	104,092	—	96,163
Shares issuable upon conversion of convertible notes	—	14,247,835	—	9,360,853
Denominator for diluted net (loss) income per share	75,559,697	88,660,280	74,203,858	83,775,353
Diluted net (loss) income per share	$ (0.40)	$ 0.70	$ (2.73)	$ 1.20

The following outstanding dilutive potential shares were excluded from the calculation of diluted net income per share due to their anti-dilutive effect:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Stock options, including shares subject to ESPP	19,099,431	12,739,884	19,072,986	11,378,471
Restricted stock units	1,820,247	8,750	1,820,247	6,442
Shares issuable upon conversion of 2022 Convertible Notes	4,473,871	—	4,473,871	—
Shares issuable upon conversion of 2026 Convertible Notes	11,942,152	—	11,942,152	—
Total	37,335,701	12,748,634	37,309,256	11,384,913

11. Income Taxes

There was no income tax expense for the three and six months ended June 30, 2021 due to a projected tax loss for 2021 and the tax effect of the valuation allowance against such loss for the year. Income tax expense of $1.3 million and $2.2 million for the three and six months ended June 30, 2020, respectively, primarily relates to state taxes in jurisdictions outside of California, for which the Company has a limited operating history. The income tax provision during the 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 Company maintains a full valuation allowance against its net deferred tax assets due to its history of losses.

12. Related Party Transactions

Convertible Notes

In February 2016, the Company issued Convertible Notes to certain related parties (certain companies affiliated with members of the Company's board of directors), for an aggregate principal amount of $25.0 million (see Note 7).

Consulting services

In October 2020, the Company entered into a consulting agreement with Lanfear Advisors owned by Mr. Jonathan Lanfear who is the brother of Dennis Lanfear, our President, Chief Executive Officer and Chairman of our Board of Directors. Mr. Jonathan Lanfear provided consulting services with respect to the Collaboration Agreement executed with Junshi Biosciences in February 2021 (See Note 6). In addition to the hourly consulting fee paid to Lanfear Advisors under the consulting agreement, the Company granted fully vested stock options to purchase 65,000 shares of common stock with an exercise price of $17.60 per share to Mr. Jonathan Lanfear in February 2021 upon the execution of the Collaboration Agreement with Junshi Biosciences. During the first quarter of 2021, the Company recognized stock-based compensation expense of $0.8 million and cash consulting expense of $0.2 million with respect to these consulting services. There was no related expense in the second quarter of 2021. Total liabilities recognized in Accounts payable and Accrued liabilities on the condensed consolidated balance sheets with respect to these services were $286,640 as of December 31, 2020, with no corresponding liability as of June 30, 2021.

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, 2020, 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 25, 2021. 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 "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 biopharmaceutical company with a mission to increase patient access to cost-effective medicines that can have a major impact on their lives and to deliver significant savings to the health care system. Our strategy is to build a leading immuno-oncology franchise in the United States and Canada funded with cash generated by our commercial biosimilar business.

Our first product, UDENYCA® (pegfilgrastim-cbqv), a biosimilar to Neulasta®, a long-acting granulocyte-colony stimulating factor, was launched commercially in the United States in January 2019. In addition to UDENYCA®, we have a product candidate pipeline that includes biosimilars of Humira®, Avastin® and Lucentis®. 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. We have become a leader in the biosimilar market by leveraging our team's collective expertise in key areas such as process science, analytical characterization, protein production, clinical-regulatory development and commercialization.

In February 2021, we in-licensed our first immuno-oncology product candidate, toripalimab, a novel anti-PD-1 antibody, from Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences"). Toripalimab has been extensively evaluated in late-stage clinical trials for the treatment of multiple tumor types. We and Junshi Biosciences have initiated the rolling submission to the United States Food and Drug Administration ("FDA") of the first toripalimab biologic license application ("BLA") for the treatment of nasopharyngeal carcinoma. Within the next several years, we anticipate submitting supplemental BLAs for multiple additional indications, including for rare and more prevalent tumor types, including non-small cell lung cancer. We have also acquired options to license two pipeline immuno-oncology product candidates from Junshi Biosciences, an anti-TIGIT antibody and a next-generation engineered IL-2 cytokine, which we plan to evaluate in combination with toripalimab.

With our UDENCYA® commercialization efforts, we have built a strong, oncology-focused commercial capability in the United States. We expect to leverage this commercial capability as we build our immuno-oncology franchise if toripalimab and potential combination product candidates are approved.

Our pipeline includes the following product candidates:

Oncology Pipeline

- Toripalimab, an anti-PD-1 antibody being developed in collaboration with Junshi Biosciences, a leading Chinese biotechnology company. More than thirty company-sponsored clinical studies have been conducted globally, including in China and the United States, evaluating toripalimab for more than fifteen indications.

We and Junshi Biosciences have initiated the rolling submission of the first toripalimab BLA to the FDA for the treatment of nasopharyngeal carcinoma ("NPC"). The completion of this submission is expected later in the third quarter of 2021. In addition to NPC, we plan to submit supplemental BLAs to the FDA for toripalimab within the next two years for the treatment of several rare and highly prevalent cancers, including non-small cell lung cancer.

In the United States, toripalimab has been granted the Breakthrough Therapy designation for the treatment of recurrent/metastatic NPC by the FDA in September 2020. The FDA has also granted toripalimab Fast Track designation for the treatment of mucosal melanoma and orphan drug designations for treatment of NPC, mucosal melanoma and soft tissue sarcoma.

- UDENYCA® (pegfilgrastim-cbqv). We are developing additional presentations of UDENYCA® in addition to the currently marketed pre-filled syringe presentation.

- CHS-305, a bevacizumab (Avastin) biosimilar. On January 13, 2020, we entered into a license agreement with Innovent Biologics (Suzhou) Co., Ltd. ("Innovent," and with respect to the license agreement with Innovent, the "Innovent Agreement") for the development and commercialization of a biosimilar version of bevacizumab (Avastin) in any dosage form and presentations ("bevacizumab Licensed Product") in the United States and Canada. We are performing a three-way pharmacokinetic ("PK") study using Avastin drug products from the United States, Avastin drug products from China and Innovent's biosimilar to bevacizumab, as well additional analytical similarity exercises prior to facilitating a potential BLA submission for CHS-305 to the FDA.

Immunology Pipeline

- CHS-1420 (our adalimumab (Humira) biosimilar candidate). We are developing CHS-1420, an anti-TNF product candidate, as an adalimumab (Humira) biosimilar. In the fourth quarter of 2020, we submitted the 351(k) BLA, which was accepted for review by the FDA in February 2021. The user fee goal date is in December 2021. If approved, we anticipate we would be able to launch CHS-1420 in the United States on or after July 1, 2023, in accordance with settlement and license agreements with AbbVie Inc. ("AbbVie") that grants us global, non-exclusive license rights under AbbVie's intellectual property to commercialize CHS-1420.

Ophthalmology Pipeline

- CHS-201, a ranibizumab (Lucentis) biosimilar. On November 4, 2019, we entered into a license agreement with Bioeq IP AG (now Bioeq AG or "Bioeq") for the commercialization of CHS-201, a biosimilar version of ranibizumab (Lucentis) in certain dosage forms in both a vial and pre-filled syringe presentation. Under this agreement, Bioeq granted to us an exclusive royalty-bearing license to commercialize CHS-201 in the field of ophthalmology (and any other approved labelled indication) in the United States.

  Bioeq submitted a BLA for CHS-201 to the FDA in the third quarter of 2021.

Small Molecule Pipeline

- CHS-131 (our oral, small-molecule drug candidate). CHS-131 is a novel, potential first-in-class, once-daily oral drug candidate for non-alcoholic steatohepatitis ("NASH") and other metabolic conditions. In February 2020, we announced that we are seeking strategic alternatives to finance this program externally.

COVID-19 Update

As a result of the COVID-19 pandemic, we have experienced and may continue to experience disruptions that could severely impact our business, clinical trials and preclinical studies. See “Risk Factors”. These and other factors arising from the COVID-19 pandemic could result in us not being able to maintain UDENYCA®’s market position or increase its penetration against all Neulasta’s dosage forms and could result in our inability to meet development milestones for our product candidates, each of which would harm our business, financial condition, results of operations and growth. Until the COVID-19 pandemic is controlled, we expect it may continue to adversely impact our sales growth. In addition, the spread of more contagious and deadly variants, such as the Delta variant, could cause the COVID-19 pandemic to last longer than expected and could result in the reinstatement of restrictive orders that could disrupt our business.

While the long-term economic impact and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, which could reduce our ability to access capital and could negatively affect our liquidity and the liquidity and stability of markets for our common stock and our convertible notes. In addition, a recession, market correction or depression resulting from the spread of COVID-19 could materially affect our business and the value of our notes and our common stock.

Financial Operations Overview

Revenue

We recorded net product revenue of $87.6 million and $135.7 million during the three months ended June 30, 2021 and 2020, respectively, and $170.7 million and $251.9 million during the six months ended June 30, 2021 and 2020, respectively.

Cost of Goods Sold

Cost of goods sold consists primarily of third-party manufacturing, distribution, and overhead costs associated with UDENYCA®. Prior to the second quarter 2021, a portion of the costs of producing UDENYCA® sold was expensed as research and development before the FDA approval of UDENYCA® and therefore was not reflected in the cost of goods sold. All the inventory expensed prior to approval of UDENYCA® was fully utilized by March 31, 2021; thus, the three months ended June 30, 2021 is the first full quarter that the costs of producing UDENYCA® are fully reflected in cost of goods sold.

On May 2, 2019, we settled a trade secret action brought by Amgen Inc. and Amgen USA Inc. (collectively “Amgen”). As a result, cost of goods sold reflects a mid-single digit royalty on net product revenue, which began July 1, 2019 and continues for five years from then.

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 research and development costs incurred on a product candidate basis only for external research and development expenses. 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;

- costs associated with manufacturing process development activities; and
- upfront and milestone payments related to licensing and collaboration agreements.

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 includes salaries, benefits and stock-based compensation; and
- facilities and other allocated expense, which includes direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization of leasehold improvements and equipment, 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 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 pipeline 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 outstanding debt agreements.

Other Income, Net

Other income, net consists primarily of interest earned from our investments in marketable securities and foreign exchange gains and losses resulting from currency fluctuations.

Significant Transactions

License Agreement with Junshi Biosciences

On February 1, 2021, we entered into an Exclusive License and Commercialization Agreement (the "Collaboration Agreement") with Junshi Biosciences for the co-development and commercialization of toripalimab, Junshi Biosciences' anti-PD-1 antibody in the United States and Canada (the "Collaboration").

Under the terms of the Collaboration Agreement, we paid $150.0 million upfront for exclusive rights to toripalimab in the United States and Canada, options in these territories to Junshi Biosciences' anti-TIGIT antibody and next-generation engineered IL-2 cytokine, and certain negotiation rights to two undisclosed preclinical immuno-oncology drug candidates. We will have the right to conduct all commercial activities of toripalimab in the United States and Canada. We will be obligated to pay Junshi Biosciences a 20% royalty on net sales of toripalimab and up to an aggregate $380.0 million in one-time payments for the achievement of various regulatory and sales milestones. If we exercise our options, we will be obligated to pay an option exercise fee for each of the anti-TIGIT antibody and the IL-2 cytokine of $35.0 million per program. Additionally, for each exercised option, we will be obligated to pay Junshi Biosciences an 18% royalty on net sales and up to an aggregate $255.0 million for the achievement of various regulatory and sales milestones. Under the Collaboration Agreement, we retain the right to collaborate in the development of toripalimab and the other licensed compounds, and will pay for a portion of these co-development activities up to a maximum of $25.0 million per licensed compound per year. We are responsible for certain associated regulatory and technology transfer costs for toripalimab and other licensed compounds and will reimburse such costs reasonably incurred by Junshi Biosciences. We recognized research and development expense of $15.5 million and $22.2 million in the condensed consolidated statement of operations for the three and six months ended June 30, 2021, respectively, and recognized $15.5 million in accrued and other current liabilities on the condensed consolidated balance sheet as of June 30, 2021 related to the co-development activities. We accounted for the licensing transaction as an asset acquisition under the relevant accounting rules. We recorded research and development expense of $145.0 million during the first quarter of 2021, related to an upfront payment for exclusive rights to toripalimab in the United States and Canada. We had entered into a Right of First Negotiation agreement with Junshi Biosciences and paid a fee of $5.0 million which was fully expensed as research and development expense in the fourth quarter of 2020 and was fully credited against the total upfront license fee obligation under the collaboration agreement. As of June 30, 2021, we did not have any outstanding milestone or royalty payment obligations to Junshi Biosciences.

The additional milestone payments, option fees for additional anti-TIGIT antibodies and the IL-2 cytokines and royalties are contingent upon future events and, therefore, will be recorded when it is probable that a milestone will be achieved, option fees will be incurred or when royalties are due.

In connection with the Collaboration Agreement, we entered into a stock purchase agreement (the "Stock Purchase Agreement") with Junshi Biosciences agreeing, subject to customary conditions, to acquire certain equity interests in the Company. Pursuant to the Stock Purchase Agreement, on April 16, 2021, we issued 2,491,988 unregistered shares of our common stock to Junshi Biosciences, at a price per share of $20.0643, for an aggregate value of approximately $50.0 million cash. Under the terms of the Stock Purchase Agreement, Junshi Biosciences is not permitted to sell, transfer, make any short sale of, or grant any option for the sale of the common stock for the two years period following its effective date. The Collaboration Agreement and the Stock Purchase Agreement were negotiated concurrently and were therefore evaluated as a single agreement. We used the "Finnerty" and "Asian put" valuation models and determined the fair value for the discount for lack of marketability ("DLOM") to be $9.0 million at the date the shares were issued. The fair value of the DLOM is attributable to the Collaboration Agreement and was included as an offset against the research and development expense in the condensed consolidated statement of operations for the three and six months ending June 30, 2021.

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.

There have been no significant changes to our accounting policies during the six months ended June 30, 2021, as compared to the significant accounting policies described in our Annual Report on Form 10-K filed with the SEC on February 25, 2021. We believe that the accounting policies discussed in the 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

For a description of the expected impact of recent accounting pronouncements, see "Note 1. Organization and Summary of Significant Accounting Policies" in the "Notes to Condensed Consolidated Financial Statements" contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Results of Operations

Comparison of Three and Six Months Ended June 30, 2021 and 2020

Net Revenue

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands)	2021	2020	Change	2021	2020	Change
Net product revenue	$87,643	$135,674	$(48,031)	$170,677	$251,854	$(81,177)

Net product revenue for the three and six months ended June 30, 2021 was $87.6 million and $170.7 million, respectively, compared to $135.7 million and $251.9 million for the three and six months ended June 30, 2020, respectively. The decreases were primarily due to a decrease in the number of units of UDENYCA® sold and an increase in discounts and allowances incurred during the three and six months ended June 30, 2021.

Our net product revenue and market penetration may rise modestly in the second half of 2021 compared to the first half of the year, assuming the impact of the COVID-19 pandemic does not worsen, and subject to pricing trends in the overall pegfilgrastim market.

Cost of goods sold

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands)	2021	2020	Change	2021	2020	Change
Cost of goods sold	$16,696	$10,139	$6,557	$24,207	$16,994	$7,213
Gross margin	81 %	93 %		86 %	93 %	

Cost of goods sold was $16.7 million and $24.2 million for the three and six months ended June 30, 2021, respectively, compared to $10.1 million and $17.0 million for the three and six months ended June 30, 2020, respectively. Cost of goods sold consists primarily of third-party manufacturing, distribution, overhead costs associated with the sale of UDENYCA® and a mid-single digit royalty cost on net product revenue to Amgen, which began on July 1, 2019 and will continue for five years from then. For the six months ended June 30, 2021 and 2020, a portion of the manufacturing costs for inventory were incurred prior to the regulatory approval of UDENYCA® and, therefore, were expensed as research and development costs prior to those periods. The cost basis of product sold that was expensed prior to approval, was $0 and $4.9 million for the three months ended June 30, 2021 and 2020, respectively and $3.3 million and $10.5 million for the six months ended June 30, 2021 and 2020, respectively. Had such inventories been valued at acquisition cost, it would have resulted in corresponding increases in cost of goods sold and corresponding decreases in gross margin prior to the three months ended June 30, 2021. All the inventory expensed prior to approval of UDENYCA® was fully utilized by March 31, 2021.

We expect our gross margin to moderately decline during the second half of 2021 compared to the first half as a result of increased cost per unit sold due to the transition in the first quarter 2021 from inventory with manufacturing costs partly recognized in research and development costs prior to the regulatory approval of UDENYCA®.

Research and Development Expense

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands)	2021	2020	Change	2021	2020	Change
Research and development	$54,766	$26,173	$28,593	$258,258	$59,280	$198,978

Research and development expense for the three months ended June 30, 2021 was $54.8 million compared to $26.2 million for the same period in 2020, an increase of $28.6 million. The increase in research and development expense was primarily due to the following:

- an increase of $15.5 million related to costs incurred for the continued co-development of toripalimab;
- an increase of $13.5 million in CHS-1420-related costs mainly due to expenses associated with FDA pre-approval inspections and scaling up Process Performance Qualification (“PPQ”) production runs;
- an increase of $8.5 million related to the development of additional presentations of UDENYCA®;
- an increase of $3.1 million in costs incurred for the continued development of bevacizumab (Avastin) biosimilar product candidate licensed from Innovent in 2020;
- an increase of $1.0 million in personnel and consulting costs to advance our research and development programs; and
- an increase of $0.6 million in stock-based compensation expense primarily related to additional equity awards granted in 2021.

The increase in research and development expense for the three months ended June 30, 2021 was partially offset by the following:

- a credit of $9.0 million in upfront license fees to Junshi Biosciences related to the fair value of the DLOM on the common shares purchased under the Stock Purchase Agreement; and

- a decrease of $4.7 million due to the discontinuation of CHS-2020 in the first quarter of 2021 resulting in no costs being incurred in the second quarter of 2021, as compared to $4.7 million in development costs incurred in the second quarter of 2020;

Excluding the upfront payment made to Junshi Biosciences in the first quarter, we project R&D expense in the second half of 2021 to be comparable to the expense in the first half.

Research and development expense for the six months ended June 30, 2021 was $258.3 million compared to $59.3 million for the same period in 2020, an increase of $199.0 million. The increase in research and development expense was primarily due to the following:

- 2021 includes license fees of $145.0 million pursuant to the Collaboration Agreement with Junshi Biosciences which was partially offset by a $9.0 million credit related to the fair value of the DLOM on the common shares purchased under the Stock Purchase Agreement, as compared to 2020 which included upfront license fees of $5.0 million to Innovent;

- an increase of $22.2 million related to costs incurred for the continued co-development of toripalimab;

- an increase of $16.6 million related to the development of additional presentations of UDENYCA®;

- an increase of $12.9 million in CHS-1420 related costs mainly due to expenses associated with FDA pre-approval inspections and scaling up PPQ production runs;

- an increase of $6.4 million in costs incurred for the continued development of bevacizumab (Avastin) biosimilar product candidate licensed from Innovent in 2020;

- an increase of $3.4 million in stock-based compensation expense primarily related to the grant of fully vested stock options to certain employees and consultants upon the execution of the Collaboration Agreement with Junshi Biosciences and additional equity awards granted in 2021;

- an increase of $3.2 million in personnel and consulting costs to advance our research and development programs;

- an increase of $2.9 million in costs related to CHS-2020 primarily attributable to $11.5 million of costs incurred in the first quarter of 2021 from discontinuation of that program compared to $8.6 million in development costs incurred in the first half of 2020; and

The increase in research and development expense for the six months ended June 30, 2021 was partially offset by a decrease of $0.7 million in CHS-131 related costs primarily due to discontinuation of the development of CHS-131 in 2021.

Selling, General and Administrative Expenses

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands)	2021	2020	Change	2021	2020	Change
Selling, general and administrative	$40,345	$34,052	$6,293	$79,736	$69,402	$10,334

Selling, general and administrative expense for the three months ended June 30, 2021 was $40.3 million compared to $34.1 million for the three months ended June 30, 2020, an increase of $6.3 million. The increase was primarily due to the following:

- an increase of $4.3 million for personnel, consulting, professional services, marketing, advertising and other related expenses due to an increase in sales force personnel and related commercial functions to support UDENYCA® sales;
- an increase of $1.4 million in stock-based compensation expense mainly related to additional equity awards granted in 2021; and
- an increase of $0.6 million in travel, offsite conference and training related expenses as a result of COVID-19 shelter-in-place restrictions in the prior year quarter resulting in less travel and related expenses.

We expect selling, general and administrative expense to increase during the remainder of 2021 as a result of anticipated increased commercial activities to support UDENYCA® sales and as a result of initiating our ophthalmology and immuno-oncology commercial activities.

Selling, general and administrative expense for the six months ended June 30, 2021 was $79.7 million compared to $69.4 million for the six months ended June 30, 2020, an increase of $10.3 million. The increase was primarily due to the following:

- an increase of $5.8 million in stock-based compensation expense mainly related to the grant of fully vested stock options to certain employees and consultants upon the execution of the collaboration agreement with Junshi Biosciences and additional equity awards granted in 2021;
- a net increase of $4.1 million for personnel, consulting, professional services, marketing, advertising and other related expenses due to an increase in sales force personnel and related commercial functions to support UDENYCA® sales; and
- an increase of $0.8 million in facilities, supplies and materials and other infrastructure related expenses to support our commercial infrastructure for UDENYCA®.

Interest Expense

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands)	2021	2020	Change	2021	2020	Change
Interest expense	$ 5,747	$ 5,408	$ 339	$11,395	$9,839	$1,556

Interest expense for the three months ended June 30, 2021 was $5.7 million compared to $5.4 million for the same period in 2020, an increase of $0.3 million. Interest expense for the six months ended June 30, 2021 was $11.4 million compared to $9.8 million for the same period in 2020, an increase of $1.6 million. The increase in interest expense for both periods is primarily due to the interest related to our 2026 convertible notes (“2026 Convertible Notes”) that were issued in April 2020.

Income Tax Provision

(in thousands)	Three Months Ended June 30, 2021	2020	Change	Six Months Ended June 30, 2021	2020	Change
Income tax provision	$ —	$ 1,294	$(1,294)	$ —	$2,227	$(2,227)

There was no income tax expense for the three and six months ended June 30, 2021 due to a projected tax loss for 2021 and the tax effect of the valuation allowance against such loss for the year. Income tax expense of $1.3 million and $2.2 million for the three and six months ended June 30, 2020, primarily related to state taxes in jurisdictions outside of California, for which we have a limited operating history. The income tax provision during the 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. 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, we have generated significant operating losses since our inception. We have funded our operations primarily through sales of our convertible preferred stock and other equity financing, issuance of debt and sales of UDENYCA®.

As of June 30, 2021, we had an accumulated deficit of $965.6 million, cash and cash equivalents of $329.7 million and investments in marketable securities of $124.7 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. We may need to raise additional funds in the future; however, there can be no assurance that such efforts will be successful or that, if they are successful, the terms and conditions of such financing will be favorable.

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 “2022 Convertible Notes”). These 2022 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 2022 Convertible Notes at a rate of up to 0.50% per annum in the aggregate. The holders of the 2022 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 2022 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 2022 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 2022 Convertible Notes were issued), subject to adjustment in certain events. Upon conversion of the 2022 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 2022 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 2022 Convertible Notes. At maturity or redemption, if not earlier converted, we will pay 109% of the principal amount of the 2022 Convertible Notes, together with accrued and unpaid interest, in cash. In April 2020, we amended the 2022 Convertible Notes purchase agreement in connection with the issuance and sale of our 2026 Convertible Notes (as defined below).

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 6.75% per annum plus LIBOR (customarily defined). Interest is payable quarterly in arrears.

We are required to pay principal on the Borrowings in equal quarterly installments beginning on the third anniversary of the Term Loan Closing Date (or, if consolidated net sales of UDENYCA® in the fiscal year ending December 31, 2021 exceed $375.0 million, beginning on the fourth anniversary of the Term Loan Closing Date, with the outstanding balance to be repaid on January 7, 2025, the maturity date. As of June 30, 2021, $11.5 million of the carrying value was reclassified to current liabilities on our condensed consolidated balance sheets based upon our expectation that principal payments will commence within twelve months of June 30, 2021.

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 third 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 third anniversary of the Term Loan Closing Date, (ii) with respect to any prepayment paid or required to be paid after the third anniversary of the Term Loan Closing Date but on or prior to the fourth 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 fourth anniversary of the Term Loan Closing Date but on or prior to the fifth 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 $150.0 million for each fiscal year after the year ended December 31, 2020. 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 April 2020, we amended the Term Loan in connection with the issuance and sale of our 2026 Convertible Notes.

In April 2020, we issued and sold $230 million aggregate principal amount of 1.5% convertible senior subordinated notes due 2026 in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act. In connection with the pricing of the 2026 Convertible Notes, we entered into privately negotiated capped call transactions with one or more of the initial purchasers or their respective affiliates and/or other financial institutions (the “option counterparties”). The cap price of the capped call transactions will initially be $25.9263 per share, which represents a premium of approximately 75.0% over the last reported sale price of our common stock of $14.815 per share on April 14, 2020, and is subject to certain adjustments under the terms of the capped call transactions. The 2026 Convertible

Notes are general unsecured obligations and will be subordinated to our designated senior indebtedness. The 2026 Convertible Notes accrue interest at a rate of 1.5% per annum, payable semi-annually in arrears on April 15 and October 15 of each year, beginning on October 15, 2020, and will mature on April 15, 2026, unless earlier repurchased or converted. At any time before the close of business on the second scheduled trading day immediately before the maturity date, holders may convert their 2026 Convertible Notes at their option into shares of our common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 51.9224 shares of common stock per $1,000 principal amount of 2026 Convertible Notes, which represents an initial conversion price of approximately $19.26 per share of common stock. The initial conversion price represents a premium of approximately 30.0% over the last reported sale of $14.815 per share of our common stock on the Nasdaq Global Market on April 14, 2020, the date the 2026 Convertible Notes were issued. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. If a “make-whole fundamental change” (as defined in the indenture for the 2026 Convertible Notes) occurs, we will, in certain circumstances, increase the conversion rate for a specified period of time for holders who convert their 2026 Convertible Notes in connection with that make-whole fundamental change. The 2026 Convertible Notes are not redeemable at our election before maturity. If a “fundamental change” (as defined in the indenture for the 2026 Convertible Notes) occurs, then, subject to a limited exception, holders may require us to repurchase their 2026 Convertible Notes for cash. The repurchase price will be equal to the principal amount of the 2026 Convertible Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the applicable repurchase date. The net proceeds from the offering were $222.2 million, net of the initial purchasers’ fees and the offering expenses. We used approximately $18.2 million of the net proceeds to fund the cost of entering into the capped call transactions.

Summary Statement of Cash Flows

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

	Six Months Ended June 30,	
(in thousands)	**2021**	**2020**
Net cash provided by operating activities	$ 1,179	$ 73,668
Net cash used in investing activities	(261,890)	(240,864)
Net cash provided by financing activities	49,291	214,345
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (211,420)	$ 47,149

Net cash provided by operating activities

Cash provided by operating activities was $1.2 million for the six months ended June 30, 2021, which was primarily due to the following:

- license fee payment to Junshi Biosciences of $145.0 million, partially offset by a $9.0 million adjustment related to the fair value of the DLOM on common stock purchased by Junshi Biosciences, was reclassified to investing activities to provide better alignment between the cash flows and the underlying nature of the transactions;

- an increase in accrued and other current and non-current liabilities of $26.5 million primarily due to clinical, regulatory and manufacturing accruals related to our research and development programs, partially offset by lower contract manufacturing accruals for UDENCYA® due to the timing of drug production runs scheduled for 2021;

- a decrease in trade receivables of $15.2 million primarily due to the timing of payments from our customers and lower revenue in 2021;

- a decrease in prepaid manufacturing services of $2.3 million primarily due to prepaid contract manufacturing related to our research and development programs partially offset by prepaid commercial manufacturing services;

- an increase in accrued rebates, fees and reserves of $2.2 million as a result of UDENYCA® sales; and

- non-cash charges related to stock-based compensation of $28.5 million, depreciation and amortization of property and equipment of $1.7 million, write-off of prepaid manufacturing services of $3.2 million related to the termination of CHS-2020 development, non-cash interest expense from amortization of debt issuance discounts of $2.1 million, non-cash operating lease expense of $1.1 million, and non-cash accretion of discount on marketable securities of $0.6 million.

The cash provided by operating activities was partially offset by the following

- net loss of $202.8 million;

- an increase in inventory of $3.9 million in order to maintain adequate supplies to meet potential future demand for UDENYCA®;

- a decrease in accrued compensation of $7.4 million primarily due to the payment of 2020 employee bonuses, which was partially offset by an increase in ESPP contributions and the additional bonus accrual for the first half of 2021;

- a decrease in accounts payable of $0.8 million primarily due to the timing of receiving and processing invoices from our vendors; and

- an increase in other prepaid, current and non-current assets of $3.6 million primarily due to timing of insurance payments and clinical services.

Cash provided by operating activities was $73.7 million for the six months ended June 30, 2020, which was primarily due to the following:

- net income of $94.6 million;

- an increase in accrued rebates, fees and reserves of $15.1 million as a result of continued growth in UDENYCA® sales;

- an upfront license fee payment of $5.0 million to Innovent is being reclassified to investing activities to provide better alignment between the cash flows and the underlying nature of the transaction;

- non-cash charges related to stock-based compensation of $19.0 million and depreciation and amortization of property and equipment of $1.4 million, non-cash interest expense from amortization of debt issuance discounts of $1.5 million, non-cash operating lease expense of $1.0 million, other non-cash adjustments of $0.3 million; and

- an increase in accrued and other current and non-current liabilities of $7.4 million primarily due to contract manufacturing accruals related to our research and development programs.

The cash provided by operating activities was partially offset by the following:

- an increase in trade receivables of $30.7 million primarily due to the timing of payment from our customers;

- an increase in inventory of $25.2 million primarily due to continued growth in UDENYCA® sales and to maintain adequate supplies in order to meet the future demand;

- an increase in prepaid manufacturing services of $5.6 million to secure drug production runs scheduled for 2020 and 2021;

- an increase in other prepaid, current and non-current assets of $2.2 million primarily due to the timing of insurance payments;

- a decrease in accrued compensation of $2.9 million primarily due to the settlement of 2019 bonus payout, which was partially offset by additional bonus accrual for the first half of 2020; and

- a decrease in accounts payable of $5.1 million primarily due to the timing of receiving and processing invoices from our vendors.

Net cash used in investing activities

Cash used in investing activities of $261.9 million for the six months ended June 30, 2021 was primarily due to the upfront license fee of $145.0 million to Junshi Biosciences partially offset by a $9.0 million adjustment related to the fair value of the DLOM on common stock purchased by Junshi Biosciences, purchases of investments in marketable securities of $140.3 million and purchases of property and equipment of $0.6 million, partially offset by proceeds from maturities of investments in marketable securities of $15.0 million.

Cash used in investing activities of $240.9 million for the six months ended June 30, 2020 was primarily due to purchases of investments in marketable securities of $231.9 million, an upfront license fee payment of $5.0 million to Innovent and purchases of property and equipment of $4.2 million.

Net cash provided by financing activities

Cash provided by financing activities of $49.3 million for the six months ended June 30, 2021 was primarily due to $50.0 million of gross proceeds from issuance of common stock to Junshi Biosciences partially offset by a credit of $9.0 million related to the fair value of the DLOM on the common stock purchased by Junshi Biosciences, $8.4 million proceeds from the exercise of stock options, and $2.0 million proceeds from purchases under the ESPP, partially offset by $1.7 million in tax payments related to net share settlement of RSUs.

Cash provided by financing activities of $214.3 million for the six months ended June 30, 2020 was primarily due to $222.8 million in proceeds from the issuance of 2026 Convertible Notes, net of issuance costs, $8.1 million proceeds from the exercise of stock options and $2.6 million in proceeds related to ESPP, partially offset by $18.2 million of capped call option purchases related to 2026 Convertible Notes and $0.9 million in tax payments related to net share settlement of bonus payout in RSUs.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

Contractual Obligations

As of June 30, 2021, there have been no material changes outside of the ordinary course of business in our contractual obligations from those as of December 31, 2020.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

As of June 30, 2021, we had cash and cash equivalents and investments in marketable securities of $454.4 million consisting of cash, investments in money market funds and investments in marketable securities. 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 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.

There were no 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. We have not experienced any material impact to our internal controls over financial reporting despite the fact that most of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 pandemic to minimize its impact on the design and operating effectiveness of our internal controls.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are

resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II – OTHER INFORMATION

ITEM 1. Legal Proceedings

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

Item 1A. *Risk Factors*

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q, including our financial statements and related notes thereto, before making investment decisions regarding our common stock.

- Our business, financial condition, results of operations and growth could be harmed by the effects of the COVID-19 pandemic.
- We have a limited operating history in an emerging regulatory environment on which to assess our business and we have a limited history of profitability.
- 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.
- As we have in-licensed development and/or commercial rights to toripalimab, CHS-201 and CHS-305, we rely on prior and ongoing preclinical, clinical, regulatory and manufacturing expertise of our collaborators in order to advance these product candidates through regulatory approvals in the United States and other licensed territories.
- UDENYCA® and our other product candidates, even if approved, will remain subject to regulatory scrutiny.
- 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 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.

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

- 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 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 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.

- 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.

- 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.

- 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.

Risk Factors

Investing in the common stock of a biotherapeutics company is a highly speculative undertaking and involves a substantial degree of risk. 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 COVID-19

Our business, financial condition, results of operations and growth could be harmed by the effects of the COVID-19 pandemic.

We are subject to risks related to public health crises such as the global pandemic associated with the novel coronavirus and the associated disease ("COVID-19"). As a result of the COVID-19 outbreak, we have experienced and may continue to experience disruptions that could severely impact our business, clinical trials and preclinical studies, including, but not limited to:

- decreased sales of UDENYCA®;
- our ability to maintain or expand the commercial use of UDENYCA® due to, among other factors, healthcare providers, payers and patients not utilizing or adopting UDENYCA® due to resources being strained or otherwise focused on the COVID-19 pandemic and our sales team efficacy in selling UDENYCA® being limited due to such strained resources or other factors such as travel restrictions;
- fewer individuals undertaking or completing cancer treatments, whether due to contracting COVID-19, self-isolating or quarantining to lower the risk of contracting COVID-19 or being unable to access care as a result of healthcare providers tending to COVID-19 patients;
- our third-party contract manufacturers and logistics providers not being able to maintain adequate (in amount and quality) supply to support the commercial sale of UDENYCA® or the clinical development of our product candidates due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays and difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff, as well as delays or difficulties in enrolling patients or maintaining enrolled patients in our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact regulatory review and approval timelines; and
- limitations on our employee resources, and those of our business partners, that would otherwise be focused on the conduct of our business in all aspects, including because of sickness of employees or their families.

These and other factors arising from the COVID-19 pandemic could result in us not being able to maintain UDENYCA®'s market position or increase its penetration against all of Neulasta's dosage forms, and could result in our inability to meet development milestones for our product candidates, each of which would harm our business, financial condition, results of operations and growth.

Numerous state and local jurisdictions have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Multiple times in 2020 and 2021, the governor of California, where our headquarters and laboratory facilities are located, issued a "shelter-in-place" order restricting non-essential activities, travel and business operations for an indefinite period of time, subject to certain exceptions for necessary activities. Such orders or restrictions, have resulted in our headquarters closing for certain periods, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. Such orders or restrictions may continue or be re-instated, as the case may be, thereby causing additional negative impact on our operations. Further, because the rollout of COVID-19 vaccines has experienced and could continue to experience significant delays

and suffered from reluctance from eligible individuals to be fully inoculated, the COVID-19 pandemic may last longer than expected and could result in additional outbreaks that prompt additional closings. In addition, the spread of more contagious and deadly variants, such as the Delta variant, could cause the COVID-19 pandemic to last longer than expected.

While the long-term economic impact and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, which could reduce our ability to access capital and could negatively affect our liquidity and the liquidity and stability of markets for our common stock and the notes. In addition, a recession, further market correction or depression resulting from the spread of COVID-19 could materially affect our business and the value of our notes and our common stock.

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 and we have a limited history of profitability, which we have not maintained and may not achieve again, and only one product that has been approved, with multiple products still early in development.

We are a biopharmaceutical company with a limited operating history in an emerging regulatory environment. We incurred net losses in each year from our inception in September 2010 through December 31, 2018, including net losses of $209.4 million for the year ended December 31, 2018 and a net loss of $202.8 million in the first half of 2021. However, while we did generate net income of $132.2 million and $89.8 million for the years ended December 31, 2020 and 2019, respectively, it is uncertain that we will be profitable in future periods as research and development is expensive and risky. The amount of our future net losses or net income will depend, in part, on the amount of our future expenditures offset by the amount of future product sales, including sales of UDENYCA or any other products that may receive regulatory approval. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk.

For example, as of June 30, 2021, we had an accumulated deficit of $965.6 million. The losses and accumulated deficit were primarily due to the substantial investments we made to identify, develop or license our product candidates, including conducting, among other things, analytical characterization, process development and manufacturing, formulation and clinical studies and providing general and administrative support for these operations.

We anticipate we will incur certain development and pre-commercial expenses for the Lucentis biosimilar candidate, which we licensed from Bioeq in November 2019, for the Avastin biosimilar candidate, which we licensed from Innovent in January 2020, and for toripalimab, the anti-PD-1 antibody we licensed from Junshi Biosciences in 2021. Advancing these candidates through clinical development will be expensive and could result in us continuing to experience future net losses.

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 which include all product candidates for which we obtained commercial rights, in those markets. However, even if additional product candidates in addition to UDENYCA® gain regulatory approval and are commercialized, we may not remain profitable.

Our expenses will increase substantially if and as we:

- further develop our sales, marketing and distribution infrastructure for UDENYCA®;
- establish a sales, marketing and distribution infrastructure to commercialize any of our product candidates for which we may obtain marketing approval;

- make upfront, milestone, royalty or other payments under any license agreements;
- 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 product candidates or products that may be complementary to our products;
- seek to create, maintain, protect and expand our intellectual property portfolio;
- engage legal counsel and technical experts to help us evaluate and avoid infringing any valid and enforceable intellectual property rights of third parties;
- engage in litigation, including patent litigation, and Inter Partes Review ("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 loss 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 continue to be 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, 2021, our cash and cash equivalents and short-term investments were $454.4 million. We expect that our existing cash and cash equivalents and cash collected from our UDENYCA® sales will be sufficient to fund our current operations for the foreseeable future. We have financed our operations primarily through the sale of equity securities, convertible notes, credit facilities, license agreements and through recent product sales of UDENYCA®.

However, our operating or investing 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 Neulasta, Neulasta Onpro® and new and existing commercial pegfilgrastim biosimilar products;
- 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;
- the timing of conversion in common shares or repayment in cash of our convertible debt, or the timing of repayment in cash, whether due or not, of our long-term debt; 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, we may be unable to use a material portion of our NOLs and other tax attributes, which 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® is our only product approved for commercialization in the United States and E.U., and we have no products approved in any other territories.

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:

- Toripalimab;
- Bioeq's ranibizumab (Lucentis) biosimilar candidate;
- Innovent's bevacizumab (Avastin) biosimilar candidate;
- CHS-1420 (our adalimumab (Humira) biosimilar candidate); and

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 continue to successfully commercialize UDENYCA®;
- competing against current and future pegfilgrastim products;
- healthcare providers, payers, and patients adopting our product candidates once approved and launched;
- our ability to procure and commercialize our in-licensed biosimilar candidates;
- 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 of 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 European Medical Agency (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 with) 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.

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 and 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 any future product candidates, if approved, will not be fully known until after they are launched and may be negatively affected by a potential poor safety experience and the track record of other biosimilar product candidates. Further, continued market acceptance of UDENYCA®, and the market acceptance of any future product candidates that may be approved, depends on 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 UDENYCA® or any future product candidates that are approved 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 sustain profitability.

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 product candidates, if approved, may not be adequate to support our commercial infrastructure. Our per-patient prices may not continue to 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, or become unavailable, 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 United States, 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 United States, 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.

Effective January 2019, the Centers for Medicare and Medicaid Services (“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 a large majority of payers have adopted the Q-Code assigned by CMS for UDENYCA®, there remains uncertainty as to whether such payers will continue to cover and pay providers for the administration and use of the product with each patient or may favor a competing product. 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 United States and abroad to control healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for 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 United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers’ facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices (“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.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, while in power, the

Trump administration took 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 whether or how these executive actions will be implemented, rescinded or replaced under the Biden administration. The policies and priorities of the Biden administration could also materially impact the regulations governing our product candidates.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, 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, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA 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 biologics or modifications to approved biologics to be reviewed and/or approved by necessary 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.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities 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 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: 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," a subsidiary of Mundipharma), 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), ranibizumab (Lucentis), bevacizumab (Avastin) and adalimumab (Humira).

UDENYCA® faces competition in the United States from Amgen, Mylan (with partner Biocon Ltd.), Sandoz, Pfizer, and may face completion from Amneal Pharmaceuticals, Inc. and Fresenius Medical Care AG & Co. KGaA, companies that announced the development of a pegfilgrastim biosimilar.

Our ranibizumab (Lucentis) biosimilar candidate licensed from Bioeq may face competition in the United States from Genentech (the manufacturer of Lucentis). Biogen with collaborator Samsung Bioepis, and Xbrane Biopharma AB (in collaboration with STADA Arzneimittel AG and Bausch + Lomb) have each disclosed the development for a Lucentis biosimilar candidate.

Our bevacizumab (Avastin) biosimilar candidate licensed from Innovent may face competition in the United States from Genentech, Inc. (the manufacturer of Avastin) as well as Amgen and Pfizer, each of which have initiated the commercial launch of an Avastin biosimilar.

Similarly, CHS-1420, our adalimumab (Humira) biosimilar may face competition from AbbVie (the manufacturer of Humira) as well as manufacturers of Humira biosimilars such as Pfizer, Boehringer Ingelheim, Amgen, Sandoz and Samsung Bioepis. There are five adalimumab biosimilar products that have been approved by the FDA in the United States, and Fujifilm and Fresenius have each disclosed development plans for a Humira biosimilar candidate. As a result of number of potential adalimumab (Humira) biosimilar competitors, we may not be able to achieve substantial topline sales for CHS-1420 in the United States, if approved.

Toripalimab may face competition from Merck, Bristol Myers Squibb, Novartis, Astrazeneca, Pfizer, Eli Lilly, Regeneron, and others who currently commercialize PD-1/PDL-1 blocking antibodies or are developing such compounds for commercialization in the United States.

These companies may 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.

Competitors in the biosimilar market have the ability to compete on price 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 more 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.

If other biosimilars of bevacizumab (Avastin), ranibizumab (Lucentis) or adalimumab (Humira), are approved and successfully commercialized before our product candidates for these originator products, our business would suffer.

We expect other companies to seek approval to manufacture and market biosimilar versions of Avastin, Lucentis or Humira. If other biosimilars of these branded biologics are approved and successfully commercialized before our biosimilar candidates, 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.

If an improved version of an originator product, such as Neulasta, Humira or Lucentis, 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, 2021, we had 311 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. There can be no assurance 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 Junshi Biosciences, Bioeq, Innovent and Orox Pharmaceuticals B.V. for the commercialization of our 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.

We have an exclusive license from Junshi Biosciences to develop and commercialize toripalimab in the United States and Canada. We have an exclusive license from Bioeq to commercialize Bioeq's ranibizumab (Lucentis) biosimilar in the United States. We have an exclusive license from Innovent to develop and commercialize Innovent's bevacizumab (Avastin) biosimilar in the United States and Canada. Our licensors are responsible for supplying us with drug substance and final drug products as well as, in the case of Innovent, the necessary regulatory data to submit a 351(k) BLA for Innovent's bevacizumab candidate in the United States and Canada.

Our exclusive licensee, Orox, is responsible for commercialization of certain of our products and product candidates, including UDENYCA® and CHS-1420, in certain Caribbean and Latin American countries (excluding Brazil, and in the case of UDENYCA®, also excluding Argentina).

Our licenses with Junshi Biosciences, Bioeq, Innovent, 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 collaboration partners may fail to provide sufficient amounts of commercial products or they may be ineffective in doing so;
- our existing and potential collaboration partners may fail regulatory inspections which may preclude or delay the delivery of commercial products;
- our existing and potential 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.

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, and potentially exacerbated by climate change.

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, including due to sudden or long-term changes in weather patterns, 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 our product candidates, we currently engage a distinct vendor or service provider for each of the principal activities supporting our manufacture and development of these 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 engaged a limited number of 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 351(k) BLA, original 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. 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, 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.

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 United States Patent and Trademark Office ("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 product candidates, including our in-licensed biosimilar candidates, 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 United States and abroad that is relevant or necessary to the commercialization of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. With respect to products we are evaluating for inclusion in our future biosimilar product pipeline, our freedom to operate analyses, including our research on the timing of potentially relevant patent expirations, are ongoing.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions, which do not require publication of patent applications until 18 months after filing. 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 United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Even if we are successful in these proceedings, we

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

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

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, our 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 our motion 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 our 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. In a Joint Status Report, dated September 20, 2019, Amgen stated that it does not intend to further appeal the Federal Circuit's decision. On October 11, 2019, we filed a Motion for Attorneys' Fees with the District Court. Amgen filed its Answering Brief in Opposition on November 8, 2019. On November 22, 2019, we filed our Reply Brief with the District Court. On November 30, 2020, the District Court issued an order denying the Company's motion.

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 United States 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 proceeding could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

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

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

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.

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. 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 United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone involved in the prosecution of the patent withheld relevant or material information related to the patentability of the invention from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during any litigation we initiate to enforce our patents. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

We employ individuals, retain independent contractors and consultants and members on our board of directors or scientific advisory board who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. For example, our Chief Executive Officer, Dennis M. Lanfear is a former employee of Amgen. Mr. Lanfear was employed at Amgen during periods when Amgen’s operations included the

development and commercialization of Neulasta and Enbrel. 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 who 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 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, which was amended, alleged 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. The complaint, as amended, sought injunctive relief and monetary damages. 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 began paying a mid-single digit royalty to Amgen for five years starting on July 1, 2019.

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

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

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

The Biologics Price Competition and Innovation Act of 2009, Title VII, Subtitle A of the Patent Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, Sections 7001-02 signed into law March 23, 2010, and codified in 42 U.S.C. §262, (the “BPCIA”), created an elaborate and complex patent dispute resolution mechanism for biosimilars that, if we choose to implement it, could prevent us from launching our product candidates in the United States or could substantially delay such launches. However, even if we elect not to implement this mechanism, the launch of our products in the United States 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.

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

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 has completed Phase 3 clinical trials or other 351(k) BLA-enabling clinical development, and toripalimab is currently being evaluated in Phase 3 clinical trials. Other than certain PK bridging studies, we have not initiated phase 3 clinical trials for other product candidates in our pipeline. 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. 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 United States, 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. For example, Innovent's bevacizumab (Avastin) biosimilar product candidate has been developed principally in China, and the FDA may not agree that Innovent's clinical development plan, even if successfully completed, will support submission of a 351(k) BLA. 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 United States, 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 United States 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. For example, during FDA's review of Bioeq's 351(k) BLA for its ranibizumab (Lucentis) biosimilar, the FDA requested that Bioeq submit additional manufacturing data for the equipment in its new location, leading Bioeq to withdraw its 351(k) BLA for this candidate in order to provide the requested data and resubmit the application thereafter. Neither we nor any collaboration partner has obtained regulatory approval for any of our product candidates, other than UDENYCA®, which has received approval from the FDA and EMA, and toripalimab, which is approved for use in China only, and it is possible that none of our other current or future product candidates will ever obtain additional regulatory approvals.

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 United States, the EEA or elsewhere;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from analytical and bioanalytical studies, nonclinical studies or clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of our collaborators or third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

Our future results of operations depend, to a significant degree, on our ability to obtain regulatory approval for and to commercialize our proposed biosimilar products. To obtain regulatory approval for the commercial sale of these product candidates, we will be required to demonstrate to the satisfaction of regulatory authorities, among other things,

that our proposed biosimilar products are highly similar to biological reference products already licensed by the regulatory authority pursuant to marketing applications, notwithstanding minor differences in clinically inactive components, and that they have no clinically meaningful differences as compared to the marketed biological products in terms of the safety, purity and potency of the products. Each individual jurisdiction may apply different criteria to assess biosimilarity, based on a preponderance of the evidence that can be interpreted subjectively in some cases. In the EEA, the similar nature of a biosimilar and a reference product is demonstrated by comprehensive comparability studies covering quality, biological activity, safety and efficacy.

It is uncertain if regulatory authorities will grant the full originator label to biosimilar product candidates when they are approved. For example, an infliximab (Remicade) biosimilar molecule was approved in Europe and in the United States for the full originator label but received a much narrower originator label when 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 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 or our collaboration partners, or both we and our collaboration partners, as the case may be, 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.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, or conducting our planned clinical trials. 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 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.

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 United States, an abbreviated pathway for approval of biosimilar products was established by the BPCIA, enacted on March 23, 2010, as part of the ACA. The BPCIA established this abbreviated pathway under section 351(k) of the 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 United States is unclear. Numerous states are considering or have already enacted laws that

regulate or restrict the substitution by state pharmacies of biosimilars for originator products already licensed by the FDA. Market success of biosimilar products will depend on demonstrating to patients, physicians, 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.

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.

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 South 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 or may require that the biosimilar product be manufactured within their region, or some countries may require both.

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

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

We 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 United States 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 United States 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 in any market. 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

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (together the “ACA”), was passed, which substantially changed the way health care is financed by both governmental and private insurers and has impacted and continues to impact the U.S. pharmaceutical industry. The ACA, among other things, addressed 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, increased 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, added 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 promoted a new Medicare Part D coverage gap discount program.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court’s decision, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and will remain open through

August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA 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 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. In addition, 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 United States 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 E.U., 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 E.U. or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the E.U., including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than E.U., 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 E.U. member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing E.U. 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 U.S. and E.U., 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 and physician payment transparency 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. 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;

- federal civil and criminal false claims laws, including the False Claims Act, 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. 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 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;
- 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 ACA, 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, as defined in the statute, including their immediate family members, certain other healthcare professionals as of 2022, and teaching hospitals and ownership and investment interests held by such physicians and their immediate family members; 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; and 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.

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 United States, 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 now 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 United States in order to obtain coverage for the product by certain government healthcare programs. These programs 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.

Risks Related to Ownership of Our Common Stock

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

The market price of our common stock has been highly volatile since our Initial Public Offering (“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 June 30, 2021 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 Quarterly Report on Form 10-Q and others such as:

- adverse results or delays in preclinical or clinical studies;
- any inability to obtain additional funding;
- any delay in filing an IND, NDA, 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; 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, 2021, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 60.9% 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 the market price of our common stock could decline. As of June 30, 2021, there were approximately 76.5 million shares of common stock outstanding.

In addition, as of June 30, 2021, approximately 26.4 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. 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 June 30, 2021, we reserved for future issuance under the 2016 Plan a total of 1.4 million 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 “2022 Convertible Notes”). The holders may convert their 2022 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 2022 Convertible Notes by a holder, the holder will receive shares of our common stock, together, if applicable, with cash in lieu of any fractional share. The initial conversion rate is 44.7387 shares of common stock per $1,000 principal amount of convertible notes, which is equivalent to an initial conversion price of approximately $22.35 per share, and is subject to adjustment in certain events.

In April 2020, we issued and sold $230.0 million aggregate principal amount of our 1.5% senior convertible notes due April 2026 (the “2026 Convertible Notes”). The holders may convert their 2026 Convertible Notes at their option at any time prior to the close of business on the second scheduled trading day immediately before April 15, 2026. Upon conversion of the 2026 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 51.9224 shares of common stock per $1,000 principal amount of convertible notes, which is equivalent to an initial conversion price of approximately $19.26 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.

General Risk Factors

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 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.

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, publicly 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. On July 1, 2020, the U.S. Court of Appeals for the Federal Circuit issued a decision that affirmed the lower court's decision upholding the validity of these patents. As a result, we discontinued the development of CHS-0214 (our etanercept (Enbrel®) biosimilar candidate).

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 United States market.

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

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

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

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

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

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

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

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

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

In addition, 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 United States and most other countries are confidential for a period of time, typically for 18 months after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013 or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the 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 United States and globally, covering our biosimilar product candidates 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 United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may choose

not to file patent applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the 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 United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Governments of foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are

deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the "first-to-file" laws in the United States and the EU, 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.

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, 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.

Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer, server, and other information technology systems as well as those of our third-party collaborators, consultants, contractors, suppliers, and service providers, may be vulnerable to damage from physical or electronic break-ins, computer viruses, “phishing” attacks, malware, ransomware, denial of service and other cyber-attacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of sensitive, and/ or proprietary data, including health-related information or other personal information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage. If we or any of our third-party collaborators were to experience any material failure or security breach, it could result in a material disruption of our development programs, reputation, and business operations. For example, the loss of clinical study data from completed or ongoing clinical studies could result in delays in any regulatory approval or clearance efforts and significantly increase our costs to recover or reproduce the data, and subsequently commercialize the product. If we or our third-party collaborators, consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal information, including health-related information, we may have to notify individuals, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. Likewise, we rely on our third-party CROs and other third parties to conduct clinical studies, and similar events relating to their computer systems could also have a material adverse effect on our business. The COVID-19 pandemic is generally increasing the attack surface available to criminals, as more companies and individuals work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from “hackers” hoping to use the recent COVID-19 pandemic to their advantage. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate or unauthorized access to or disclosure or use of confidential, proprietary, or other sensitive, personal information, including health-related information, we could incur liability and suffer reputational harm, and the development and commercialization of our products could be delayed. Our insurance policies may not be adequate to compensate us for the potential losses arising from such disruptions, failure, or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly, divert management attention, and harm our reputation.

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 United States, 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 may be subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA and the CCPA (defined below), and, in the E.U. and 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 the United States, we and our partners may be subject to numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA.

Even when HIPAA does not apply, according to the Federal Trade Commission ("FTC"), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, state laws govern 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 requirements, thus complicating compliance efforts. By way of example, California enacted the California Consumer Privacy Act (the "CCPA") on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the CPRA recently passed in California, which will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. The CCPA and the CPRA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states.

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. The GDPR is applicable in each EEA member state and applies to companies established in the EEA as well as companies that collect and use personal data to offer goods or services to, or monitor the behavior of, individuals in the EEA, including, for example, through the conduct of clinical trials. GDPR introduces more stringent data protection obligations for processors and controllers of personal data. Among other things, the GDPR requires the establishment of a lawful basis for the processing of data, includes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators, as well as requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. For example, on July 16, 2020, the Court of Justice of the European Union ("CJEU") invalidated the EU-US Privacy Shield Framework ("Privacy Shield") under which personal data could be transferred from the EEA to United States entities that had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard

contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. 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.

Additionally, as of January 1, 2021, we have to comply with the GDPR and the GDPR as implemented in the United Kingdom, each regime having the ability to fine up to the greater of €20 million/ £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the E.U. with respect to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure. Currently there is a four to six-month grace period agreed in the E.U. and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. The European Commission published a draft adequacy decision on February 19, 2021. If adopted, the decision will enable data transfers from E.U. member states to the United Kingdom for a four-year period, subject to subsequent extensions.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and have a material adverse effect on our business, financial condition and results of operations.

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

- expose us to sanctions, such as the sanctions levied by U.S., E.U. and Russian regulatory bodies in connection with Russia's military intervention in the Ukraine in March 2014; 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.

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.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

In connection with the Collaboration Agreement and the Stock Purchase Agreement with Junshi Biosciences, the Company issued 2,491,988 unregistered shares of its common stock to Junshi Biosciences on April 16, 2021, at a price per share of $20.0643, for an aggregate value of approximately $50.0 million. Such shares were issued pursuant to the exemption from the registration requirements of the Securities Act afforded by Section 4(a)(2) and Rule 506 promulgated under the Securities Act of 1933, as amended. The issuance and sale of shares were not in connection with any public offering, general solicitation, or advertisement.

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	
4.1	Reference is made to exhibits 3.1 and 3.2				
4.2	Form of Common Stock Certificate.	S-1/A	4.2	10/24/2014	
4.3	Description of Coherus' Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	10-K	4.3	2/27/2020	
4.4	Indenture, dated as of April 17, 2020, between Coherus Biosciences, Inc. and U.S. Bank National Association, as Trustee.	8-K	4.1	4/17/2020	
4.5	Form of certificate representing the 1.5% Convertible Senior Subordinated Notes due 2026.	8-K	4.2	4/17/2020	
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

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
101	The following materials from Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 formatted in inline eXtensible Business Reporting Language (iXBRL) includes: (i) Condensed Consolidated Balance Sheets at June 30, 2021 (unaudited) and December 31, 2020, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2021 and 2020, (iii) Condensed Consolidated Statements of Comprehensive Income (unaudited) for the three and six months ended June 30, 2021 and 2020, (iv) Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the three and six months ended June 30, 2021 and 2020, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2021 and 2020, and (vi) Notes to the Condensed Consolidated Financial Statements.				X
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 has been formatted in Inline XBRL.				X

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, 2021

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

Date: August 5, 2021

/s/ McDavid Stilwell
McDavid Stilwell
Chief Financial Officer
(Principal Financial and Accounting Officer)

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, 2021

/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, McDavid Stilwell, 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, 2021

/s/ McDavid Stilwell
McDavid Stilwell
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, 2021 (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, 2021

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

Date: August 5, 2021

By: /s/ McDavid Stilwell
Name: McDavid Stilwell
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.