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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

☐ **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 001-35420

ChemoCentryx, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**94-3254365**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
850 Maude Avenue Mountain View, California	**94043**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 210-2900

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, par value $0.001 per share	CCXI	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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 such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $1.9 billion, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market of $57.54 per share.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of February 22, 2021 was 69,613,267.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2021 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Annual Report on Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2020.

CHEMOCENTRYX, INC.

FORM 10-K — ANNUAL REPORT

For the Fiscal Year Ended December 31, 2020

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PART I

Forward-Looking Statements and Market Data

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “could,” “will,” “would,” “should,” “expect,” “plan,” “aim,” “anticipate,” “believe,” “estimate,” “intend,” “predict,” “seek,” “contemplate,” “potential” or “continue” or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- our ability to advance drug candidates into, and successfully complete, clinical trials;
- the anticipated impact of the novel coronavirus disease 2019, or COVID-19, pandemic on our business, preclinical studies and clinical trials;
- the commercialization of our drug candidates;
- the implementation of our business model, strategic plans for our business, drug candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our drug candidates and technology;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the timing or likelihood of regulatory filings and approvals;
- our ability to maintain and establish collaborations or obtain additional government grant funding;
- our financial performance; and
- developments relating to our competitors and our industry.

These statements relate 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 “Item 1A. Risk Factors” and elsewhere in this Annual Report on Form 10-K.

Any forward-looking statement in this Annual Report on Form 10-K reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. 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 Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates, the incidence of certain medical conditions, statements that certain drugs, classes of drugs or dosages are the most widely prescribed in the United States or other markets, the perceptions and preferences of patients and physicians regarding certain therapies and other prescription, prescriber and patient data, as well as data regarding market research, estimates and forecasts prepared by our management. 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. In particular, unless otherwise specified, all prescription, prescriber and patient data in this Annual Report on Form 10-K is from Datamonitor or

Global Data. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

ChemoCentryx® and the ChemoCentryx logo are our trademarks in the United States, the European Community, Australia and Japan. EnabaLink® and RAM® are our trademarks in the United States. Each of the other trademarks, trade names or service marks appearing in this Annual Report on Form 10-K belongs to its respective holder.

Unless the context requires otherwise, in this Annual Report on Form 10-K the terms “ChemoCentryx,” “we,” “us” and “our” refer to ChemoCentryx, Inc., a Delaware corporation, and our subsidiaries taken as a whole unless otherwise noted.

Item 1. Business.

Overview

ChemoCentryx is a biopharmaceutical company focused on the development and commercialization of new medications targeting inflammatory disorders, autoimmune diseases and cancer. Each of our drug candidates is designed to selectively block a specific chemoattractant receptor, leaving the rest of the immune system intact. Our drug candidates are small molecules, which are orally administered, and, if approved, could address unmet medical needs, including improved efficacy, and offer significant quality of life benefits. Since patients swallow a capsule or pill instead of having to visit a clinic for an infusion or undergo an injection, our drug candidates may improve patient compliance.

We are preparing for a potential commercial launch of avacopan, an orally-administered selective complement 5a receptor inhibitor, for the treatment of patients with anti-neutrophil cytoplasmic autoantibody-associated vasculitis, or ANCA vasculitis. In November 2019, we announced positive topline data from the pivotal Phase III ADVOCATE trial of avacopan for the treatment of patients with ANCA vasculitis. In September 2020, we announced that the FDA had accepted for review the avacopan New Drug Application, or NDA, for the treatment of ANCA vasculitis in the United States and had set July 7, 2021 as the Prescription Drug User Fee Act, or PDUFA, target goal date for the avacopan NDA. If the NDA is approved, we plan to commercialize avacopan in the United States on our own. We also plan to commercialize avacopan internationally through our kidney health alliance with Vifor Fresenius Medical Care Renal Pharma Ltd. and its affiliates and sublicensees, or collectively, Vifor. In November 2020, Vifor announced that the Marketing Authorisation Application, or MAA, for avacopan in the treatment of ANCA vasculitis was accepted for review (validated) by the European Medicines Agency, or EMA, for which a decision is expected in the second half of 2021.

Our pipeline includes the following programs:

Avacopan:

- We are also developing avacopan for the treatment of severe (Hurley Stage III) hidradenitis suppurativa, or HS. In October 2020, we announced positive topline data in severe HS patients from the Phase II AURORA trial of avacopan. We plan to advance avacopan into a Phase III clinical trial for the treatment of severe HS in the second half of 2021.
- In December 2020, we announced topline data from the Phase II ACCOLADE trial of avacopan for the treatment of patients with complement 3 glomerulopathy, or C3G. We plan to discuss the evidence of clinical benefit of avacopan in C3G with the FDA in 2021.
- Based on the renal improvement results observed with avacopan treatment in both the ADVOCATE trial in ANCA vasculitis and the ACCOLADE trial in C3G, as measured by an increase in estimated glomerular filtration rate, we plan to develop avacopan in additional complement-mediated renal indications such as lupus nephritis, or LN. We plan to initiate a registrational clinical trial of avacopan for the treatment of LN in the second half of 2021.

Immuno-Oncology

- CCX559 is our orally-administered inhibitor for programmed death protein 1/programmed death-ligand 1, or PD-1/PD-L1, which we are developing for the treatment of various cancers. We plan to initiate a Phase I clinical trial of CCX559 in the first half of 2021.

Our Strategy

The key elements to our commercial and scientific strategy are to:

- Obtain regulatory approval of avacopan for the treatment of ANCA vasculitis in the United States on our own, and support our international commercialization partner Vifor and its Japanese sublicensee Kissei Pharmaceutical, Co., Ltd., or Kissei, in their regulatory approval applications;
- Commercialize avacopan in the United States on our own, where we believe a company of our size can effectively compete in rare disease markets. If our avacopan NDA is approved by the FDA, we plan to

deploy a specialty sales force primarily targeting that subset of nephrologists and rheumatologists treating ANCA vasculitis patients in the United States;

- Develop and commercialize avacopan for additional indications, including C3G, severe HS, and additional complement-mediated renal indications such as LN;
- Develop our other drug candidates and establish collaborations with pharmaceutical and biotechnology companies to further develop and market our drug candidates; and
- Discover and validate new drug candidates.

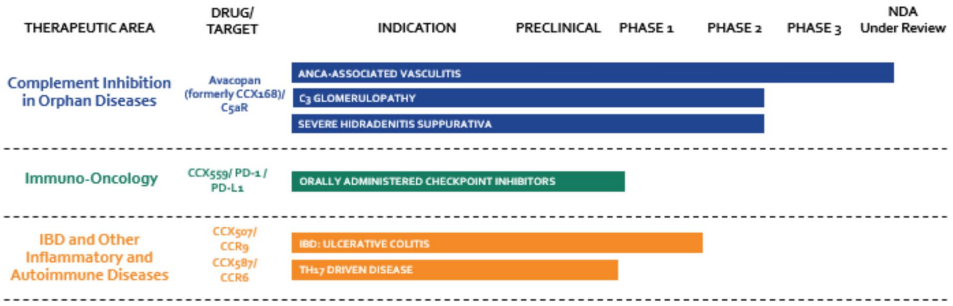
Recent Developments

In February 2021, results from our Phase III ADVOCATE trial of avacopan for the treatment of patients with ANCA vasculitis were published as a peer reviewed journal article in The New England Journal of Medicine, or NEJM.

In February 2021, Vifor and Kissei filed the Japanese NDA, or JNDA, for avacopan in the treatment of ANCA vasculitis with the Japanese Pharmaceuticals and Medical Device Agency, or PMDA.

Our Drug Candidate Pipeline

The following table summarizes our drug candidate pipeline:



Avacopan (CCX168) – Inhibition of Complement-Mediated Pathways in Orphan Diseases

The complement system is a group of proteins that work together to regulate aspects of host defense against bacteria and viruses, trigger inflammation, and remove debris from cells and tissues. The complement system must be carefully regulated so it targets only unwanted materials and does not attack the body's healthy cells. In certain autoimmune diseases (including those in which we are engaged in clinical trials), components of the complement system have become dysregulated.

In our complement inhibition orphan disease program, our lead drug candidate is avacopan. Avacopan is a potential first-in-class, orally-administered molecule that employs a novel, highly targeted mode of action in the treatment of ANCA vasculitis and other complement-driven autoimmune and inflammatory diseases. Avacopan precisely blocks a specific receptor (C5aR) for the pro-inflammatory complement system fragment known as C5a on destructive inflammatory cells such as blood neutrophils. Avacopan thereby arrests the ability of those cells to do damage in response to C5a activation, which is known to be the driver of ANCA vasculitis and other complement-driven autoimmune and inflammatory diseases. Current therapies for such diseases typically include broad immunosuppression with high doses of glucocorticoids (steroids) such as prednisone or methylprednisone, which may cause significant illness and even death. Avacopan therapy was designed to prevent these outcomes. Avacopan does not affect formation of the C5b-9 terminal complement complex, or MAC, unlike the anti-C5-antibody, eculizumab (Soliris®). Therefore, we believe avacopan does not increase the susceptibility to infections for which MAC is important in host defense. Moreover, there are two distinct receptors for C5a: the pro-inflammatory C5a receptor known as C5aR, the target of avacopan, and the anti-inflammatory C5a-like receptor, or C5L2, which plays an important role in homeostasis. Accordingly, precisely inhibiting C5a at the level of C5aR is thought to block the pro-inflammatory effects of C5a, while leaving the protective effects of C5L2 functional. Avacopan does not bind into C5L2, thereby not interfering with the protective effects of C5L2.

We have successfully completed and reported positive topline clinical data from our pivotal Phase III clinical trial known as ADVOCATE in ANCA vasculitis. We have also reported positive topline data in Hurley Stage III patients from our Phase II clinical trial known as AURORA in HS after 12 weeks of treatment, as well as topline data from our Phase II clinical trial known as ACCOLADE in C3G where avacopan demonstrated statistically significant improvement in renal function as measured by estimated glomerular filtration rate, or eGFR, compared to placebo over 26 weeks of blinded treatment.

ANCA Vasculitis

ANCA vasculitis is an orphan, severe, and often fatal autoimmune disease that is characterized by elevated levels of autoantibodies called anti-neutrophil cytoplasmic autoantibodies and by inflammation that can affect many different organ systems, and commonly involves the kidneys. ANCA vasculitis affects approximately 40,000 to 100,000 people in the United States, with approximately 4,000 to 8,000 new cases each year; similarly, ANCA vasculitis affects approximately 50,000 to 100,000 people in Europe, with approximately 5,000 new cases each year.

ANCA vasculitis is currently treated with courses of immuno-suppressants (cyclophosphamide, or CYC, or rituximab, or RTX) combined with high-dose prednisone administration. Complete remission is achieved in only 60-80% of patients and relapse is common. Following initial treatment, up to 30% of patients relapse within six to 18 months, and up to 50% of patients relapse within three to five years. Each relapse can lead to irreversible organ damage.

The current standard of care, or SOC, for ANCA vasculitis is associated with significant safety risks due to general immunosuppression including increased infection rates and dose-related increases in hematological and solid organ malignancies, as well as metabolic and other toxicities associated with glucocorticoids. First year mortality is approximately 11% to 18%, with the single greatest cause of this premature mortality being not disease related, but rather infection and other side effects that are thought largely to be a consequence of prednisone administration. The multiple adverse effects of acute and chronic prednisone treatment often required in the treatment plan are major causes of both short-term and long-term morbidity including the increased infection risk. Glucocorticoid therapy-related adverse events contribute significantly to patient care costs, as well as to the diminution of quality of life for patients.

Role of C5a and C5aR in ANCA Vasculitis

Complement 5a, or C5a, acting through its receptor C5aR, sometimes called C5aR1 or CD88, is thought to play a pro-inflammatory role in ANCA vasculitis. Autoantibodies against neutrophil enzymes lead to the priming and activation of neutrophils and activation of the complement cascade. Activation of the complement cascade leads to production of C5a, one of the most potent pro-inflammatory mediators of the complement system. C5a, through binding to its receptor C5aR, induces expression of adhesion molecules and chemotactic migration of neutrophils and other white blood cells. These accumulating adhering neutrophils initiate an inflammatory cascade in the small blood vessels by secreting pro-inflammatory cytokines and chemoattractants that lead to necrotizing vasculitis.

Avacopan Phase III Clinical Trial in ANCA Vasculitis

We have successfully completed and reported positive topline clinical data from our pivotal Phase III clinical trial of avacopan for the treatment of ANCA vasculitis, known as the ADVOCATE trial. The ADVOCATE trial was a global, randomized, double-blind, active-controlled, double-dummy Phase III trial in 331 patients with ANCA vasculitis in 20 countries. Eligible patients were randomized to receive either 30 mg twice-daily oral doses of avacopan or a standard regimen of high-dose chronic prednisone. In addition, all patients received standard background therapy of either: (a) rituximab for 4 weeks; or (b) cyclophosphamide for 13 weeks followed by azathioprine/mycophenolate, evenly balanced between the avacopan and prednisone groups.

The ADVOCATE trial met both of its primary endpoints, demonstrating disease remission at 26 weeks and sustained remission at 52 weeks, as assessed by the Birmingham Vasculitis Activity Score (BVAS). Specifically, BVAS remission at week 26 was achieved in 72.3% of the avacopan treated patients vs. 70.1% of subjects in the prednisone group ($p<0.0001$ for non-inferiority). Sustained remission at 52 weeks was observed in 65.7% of the avacopan treated subjects vs. 54.9% in the prednisone group, achieving both non-inferiority and superiority to the prednisone group ($p=0.007$ for superiority of avacopan).

Additionally, results published in the NEJM also show that, compared to the prednisone group, avacopan treatment:

- Reduced the risk of vasculitis relapse by 54%; there was a 10.1% relapse rate in the avacopan group compared to 21.0% in the prednisone group.
- Demonstrated greater improvement in kidney function, with a mean increase from baseline to week 52 in eGFR of 7.3 mL/min/1.73 m^2 with avacopan therapy vs. an increase in eGFR of 4.1 mL/min/1.73 m^2 in the prednisone group, and the difference between groups was 3.2 mL/min/1.73 m^2 (95% CI, 0.3 to 6.1).
- Significantly lowered glucocorticoid toxicity, with avacopan therapy 39.7 vs. 56.6 in the prednisone group in the Glucocorticoid Toxicity Index, or GTI, Cumulative Worsening Score with a difference between groups of −16.8 points (95% CI, −25.6 to −8.0), and 11.2 with avacopan therapy vs. 23.4 for the prednisone group in the GTI Aggregate Improvement Score, with a difference between groups of −12.1 points (95% CI, −21.1 to −3.2).
- Led to greater improvement in health-related quality of life, measured by the Short Form 36 version 2 and the EuroQOL-5D-5L instrument (both Visual Analogue Scale and EQ Index), compared to the prednisone group.

Avacopan demonstrated favorable safety results in this serious and life-threatening disease, with fewer subjects having serious adverse events in the avacopan group than in the prednisone group.

Avacopan Regulatory Matters in ANCA Vasculitis

Based on the success of the avacopan clinical studies in ANCA vasculitis, we filed an NDA with the FDA in July 2020, which is currently under review by the FDA. The FDA has set July 7, 2021 as the PDUFA target goal date for the avacopan NDA. In November 2020, Vifor announced that the MAA for avacopan in the treatment of ANCA vasculitis was accepted for review (validated) by the EMA, for which a decision is expected in the second half of 2021. In February 2021, Vifor and Kissei filed the JNDA for avacopan in the treatment of ANCA vasculitis with the PMDA. We are supporting Vifor and Kissei with their applications for regulatory approval internationally.

Avacopan has been granted orphan drug designation by the FDA for the treatment of ANCA-associated vasculitides (granulomatosis with polyangiitis or Wegener's granulomatosis), microscopic polyangiitis, and Churg-Strauss syndrome, and by the EMA for treatment of microscopic polyangiitis and granulomatosis with polyangiitis, both forms of ANCA vasculitis.

Complement 3 Glomerulopathy (C3G)

C3G disease is an ultra-rare disease of the kidney that is characterized by deposition of the complement fragment known as C3 in the glomeruli, or filtration units of the kidney, leading to inflammatory cell accumulation, potentially leading to significant kidney damage and eventual renal failure. The incidence rate of C3G is estimated

at two to three per million people in the United States. The prevalence of C3G is estimated at approximately 1,000 to 3,800 patients in the United States and approximately 2,000 in Europe.

There is currently no approved effective standard therapy for C3G. Typically, patients receive one or more non-specific immunosuppressants. Without treatment, C3G may lead to kidney failure, and the current array of unapproved therapies at best only delays end stage renal disease, or ESRD. Kidney transplant is frequently the only option, and even after transplantation, the disease returns in a significant number of affected individuals.

Role of C5a and C5aR in C3G

While the disease name refers to complement 3, it is well known that the C5a receptor pathway, which is further downstream of C3 in the complement cascade and the target of avacopan, is an essential part of the disease causing pathology. Hence, C3 is a marker of more general complement activation.

Avacopan Phase II Clinical Trial in C3G

In December 2020, we reported topline clinical data from our Phase II clinical trial of avacopan for the treatment of patients with C3G, known as the ACCOLADE trial. The ACCOLADE trial is the largest, randomized, blinded, placebo-controlled trial in C3G to date, having enrolled 57 patients with C3G, including both C3 Glomerulonephritis and Dense Deposit Disease. Patients received avacopan 30 mg or matching placebo orally twice-daily. The placebo-controlled treatment period was 26 weeks (182 days). This will be followed by a 26 week study period during which time all patients will receive avacopan 30 mg orally twice-daily. Thereafter, all patients will be followed for eight weeks (56 days) without study drug treatment.

The primary efficacy endpoint of the study was change from baseline to week 26 in the C3G Histologic Index for Disease Activity, comparing the changes in kidney histology from biopsy sections taken from patients characterized by elevated levels of C5b-9 complement markers in the blood at time of study entry (baseline). Biopsies, taken at baseline and after 26 weeks of treatment showed that the placebo group worsened by 38% on average in the C3G Activity Score while the avacopan group improved by 2% on average. This approximately 40% average difference between the two treatment arms did not constitute statistical significance due to the high patient to patient variability and small sample size. Comparison of the C3G Activity Score of all C3G subjects (comprising those with both elevated levels of C5b-9 as well as those with normal levels of C5b-9) yielded similar results: the placebo group worsened by 26% on average in the C3G Activity Score, while avacopan therapy resulted in an improvement of 6% on average.

Importantly, those patients who received avacopan experienced significant benefits in terms of kidney function and other parameters compared to those who received placebo. These benefits, assessed as pre-specified secondary endpoints, include:

1. Slowing of Fibrosis Progression

Avacopan therapy demonstrated evidence for a significant slowing of the progression of fibrosis as assessed by the C3G Histologic Index for Disease Chronicity. The placebo group overall exhibited a 26 percentage point higher change from baseline to Week 26 in the C3G Index for Disease Chronicity than avacopan (58% versus 32%, respectively) representing a worsening in disease chronicity. The mean change from baseline to week 26 was 1.6 for placebo versus 0.8 for avacopan ($P<0.05$) in all C3G subjects. This result is notable because published literature shows that each 1-unit increase in C3G Histologic Index for Disease Chronicity from baseline increases by 59% ($P < 0.001$) the risk of doubling of creatinine, progression to chronic kidney disease stage 5, ESRD requiring dialysis or transplantation, or death.

2. Improvement in Kidney Function

The avacopan group demonstrated a statistically significant improvement in eGFR from baseline to week 26. Overall, the eGFR in the avacopan group improved 5% on average from baseline while the placebo group worsened by 6% ($P = 0.0221$) in all C3G subjects. Renal improvement was particularly pronounced for C3G subjects with eGFR of < 60 mL/min/1.73 m^2 at baseline, as their eGFR on average increased relative to placebo by nearly 20% after 26 weeks (13% improvement for avacopan versus 6% worsening from baseline for placebo, $P = 0.0199$). This was equivalent to a mean increase of about 5 mL/min/1.73 m^2 on avacopan versus a decrease of 1.4 mL/min/1.73 m^2 in the placebo group. Significant improvement in eGFR in a blinded comparative setting over 26

weeks has not been noted in C3G studies prior to this, but the improvement in eGFR with avacopan is reminiscent of a similar improvement seen with avacopan therapy in ANCA–associated vasculitis with renal dysfunction.

Other measures of kidney function include UPCR (proteinuria), where high UPCR is known to be associated with higher risk of ESRD in C3G as well as other renal diseases, and urinary MCP-1 creatinine ratio, a marker of glomerular inflammation.

In the ACCOLADE study, avacopan therapy was associated with a rapid reduction in UPCR (proteinuria). From baseline, a progressive proteinuria drop was seen in the avacopan group: at week 16 there was a 35% mean decrease in UPCR with avacopan versus a 1% decrease in the placebo group ($P < 0.05$), and at the end of 26 weeks UPCR was reduced by 26% in the avacopan group versus 14% in the placebo group.

Similar reductions were seen in urinary MCP-1 creatinine ratio in the avacopan group versus the placebo group throughout the 26-week treatment period, with the avacopan group consistently exhibiting lower levels of the kidney inflammation marker being shed in the urine. Avacopan also appeared safe and well-tolerated in patients with C3G.

In the ongoing phase of the study (after the 26 week blinded treatment period), all patients receive avacopan as part of an open label extension for a further 26 weeks, and are followed for an additional 8 weeks without study treatment. Data from the open label and follow up period will be analyzed and is expected to be presented during the second half of 2021.

Based on the data described above, reflecting results of a blinded therapy regimen which resulted in evidence of avacopan's ability to improve renal function, being well-tolerated in C3G patients to date, and the significant unmet medical need for C3G patients for whom there are no approved therapies to treat renal function decline, we plan to complete an in-depth review of the study data to confirm our findings, and then discuss the evidence of clinical benefit of avacopan in C3G with the FDA in 2021.

Hidradenitis Suppurativa (HS)

HS is a chronic, inflammatory, debilitating skin disease characterized by recurrent, painful, nodules and abscesses, ultimately leading to the formation of draining fistulas (also known as sinus tracts) as well as scarring. The disease originates from inflammation and occlusion of the hair follicle. Apart from pain, the nodules may rupture, and often extrude a purulent, foul-smelling discharge leading to substantial social embarrassment for these patients. Due to its chronic nature and frequently occurring relapses of the skin lesions, HS has a great impact on the patient's quality of life, deeply affecting social, working, and psychological aspects.

In the United States, the estimated prevalence of HS is 0.1%, of which we estimate 15% are severe (Hurley Stage III) patients (up to approximately 50,000 patients). In Europe, the number of affected patients is believed to be greater, with higher prevalence.

Depending on the severity of disease, the current SOC for HS patients includes topical, oral or intravenous antibiotic treatment, as well as surgery. Adalimumab, an anti-TNF-alpha monoclonal antibody, is the only drug indicated for the treatment of patients with moderate-to-severe HS. Two pivotal adalimumab trials showed that approximately 50% of the patients who were treated with adalimumab achieved an improvement in their skin lesion, as measured by the widely accepted Hidradenitis Suppurativa Clinical Response, or HiSCR, assessment instrument. There remains a high unmet medical need, however, as a very large proportion of the patients with moderate-to-severe HS do not adequately respond to adalimumab or other therapies used in the SOC.

Role of C5a and C5aR in HS

Neutrophils are believed to play an important disease-promoting role, as well as certain cytokines and mediators commonly found in autoimmune diseases, such as TNF-alpha, IL-17, IL-1 and others such as C5a. C5a promotes inflammatory mediators and is a strong activator of neutrophils. HS is a neutrophil-driven skin disease and C5a has been found activated and significantly elevated in plasma of HS patients, as compared to healthy controls.

With the role of C5a in HS, our C5aR inhibitor avacopan could be effective in mediating the disease course of HS. Avacopan is a small molecule that is conveniently administered as an oral medication and could present itself as advantageous over intravenous or subcutaneous injections treatments for this condition.

Avacopan Phase IIb Clinical Trial in HS

In November 2020, we reported positive topline clinical data in Hurley Stage III patients from our Phase II trial of avacopan for the treatment of patients with HS, known as the AURORA trial. The AURORA trial is a randomized, double-blind, placebo-controlled, three arm Phase IIb trial in 398 subjects with moderate HS (Hurley Stage II) or severe HS (Hurley Stage III), which were stratified evenly across the three treatment arms. Subjects were randomized 1:1:1 to a treatment of 10 mg avacopan twice-daily, 30 mg avacopan twice-daily or placebo for 12 weeks. Subjects treated with 10 mg or 30 mg twice-daily during the blinded, placebo-controlled 12-week treatment period will be followed for an additional 24-week, active treatment period during which they will continue to receive the same dose regimen, either 10 mg or 30 mg avacopan twice-daily. Subjects on placebo who complete the blinded, placebo-controlled 12-week period will be re-randomized 1:1 to receive 10 mg or 30 mg avacopan twice-daily during the 24-week active treatment period. Thereafter, subjects will be followed without study drug for eight weeks before they exit the study.

The primary endpoint of HiSCR was assessed for 10 mg twice daily, or BID, and 30 mg BID dosing regimens of avacopan against placebo after 12 weeks of treatment. In the combined study population of both moderate HS plus severe HS, no statistical significant difference was achieved at either dose level compared to placebo, although a numerical improvement was noted at the 30mg BID dose. Importantly, avacopan 30mg BID demonstrated a statistically significant higher response than placebo in Hurley Stage III HS patients.

An effect with avacopan was noted in Hurley Stage III patients across other secondary endpoint assessed to date. Numerically favorable reductions for avacopan were observed in International HS Severity Score, as well as reduction in abscesses and inflammatory nodules, draining fistula, and abscess count at week 12 (all % change from baseline to week 12), relative to placebo.

Avacopan demonstrated a favorable safety profile. Treatment emergent adverse events, or TEAEs, of all types by week 12 were observed to be fewer in the avacopan groups (48.5%) than with placebo (55%). The majority of TEAEs were related to underlying HS and were mild to moderate. Serious TEAEs were observed in 2.3% of placebo patients vs. 1.5% on avacopan.

We expect to report topline data from the completed AURORA trial (following the 24-weeks of treatment period and further eight week period without study drug) in 2021.

Based on the results of the AURORA trial to date, we plan to advance avacopan into Phase III development for the treatment of severe HS.

Avacopan Commercialization Strategy

We are currently building a commercial infrastructure in the United States to commercialize avacopan in ANCA vasculitis. If approved, we plan to initially focus on key prescribers in the rheumatology and nephrology area who primarily treat this disease. In anticipation of our potential approval, we have hired our commercial leadership team and are now focused on building a specialty field force of approximately 75 professionals.

In territories outside of the United States, our partner Vifor would be responsible for the commercialization of avacopan.

Kidney Health Alliance with Vifor

In May 2016, we entered into a collaboration and license agreement with Vifor, which we refer to as the Avacopan Agreement, to commercialize avacopan for orphan renal diseases in Europe and certain other markets. In connection with the Avacopan Agreement, we received a non-refundable upfront payment of $85.0 million, comprising $60.0 million in cash and $25.0 million in the form of an equity investment to purchase 3,333,333 shares of our common stock at a price of $7.50 per share. In February 2017, we and Vifor entered into the Avacopan Amendment to expand the licensed territory to include all markets outside the United States and China and we received an additional $20.0 million upfront cash commitment. Upon achievement of certain regulatory and sales based milestones with avacopan, we will receive additional payments under this agreement. In addition, we will receive royalties, with rates ranging from the teens to mid-twenties, on future potential net sales of avacopan by

Vifor in the licensed territories. In December 2017, we achieved the first regulatory milestone under the Avacopan Agreement in the amount of $50.0 million, following the EMA's validation of the conditional marketing authorization, or CMA, application for avacopan for the treatment of patients with ANCA vasculitis. In June 2018, we and Vifor entered into the Avacopan Letter Agreement to further expand the Vifor territories under the Avacopan Agreement to provide Vifor with exclusive commercialization rights in China and we received a $5.0 million payment for the expanded rights. We retain control of ongoing and future development of avacopan (other than country-specific development in the licensed territories) and all commercialization rights to avacopan in the United States. In October 2020, we entered into a manufacturing and supply agreement with Vifor. Under this agreement, we will supply avacopan bulk drug product to Vifor for Vifor's commercial use outside of the United States.

Under a prior development and commercialization agreement with Glaxo Group Limited, or GSK, an affiliate of GlaxoSmithKline, which ended in 2013, we are subject to reverse royalties to GSK of 3% on annual worldwide net sales of avacopan, not to exceed $50.0 million in total royalties.

In December 2016, we entered into a second collaboration and license agreement with Vifor, which we refer to as the CCX140 Agreement, pursuant to which we granted Vifor exclusive rights to commercialize CCX140, an inhibitor of the C-C chemokine receptor known as CCR2, in rare renal diseases in markets outside the United States and China. We are responsible for the clinical development of CCX140 in rare renal diseases, while sharing the cost of such development with Vifor. In connection with the CCX140 Agreement, we received a non-refundable upfront commitment totaling $50.0 million and are eligible to receive additional payments upon the achievement of certain regulatory and sales based milestones, as well as tiered double-digit royalties on potential net sales of CCX140 in the licensed territories. Under the CCX140 Agreement, Vifor retains an option to solely develop and commercialize CCX140 in more prevalent forms of chronic kidney disease, or CKD. In June 2018, we and Vifor entered into the CCX140 Letter Agreement to further expand the Vifor territories under the CCX140 Agreement to provide Vifor with exclusive commercialization rights in China and we received a non-refundable $5.0 million payment for the expanded rights. Additionally, in June 2018, we and Vifor entered into an amendment to the CCX140 Agreement, which we refer to as the CCX140 Amendment, to clarify the timing of certain payments with respect to development funding of the CCX140 program by Vifor, and we received a non-refundable payment of $11.5 million. We retain control of ongoing and future development of CCX140 (other than country-specific development in the licensed territories) and all commercialization rights to CCX140 in the United States.

In May 2020, we announced that the results of Phase II clinical trial known as LUMINA-1 of CCX140 for the treatment of primary Focal Segmental Glomerulosclerosis, or FSGS. In the trial, CCX140 did not demonstrate a meaningful reduction in proteinuria relative to the control group after 12 weeks of blinded treatment. As such, CCX140 will not be further developed in FSGS. Should Vifor later exercise the CKD option, we would receive co-promotion rights in CKD in the United States.

Early Stage Drug Candidates

Immuno-Oncology

Anti-PD-1 and anti-PD-L1 monoclonal antibody therapies have emerged as front-line treatment for several cancers. In such cancers, the interaction of PD-L1 on cancer cells with PD-1 on T cells prevents the T cells from attacking the cancer cells. Accordingly, blocking the interaction of PD-L1 with PD-1 can prevent cancer cells from evading the immune system. We have further optimized our unique class of human PD-L1 small molecule inhibitors. Our lead drug candidate, CCX559, possesses high oral bioavailability and has exhibited a desirable safety profile. CCX559 also exhibited activity in blocking the PD-1/PD-L1 interaction in multiple biochemical and cell-based assays. Non-clinical data suggest that CCX559 prevented the PD-1/PD-L1 interaction by inducing dimerization of the PD-L1 protein. In animal tumor models, CCX559 potently inhibited tumor growth with the activity being similar to a clinically-proven anti-human PD-L1 antibody. We believe CCX559 could provide a valuable orally dosed alternative to the current antibody-based PD-1/PD-L1 therapeutics. We plan to advance CCX559 into a Phase I clinical trial in the first half of 2021.

Other Inflammatory and Autoimmune Diseases

Inflammatory Bowel Disease, or IBD, (Crohn's Disease and Ulcerative Colitis) and CCR9

IBD refers to two diseases – Crohn's disease and ulcerative colitis – both characterized by inflammation of the gastrointestinal tract. Crohn's disease can cause inflammation in any part of the digestive tract but often affects the

tail end of the small intestine. Ulcerative colitis is inflammation of the large intestine. Both Crohn's disease and ulcerative colitis are chronic and recurring inflammatory conditions. Researchers believe that these conditions occur when the body's inflammatory cells become over-reactive and mount a destructive inflammatory response. Current treatments for IBD include steroids, 5-aminosalicylic acids, immunosuppressive therapies, such as azathioprine or biologic agents such as TNF-α inhibitors and integrin inhibitors, such as the anti-α4β7 antibody, vedolizumab, and when all else fails, surgery.

CCX507 is our second generation, orally-administered inhibitor of the chemokine receptor known as CCR9 for the treatment of IBD. CCX507 builds on our expertise in the area of CCR9 inhibitors and IBD. CCX507 is selective for CCR9 relative to all other chemokine receptors, orally bioavailable, and has an excellent preclinical safety profile. CCX507 has shown greater potency towards CCR9 than vercirnon, our first generation CCR9 inhibitor, in non-clinical studies. We completed Phase I clinical development, which identified an oral dose regimen of CCX507 that was safe and well-tolerated, and effectively blocked CCR9 on circulating leukocytes. Additionally, preclinical data of CCX507 in combination with an anti-α4β7 antibody or anti-TNFα antibody showed that combined treatment reduced the severity of colitis better than monotherapy with either drug alone. We plan to move CCX507 forward to Phase II clinical trials, either by ourselves or with a strategic partner.

Th17 Driven Diseases and CCR6

One of the most intriguing areas of current research in immunology involves a relatively recently discovered type of helper T cells known as Th17 cells. There is a large amount of preclinical and clinical data that implicate Th17 cells, as well as Interleukin 17, or IL-17, in the development of a large number of autoimmune diseases, including psoriasis, rheumatoid arthritis, asthma, and multiple sclerosis.

Activated Th17 cells isolated from chronically inflamed human tissues produce high levels of TNF-α and other cytokines. A hallmark of Th17 cells is that they express high levels of the chemokine receptor known as CCR6, which is not found on Th1 and Th2 cells. High levels of the CCR6 chemokine ligand, CCL20, have been found in psoriatic skin, in rheumatoid arthritis joint biopsies, and in asthmatic lungs.

We believe that these are potential therapeutic opportunities for a CCR6 inhibitor. We have produced several unique CCR6 inhibitor leads, which are now being optimized through medicinal chemistry approaches and undergoing further evaluation in preclinical pharmacology models.

We have shown in preclinical models that an orally bioavailable, small molecule inhibitor of the chemokine receptor known as CCR6 confers protection against IL17-mediated inflammation. We have generated potent orally bioavailable CCR6 inhibitors that inhibit CCL20-mediated chemotaxis of both human and mouse CCR6-positive cells. The utility of CCR6 inhibition was tested in preclinical models of psoriasis, and demonstrated that animals treated with our CCR6 inhibitor were protected against imiquimod induced skin thickening. Histological analysis of the skin confirmed the protective effect of our CCR6 inhibitor compared to an aqueous vehicle control and significantly reduced ear-thickening induced by intradermal injections of Interleukin 23, or IL-23, a cytokine that is important for the terminal differentiation and pathogenicity of Th17 cells.

The mechanism of action for CCR6 inhibitors is different from other therapeutics targeting IL-17, because inhibition of CCR6 disrupts the recruitment of infiltrating leukocytes into the epidermis upon skin damage, thereby protecting against epidermal hyperplasia, or an abnormal increase in the number of cells on the skin. Thus, pharmacological inhibition of CCR6 with an orally bioavailable small molecule inhibitor mitigates IL-17-driven inflammation in psoriasis models, and its distinct mechanism of action suggests it may offer additional efficacy when added to current SOC.

We presented data from in vivo models of psoriasis with a selective orally-administered CCR6 inhibitor. Genetically modified mice demonstrate that psoriatic lesions do not progress in mice lacking chemokine receptor CCR6. CCL20, the only known chemokine ligand for CCR6, is highly expressed in psoriatic plaques. Our potent, orally bioavailable small-molecule inhibitor of CCR6 ameliorated skin inflammation in the IL-23 and imiquimod induced models of psoriasis, and in the IL-36 induced model representative of rare form of psoriasis referred to as generalized pustular psoriasis. CCR6 antagonists present a novel therapeutic approach to treating multiple forms of psoriasis.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, novel biological discoveries, screening and drug development technology and other know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary

rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position.

As for the pharmaceutical products we develop and commercialize, as a normal course of business, we intend to pursue composition-of-matter patents, where possible, manufacturing, salts and polymorphs, dosage, combinations and formulation patents, as well as method of use patents on novel indications for known compounds. We also seek patent protection with respect to novel biological discoveries, including new targets and applications as well as adjuvant and vaccine candidates. We have also pursued patents with respect to our proprietary screening and drug development processes and technology. We have sought patent protection, either alone or jointly with our collaborators, as our collaboration agreements may dictate.

As of December 31, 2020, our patent estate, on a worldwide basis, included approximately 953 issued or allowed patents and approximately 525 pending patent applications. This includes approximately 144 issued or allowed patents and 86 patent applications pending for avacopan, 51 issued or allowed patents and 24 patent applications pending for CCX507, our lead drug candidate in the CCR9 program, 4 issued or allowed patents and 53 pending patent applications in our PD-1/PD-L1 program, and 29 issued or allowed patents and 31 patent applications pending for our CCR6 program.

Avacopan, our lead drug candidate in the C5aR program, is covered by an issued patent in the United States covering the composition-of-matter of avacopan and pharmaceutical compositions thereof, which will expire in 2031 (not including patent term extension that may be available to extend the term of the patent). Avacopan is also covered by an additional issued patent covering the composition-of-matter of avacopan in the United States with an expiration date of 2029. Corresponding patents covering the composition of matter of avacopan have issued in 51 foreign countries, with an expiration date of 2029 (not including a supplementary protection certificate or other patent extension opportunities that may be available to extend the term of the patent), and are pending in seven other foreign countries. We have issued patents in the United States and 24 other countries covering certain synthetic methods related to making avacopan, which are anticipated to expire in 2035 (not including any possible patent term extension). Corresponding patent applications covering certain synthetic methods related to making avacopan are pending in 13 jurisdictions that, if issued, are anticipated to expire in 2035. More recent patent application filings in the avacopan family are directed towards specific therapeutic indications, formulations, and certain solid forms, which, if issued, are anticipated to expire between 2037 and 2041.

CCX507, our lead drug candidate in the CCR9 program, is covered by two issued patents in the United States covering the composition-of-matter of CCX507 that will each expire in 2033 (not including patent term extension that may be available to extend the term of the patent). Corresponding patent applications have been filed in foreign jurisdictions and are at various stages of prosecutions or have issued. We also have a granted United States patent covering certain methods of use of CCX507, which will expire in 2035 (not including patent term extension that may be available to extend the term of the patent), with corresponding patent applications pending in foreign countries. Nonetheless, the actual protection afforded by a patent varies on a product by product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with our commercial partners and selected consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future drugs may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the U.S. Patent and Trademark Office, or USPTO, to determine priority of invention.

Competition

We compete in the pharmaceutical, biotechnology and other related markets that address ANCA vasculitis, HS, C3G, LN and other renal diseases, IBD, rheumatoid arthritis, psoriasis, other autoimmune diseases and inflammatory disorders, and cancer. We face significant competition from many pharmaceutical and biotechnology companies that are also researching and selling products designed to address these markets. Many of our competitors have materially greater financial, manufacturing, marketing, research, and drug development resources than we do. Large pharmaceutical companies in particular have extensive expertise in preclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors.

It is possible that our competitors will develop and market drugs that are less expensive and more effective than our drug candidates, or that will render our drug candidates obsolete. It is also possible that our competitors will commercialize competing drugs before we or our partners can launch any drugs developed from our drug candidates.

Avacopan, our C5aR inhibitor, if approved for marketing by the FDA or other regulatory agencies for the treatment of ANCA vasculitis, might compete with current treatments, such as prednisone, CYC, RTX, azathioprine, methotrexate, and mycophenolate mofetil. If avacopan is approved for marketing by the FDA or other regulatory agencies for the treatment of C3G, avacopan might compete with treatments that are in development. If avacopan were approved for the treatment of HS, it would potentially compete with adalimumab (Humira®) or other anti-TNF-alpha antibodies which physician sometimes prescribe off-label for the treatment of HS.

Many of these currently approved treatments have notable and common adverse events including liver and bone marrow toxicity, renal toxicity, pneumonitis, immunosuppression, allergic reactions, autoimmune diseases and infections.

We expect that competition among any of our drugs approved for sale will be based on various factors, including drug safety and efficacy, prevalence of negative side effects, reliability, ease of administration, availability, approved labeling, price, insurance coverage and reimbursement status and patent position. We believe that our ability to compete depends largely upon our ability to research, develop and commercialize our existing and future drug candidates. Further, we need to continue to attract and retain qualified personnel, obtain patent protection, develop proprietary technology or processes and secure sufficient capital resources for the substantial time period between technological conception and commercial sales of drugs. Our ability to compete will also be affected by the speed at which we are able to identify and develop, conduct clinical testing and obtain regulatory approvals of our drug candidates. Potential competitors may develop treatments that are more effective and/or safer than our drug candidates or that would make our technology and drug candidates obsolete or non-competitive.

Established pharmaceutical companies that currently sell or are developing drugs in our markets of interest include, but are not limited to, AbbVie, Alexion, Amgen, AstraZeneca, Aurinia, Bayer, Biogen, Elan, GlaxoSmithKline, Johnson & Johnson, Mallinckrodt, Merck, Merck Serono, Novartis, Pfizer, Travere, Roche/Genentech, Sanofi, Sarfez, Takeda and Teva. In addition, in some instances we may face competition from companies that sell generic versions of approved drugs that are part of the current SOC. Many or all of these established competitors are also involved in research and drug development regarding various chemokine receptors. Pharmaceutical and biotechnology companies which are known to be involved in chemokine and chemoattractant research and related drug development include, but are not limited to, Pfizer, GlaxoSmithKline, Bristol-Myers Squibb, Merck, Takeda, Sanofi, Incyte, Alexion, Allergan, Appellis, Omeros, InflaRx, X4 Pharmaceuticals, Mitsubishi Tanabe, Biolinerx, Akari Therapeutics and UCB Pharma, among others. These companies and others also compete with us in recruiting and retaining qualified scientific and management personnel, and in acquiring technologies complementary to, or necessary for, our programs.

Manufacturing

Avacopan, as well as our other drug candidates, are manufactured using commonly used chemical synthetic and engineering processes using readily available or made to order raw materials. We rely on contract manufacturing organizations, or CMOs, for all of our requirements of raw materials, drug substance and drug product for our commercial, clinical and nonclinical activities for our portfolio, and we have entered into commercial manufacturing agreements with some of our CMOs to support avacopan commercialization. We expect to continue to rely on contract manufacturers for the manufacture of clinical and commercial supplies of our compounds.

We are commercializing an oral capsule formulation of avacopan. We currently rely on single source suppliers, including for avacopan active pharmaceutical ingredient, or API, which is manufactured by Hovione LLC, and for avacopan drug product, which is manufactured by Patheon Pharmaceuticals Inc. To decrease the risk of an interruption to our drug supply, we intend to maintain a safety stock of certain materials to help avoid delays in production, but we do not know whether such stock will be sufficient. In addition, while we currently have only one commercial manufacturer for avacopan API and drug product, we have identified potential second sources and are working to establish additional sources of commercial supply. There is no guarantee as to if or when we may establish such additional sources or whether they will be adequate in all circumstances we may encounter.

For clinical supply, we purchase quantities of our drug candidates from our contract manufacturers pursuant to purchase orders that we place with them. If we were unable to obtain sufficient quantities of drug supply or receive raw materials in a timely manner, or secure the manufacturing and release of drug product by the contract manufacturer, we could be required to delay our ongoing clinical trials as we seek, engage and enable alternative manufacturers, which would be costly and time-consuming.

Government Regulation

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, export and import of our drug candidates.

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act and the FDA's implementing regulations. If we fail to comply with applicable FDA or other requirements at any time during the drug development process, clinical testing, the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on us. The process required by the FDA before our drug candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies all performed in accordance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug, or IND, application which must become effective before human clinical trials in the United States may begin;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice requirements, or GCP, to establish the safety and efficacy of the drug candidate for each proposed indication;
- submission to the FDA of a new drug application, or NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices, or cGMP, regulations, and of selected clinical investigation sites to assess compliance with GCP; and
- FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our drug candidates will be granted on a timely basis, if at all.

Once a pharmaceutical drug candidate is identified for development, it enters the preclinical testing stage. Preclinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may result in the FDA not allowing the clinical trials to commence or not allowing the clinical trials to commence on the terms originally specified in the IND. A separate submission to an

existing IND must also be made for each successive clinical trial conducted during drug development, and the FDA must grant permission, either explicitly or implicitly by not objecting, before each clinical trial can begin.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be used. Each protocol must be submitted to the FDA as part of the IND. An independent institutional review board, or IRB, for each medical center proposing to conduct a clinical trial must also review and approve a plan for any clinical trial before it can begin at that center and the IRB must monitor the clinical trial until it is completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP requirements, including the requirements for informed consent.

All clinical research performed in the United States in support of an NDA must be authorized in advance by the FDA under the IND regulations and procedures described above. However, a sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA so long as the clinical trial is conducted in accordance with GCP, and so long as the FDA is able to validate the data from the study through an onsite inspection if necessary. We have open INDs in the United States for avacopan, CCX140, and CCX872. All of our clinical trials are designed to comply with FDA regulatory requirements so that the data from all trials can be used to support a regulatory filing in the United States. Other planned studies with avacopan and CCX507 will likely include the United States and Europe, and potentially other geographies.

Clinical Trials

For purposes of NDA submission and approval, clinical trials are typically conducted in three sequential phases, which may overlap or be combined.

- Phase I clinical trials are initially conducted in a limited population of subjects to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients with severe problems or life-threatening diseases to gain an early indication of its effectiveness.
- Phase II clinical trials are generally conducted in a limited patient population to:
  - evaluate dosage tolerance and appropriate dosage;
  - identify possible adverse effects and safety risks; and
  - evaluate preliminarily the efficacy of the drug for specific targeted indications in patients with the disease or condition under study.
- Phase III clinical trials, commonly referred to as pivotal studies, are typically conducted when Phase II clinical trials demonstrate that a dose range of the drug candidate is effective and has an acceptable safety profile. Phase III clinical trials are generally undertaken with large numbers of patients, such as groups of several hundred to several thousand, to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically-dispersed clinical trial sites. An exception might be drugs developed for an orphan indication, where smaller clinical trials might be acceptable to the FDA and the EMA.

In some cases, the FDA may condition approval of an NDA on the sponsor’s agreement to conduct additional clinical trials to further assess the drug’s safety and effectiveness after NDA approval. Such post-approval clinical trials are typically referred to as Phase IV clinical trials.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

New Drug Applications

The results of preclinical studies and of the clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. The FDA reviews an NDA to determine, among other things, whether a drug is safe and effective for its intended use. Under the PDUFA guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The FDA may deny approval of an NDA if the applicable statutory and regulatory criteria are not satisfied, or it may require additional clinical data or an additional Phase III clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret data. Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase IV clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a risk evaluation and mitigation strategy, or REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Once the FDA approves an NDA, or supplement thereto, the FDA may withdraw the approval if ongoing regulatory requirements are not met or if safety problems are identified after the drug reaches the market. Where a withdrawal may not be appropriate, the FDA still may seize existing inventory of such drug or request a recall of any drug already on the market. In addition, the FDA may require testing, including Phase IV clinical trials and surveillance programs to monitor the effect of approved drugs which have been commercialized. The FDA has the authority to prevent or limit further marketing of a drug based on the results of these post-marketing programs.

Expedited Development and Review Programs

A sponsor may also seek approval of its drug candidates under programs designed to accelerate the FDA's review and approval of NDAs. For instance, a sponsor may seek FDA designation of a drug candidate as a "fast track product." Fast track products are those products intended for the treatment of a serious or life-threatening disease or condition and which demonstrate the potential to address unmet medical needs for such disease or condition. If fast track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for submission to the FDA of the remaining information. In some cases, products studied for their safety and

effectiveness in treating serious or life-threatening illnesses and that are shown to provide a meaningful therapeutic benefit over existing treatments may be approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Approvals of this kind, referred to as accelerated approvals, typically include requirements for appropriate post-approval Phase IV clinical trials to validate the surrogate endpoint or otherwise confirm the effect of the clinical endpoint.

In addition, the Food and Drug Administration Safety and Innovation Act, or FDASIA, which was enacted and signed into law in 2012, established a category of drugs referred to as "breakthrough therapies." A sponsor may seek FDA designation of a drug candidate as a "breakthrough therapy" if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation provides all of the benefits of fast track designation, but provides for more intensive FDA guidance on efficient drug development.

Drug candidates designed to prevent, diagnose, or treat serious diseases or conditions may also be eligible for "priority review," or review within a six-month timeframe from the date an NDA for a new molecular entity is accepted for filing, if a sponsor shows that its drug candidate, if approved, would provide a significant improvement in safety or effectiveness over existing therapies.

Fast track designation, breakthrough therapy designation and priority review do not change the standards for approval, but may expedite the development or approval process. When appropriate, we intend to seek fast track designation, accelerated approval, breakthrough therapy designation and priority review, as applicable, for our drug candidates. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation

In the United States, under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition. Such diseases and conditions are those that affect fewer than 200,000 individuals in the United States, or if they affect more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug available in the United States for these types of diseases or conditions will be recovered from sales of the drug. Orphan drug designation must be requested before submitting an NDA. If the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by that agency. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but it can lead to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers.

If a drug that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the drug is entitled to orphan drug marketing exclusivity for a period of seven years. Orphan drug marketing exclusivity generally prevents the FDA from approving another application, including a full NDA, to market the same drug or biological product for the same indication for seven years, except in limited circumstances, including if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines "same drug" as a drug that contains the same active chemical entity and is intended for the same use as the drug in question. A designated orphan drug may not receive orphan drug marketing exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Orphan drug marketing exclusivity rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

The criteria for designating an orphan medicinal product in the European Union, or EU, are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (i) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (ii) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted.

The ten-year market exclusivity in the EU may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual program user fee requirements for any marketed products.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase IV clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval of a drug is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;

- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

Healthcare Reform

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively known as the Affordable Care Act, was signed into law. The Affordable Care Act substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which have impacted existing government healthcare programs and resulted in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. Additionally, the Affordable Care Act:

- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs;
- increased the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70% (in 2021) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- mandated a further shift in the burden of Medicaid payments to the states;
- created the Independent Payment Advisory Board, which, once empaneled, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs; and
- established a Center for Medicare Innovation at the Department of Health and Human Services Centers for Medicare and Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act of 2017, or the Jobs Act, was enacted, which, among other things, removed penalties for not complying with the individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in Texas ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Jobs Act. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On November 10, 2020, the U.S. Supreme Court heard oral arguments over the constitutionality of the individual mandate and whether the rest of the Affordable Care Act can be severed if the

mandate is unconstitutional. It is unclear how these decisions, subsequent appeals, if any, or other efforts to challenge, repeal or replace the Affordable Care Act will impact the law or our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2029 unless additional Congressional action is taken. In January 2013, American Taxpayer Relief Act of 2012, or the ATRA, was enacted, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently, there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. The full impact on our business of the Affordable Care Act and other new laws is uncertain. Nor is it clear whether other legislative changes will be adopted, if any, or how such changes would affect the demand for our drugs if commercialized.

Third-Party Payor Coverage and Reimbursement

Although none of our drug candidates has been commercialized for any indication, if they are approved for marketing, commercial success of our drug candidates will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state, and private levels. Government payor programs, including Medicare and Medicaid, private health care insurance companies, and managed-care plans have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or drug treatments. The U.S. Congress and state legislatures from time to time propose and adopt initiatives aimed at cost-containment. Ongoing federal and state government initiatives directed at lowering the total cost of health care will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid payment systems. Examples of how limits on drug coverage and reimbursement in the United States may cause reduced payments for drugs in the future include:

- changing Medicare reimbursement methodologies;
- fluctuating decisions on which drugs to include in formularies;
- revising drug rebate calculations under the Medicaid program; and
- reforming drug importation laws.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. In order to secure coverage, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the drug product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, drug products may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a drug product could reduce physician utilization and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage and reimbursement for the drug product, and the level of coverage and reimbursement can differ significantly from payor to payor. Even if favorable coverage and reimbursement status is attained for a drug product, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, reimbursement of drug products is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory approval for a drug product and may require conduct a clinical trial that compares the cost effectiveness of our drug products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization efforts. Third-party payors are challenging the prices charged for drug products and services, and many third-party payors limit reimbursement for newly-approved drug products. Recent budgetary pressures in many EU countries are also causing governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates. If budget pressures continue, governments may implement additional cost-containment measures. Cost-control initiatives could decrease the price we might establish for products that we may develop or sell, which would result in lower product revenues or royalties payable to us. There

can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our drug products.

While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our drug candidates and operate profitably.

Other Healthcare Laws and Regulations

We are also subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute may result in significant civil monetary penalties. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and individual imprisonment. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose significant civil fines and penalties, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or 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 in order to have committed a violation;
- the federal Physician Sunshine Act, which requires certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, or CHIP, to report annually to CMS, information related to payments and other transfers of value to physicians, which is defined broadly to include other healthcare providers and teaching hospitals, and applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are required to submit annual reports to CMS. Failure to submit required information may result in significant civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in significant civil monetary

penalties, criminal penalties and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state; and

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

International Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our future drugs. Whether or not we obtain FDA approval for a drug, we must obtain approval of a drug by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the drug in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under the European Economic Area, or EEA (which is comprised of the 28 member states of the European Union plus Norway, Iceland and Liechtenstein), regulatory systems, marketing authorizations may be submitted either under the Centralized, Mutual Recognition, Decentralized or national EEA member state procedures. The Centralized Procedure provides for the grant of a single marking authorization that is valid for all member states of the EEA. The Mutual Recognition Procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marking authorization may submit an application to the remaining Member States. Under the Decentralized Procedure, if the product has not received a marketing authorization in any EEA member state at the time of application, the applicant can file an application to various EEA member states (choosing once as the so-called reference member states) of its choice which will be reviewed and approved simultaneously by them.

In addition to regulations in Europe and the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of our future drugs.

Human Capital Management

Employees

As of December 31, 2020, we had 133 full-time employees, 44 of whom hold Ph.D.s, M.D.s or both. Of our total workforce, 83 employees are engaged in research and development, and 50 employees in general and administrative, which includes our commercialization personnel. We have no collective bargaining agreements with our employees and we have not experienced any work stoppages nor are we aware of any employment circumstances that are likely to disrupt work at any of our facilities. We believe that our relations with our employees are good.

Turnover

We continually monitor employee turnover rates as our success depends upon retaining our highly trained personnel. We believe the competitive combination of compensation and career growth have helped increase employee tenure and reduce voluntary turnover.

Diversity and Inclusion

Diversity and inclusion are priorities for us. We believe that a rich culture of inclusion and diversity enables us to create, develop and fully leverage the strengths of our workforce.

Human Resources, Hiring and Professional Development

The development, attraction and retention of employees is critical to our success. We work diligently to attract the best talent from a diverse range of sources in order to meet the current and future demands of our business. We leverage both formal and informal programs to identify, foster and retain top talent.

Business Ethics

Our Code of Business Conduct and Ethics ensures that our conduct of business is consistent with the highest standards of business ethics. Our Code of Business Conduct and Ethics serves as a critical tool to help employees recognize and report unethical conduct, while preserving our culture of excellence. Our board of directors, management and staff are provided with training regarding our Code of Business Conduct and Ethics.

Recent Developments

In December 2019, a disease caused by a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and has spread to nearly every country and region in the world, including those in which we have active clinical trial sites or contract manufacturing sites. The length of the pandemic and its related restrictions and their consequences for us remain subject to a number of risks and uncertainties. We experienced a delay in topline clinical data from our ongoing AURORA trial to the fourth quarter of 2020 due to COVID-19 impacting certain sites where the trial was being conducted. We do not currently anticipate any material delays in our preparation for commercial readiness to launch avacopan for the treatment of ANCA vasculitis, if approved, nor are we currently anticipating any material disruption in our clinical drug supply as a result of the pandemic.

About ChemoCentryx

We commenced operations in 1997. Our principal offices are located at 850 Maude Avenue, Mountain View, California 94043, and our telephone number is (650) 210-2900. Our website address is www.chemocentryx.com. The information contained in, or that can be accessed through, our website is not part of this Annual Report on Form 10-K. We have two wholly owned inactive subsidiaries, ChemoCentryx Limited, organized under the laws of the United Kingdom and ChemoCentryx Ireland Limited, organized under the laws of Ireland.

Available Information

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. We make available on our website at www.chemocentryx.com, free of charge, copies of these reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors.

The following section includes the most significant factors that may adversely affect our business and operations. You should carefully consider the risks and uncertainties described below and all information contained in this Annual Report on Form 10-K before deciding to invest in our common stock. If any of the following risks actually occur, our business, financial condition, results of operations and growth prospects would likely be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose all or part of your investment.

Summary of Risk Factors

An investment in us is subject to a number of risks, including risks related to our financial position and capital requirements, risks related to the discovery, development and regulatory approval of our product candidates, risks related to our reliance on third parties, risks related to commercialization of our product candidates, risks related to our business operations and industry, risks related to intellectual property and risks related to making an investment in our securities. The following list summarizes some, but not all, of these risks. Please read the information in the following section entitled in its entirety for a more thorough description of these and other risks.

- We anticipate that we will continue to incur significant losses for the foreseeable future, and if we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.
- If we are unable to obtain regulatory approval to market avacopan or other drug products in the United States and foreign jurisdictions, we will not be permitted to commercialize such drug products.
- Even if we obtain regulatory approval for avacopan in ANCA vasculitis, or for any of our other drug candidates for other indications, we or our collaborative partners will still face extensive regulatory requirements and our drug products may face future development and regulatory difficulties.
- If any of our drug candidates receives regulatory approval and we or others later identify undesirable side effects caused by the drug candidate, our ability to market and derive revenue from the drugs could be compromised.
- Even if our drug candidates do obtain regulatory approval they may never achieve market acceptance or commercial success.
- The development of new drugs is a highly risky undertaking which involves a lengthy process, and our drug discovery and development activities therefore may not result in products that are approved for marketing and sale by the applicable regulatory authorities on the time schedule we have planned, or at all, or result in substantial payments to us.
- If we are required to suspend or discontinue clinical trials due to side effects or other safety risks, or if we are required to conduct studies on the long-term effects associated with the use of our drug candidates, our efforts to commercialize our products could be delayed or halted.
- Interim, “top-line,” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We rely on third parties to conduct all our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize any of our drug candidates.
- The terms of our credit facility place restrictions on our operating and financial flexibility.
- Any orphan drug designations we receive may not confer marketing exclusivity or other benefits.
- We rely on third party contract manufacturing organizations to manufacture and supply our drug candidates for us. If one of our suppliers or manufacturers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers or manufacturers. We may also face delays in the development and commercialization of our drug candidates.

- We face substantial competition and our competitors may discover, develop or commercialize products faster or more successfully than us.
- We may be subject to costly product liability claims related to our clinical trials and drug candidates and, if we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition.
- We are highly dependent on the services of our founder, President and Chief Executive Officer, Dr. Thomas J. Schall, and if we are not able to retain Dr. Schall or other members of our management or recruit additional management, clinical and scientific personnel, our business will suffer.
- We may be adversely affected by the economic environment.
- Our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.
- Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.
- The outbreak of the novel coronavirus disease 2019, or COVID-19, could adversely impact our business, manufacturing operations, preclinical studies and clinical trials.
- Our proprietary rights may not adequately protect our technologies and drug candidates. If we are unable to protect our drug candidates and our intellectual property rights, it may materially adversely affect our position in the market.
- Changes in patent law in the United States or in other countries could diminish the value of patents in general, thereby impairing our ability to protect our drug products and candidates.
- We may become subject to third parties' claims alleging infringement of patents and proprietary rights or seeking to invalidate our patents or proprietary rights, which would be costly, time-consuming and, if successfully asserted against us, delay or prevent the development and commercialization of our products.
- Restrictions on our patent rights relating to our drug candidates may limit our ability to prevent third parties from competing against us.
- We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.
- The regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our drug candidates.
- Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.
- The availability of adequate third-party coverage and reimbursement for newly approved drugs is uncertain, and failure to obtain adequate coverage and reimbursement from third-party payors could impede our ability to market any future products we may develop and could limit our ability to generate revenue.
- Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.
- Healthcare reform measures could hinder or prevent our drug candidates' commercial success.
- Even if we are able to commercialize one or more of our drug candidates, the drugs may become subject to unfavorable pricing regulations or third party reimbursement practices, which could harm our business.

- If we fail to comply with healthcare laws and regulations, we could face investigations, substantial civil or criminal penalties and our business, operations and financial condition could be adversely affected. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

Risks Related to Our Business

We anticipate that we will continue to incur significant losses for the foreseeable future, and if we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

We are a clinical-stage biopharmaceutical company. We do not currently have any products approved for sale, and we continue to incur significant research *and* development and general and administrative expenses related to our operations. Our net (loss) income for the years ended December 31, 2020, 2019 and 2018 was $(55.4)million, $(55.5) million and $(38.0) million, respectively. As of December 31, 2020, we had an accumulated deficit of $485.3 million. We expect to continue to incur significant losses for the foreseeable future. We expect these losses and our cash utilization to increase in the near term as we continue to conduct clinical trials for avacopan, CCX559 and CCX507 and conduct research and development of our other drug candidates. To date, we have derived all of our revenues from upfront fees and milestone payments, other payments pursuant to our collaboration agreements and government grants and contracts for research and development. For example, in May 2016 and December 2016, we entered into collaboration and license agreements with Vifor (International) Ltd. and/or its affiliates, or collectively, Vifor, for the commercialization of avacopan and CCX140, respectively. In addition, if approved, we expect to incur significant costs to commercialize our drug products and our drug products may never gain market acceptance. If our drug candidates fail to demonstrate safety and efficacy in clinical trials, do not gain regulatory approval, or do not achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or whether we will become profitable.

If we are unable to obtain regulatory approval to market avacopan or other drug products in the United States and foreign jurisdictions, we will not be permitted to commercialize such drug products.

We are seeking regulatory approval for avacopan in ANCA vasculitis pursuant to a new drug application, or NDA, that we filed with the FDA in July 2020. Before receiving regulatory approval to market a drug product, we must demonstrate with substantial clinical evidence to the satisfaction of the FDA or other regulatory authority that the drug product is safe and effective in the patient population and the indication that will be treated. Data obtained from preclinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory approvals. In addition, delays or rejections may be encountered based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, adverse publicity, as well as other regulatory action against our potential drug products or us.

If regulatory approval of a drug product is granted, such approval will be limited to those indications or disease states and conditions for which the drug product is demonstrated through clinical trials to be safe and effective. We cannot assure you that any drug product developed by us, alone or with others, will be demonstrated to be safe and efficacious in clinical trials and will meet all of the applicable regulatory requirements needed to receive regulatory approval.

Outside the United States, our ability, or that of our collaborative partners, to market a drug product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process typically includes all of the risks and costs associated with FDA approval described above and may also include additional risks and costs, such as the risk that such foreign regulatory authorities, which often have different regulatory and clinical trial requirements, interpretations and guidance from the FDA, may require additional clinical trials or results for approval of a drug candidate, any of which could result in delays, significant additional costs or failure to obtain such regulatory approval. For example, there can be no assurance that we or our collaborative partners will not have to provide additional information or analysis, or conduct additional clinical trials, before receiving approval to market drug candidates.

Even if we obtain regulatory approval for avacopan in ANCA vasculitis, or for any of our other drug candidates for other indications, we or our collaborative partners will still face extensive regulatory requirements and our drug products may face future development and regulatory difficulties.

Even if we obtain regulatory approval for avacopan or any of our other drug candidates, our products and manufacturing operations will remain subject to continual review by the FDA, the EMA and EU Member State Competent Authorities, and/or non-U.S./non-EU regulatory authorities. Any regulatory approval that we receive for our drug candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and efficacy of the product. The FDA and the EMA also have authority to require a risk evaluation and mitigation strategy, or REMS, or risk management plan, as part of an NDA, CMA, marketing authorization application, or MAA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring treated patients to enroll in a registry. In addition, if the FDA, the EMA, EU Member State Competent Authorities, and/or non-U.S./non-EU regulatory authorities approve any of our drug candidates, we will be subject to extensive and ongoing regulatory requirements by the FDA, the EMA, EU Member State Competent Authorities, and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. The FDA and the EMA, the European institutions and the EU Member State Competent Authorities, strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or the European Commission as reflected in the product's approved labeling. If we receive regulatory approval for any of our drug candidates, physicians may nevertheless prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such unapproved uses, we may become subject to significant liability and government fines.

In addition, manufacturers of drug products are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must authorize manufacturing facilities before they can be used to manufacture our drug products, and such facilities will remain subject to continual review and periodic inspections by the FDA, the EMA, EU Member State Competent Authorities, and other regulatory authorities for compliance with cGMP regulations.

If we or a regulatory authority discovers previously unknown problems with a drug product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug product is manufactured, a regulatory authority may impose restrictions on that drug product, the manufacturer or us, including imposition of a REMS, or similar risk management measures, or requesting recall or withdrawal of the drug product from the market or suspension of manufacturing. If we, our drug products or the manufacturing facilities for our drug products fail to comply with regulatory requirements of the FDA, the EMA, the EU institutions, the EU Member State Competent Authorities and/or other non-U.S./non-EU regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

- warning letters, untitled letters or other communications asserting that we are in violation of law;
- injunctions, civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approvals;
- suspension of ongoing clinical trials;

- restrictions on operations, including costly new manufacturing requirements;
- refusal to approve pending applications seeking regulatory approval for new drugs or supplements to approved applications submitted by us;
- product recalls;
- drug product detentions or seizures; or
- refusal to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may delay or inhibit our ability to successfully commercialize our products and generate revenues.

The regulatory requirements and policies may change and additional government regulations may be enacted for which we may also be required to comply. 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 will not be permitted to market our future products and our business will suffer.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States, the EU or in other countries or jurisdictions. For example, certain policies of President Biden's administration may impact our business and industry. The previous 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 how and if these changes will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

If any of our drug candidates receives regulatory approval and we or others later identify undesirable side effects caused by the drug candidate, our ability to market and derive revenue from the drugs could be compromised.

If any of our drug candidates receives regulatory approval and we or others later identify undesirable side effects caused by one of our drugs, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the drug or seize the drug;
- we may be required to recall the drug or change the way the drug is administered;
- additional restrictions may be imposed on the marketing of the particular drug or the manufacturing processes;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the drug may become less competitive; and
- our reputation may suffer.

Any of these could result in the loss of significant revenues, which would materially and adversely affect our results of operations and business.

Even if our drug candidates do obtain regulatory approval they may never achieve market acceptance or commercial success.

Even if we obtain FDA or other regulatory approvals, our drug products may not achieve market acceptance among physicians, patients and third-party payors and, ultimately, may not be commercially successful. Market acceptance of our drug candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the drug is approved;
- acceptance by physicians, major operators of clinics and patients of the drug as a safe and effective treatment;
- the potential and perceived advantages of our drug products over alternative treatments;
- the willingness of physicians and healthcare organizations to change their current treatment practices;
- the price we charge for our drug products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

Any failure by our drug candidates that obtain regulatory approval to achieve market acceptance, or our drug products, if any, to achieve commercial success, would adversely affect our financial results.

Forecasting potential sales for any of our drug candidates will be difficult, and if our projections are inaccurate, our business may be harmed and our stock price may be adversely affected.

Our business planning requires us to forecast or make assumptions regarding product demand and revenues for any of our drug candidates if they are approved, despite numerous uncertainties. These uncertainties may be increased if we rely on our collaborators or other third parties to conduct commercial activities in certain jurisdictions and provide us with accurate and timely information. Actual results may differ materially from projected results for various reasons, including the following, as well as risks identified in other risk factors:

- the efficacy and safety of our drug products, if any, including as relative to marketed products and drug candidates in development by third parties;
- pricing (including discounting and other promotions), reimbursement, product returns or recalls, competition, labeling, adverse events and other items that impact commercialization;
- the rate of adoption in the particular market, including fluctuations in demand for various reasons;
- potential market size;
- lack of patient and physician familiarity with the drug product;
- lack of patient use and physician prescribing history;
- lack of commercialization experience with the drug product; and
- uncertainty relating to when the drug may become commercially available to patients and rate of adoption.

We expect that our revenues from sales of our drug products, if any, will be based in part on estimates, judgment and accounting policies. Any incorrect estimates or disagreements with regulators or others regarding such estimates, judgment or accounting policies may result in changes to our guidance, projections or previously reported results. Expected and actual product sales and quarterly and other results may greatly fluctuate, including in the near-term, and such fluctuations can adversely affect the price of our common stock, perceptions of our ability to forecast demand and revenues, and our ability to maintain and fund our operations.

We are in the early stages of developing our commercialization infrastructure in the United States. If we are unable to develop a sales and marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our future products.

We are in the early stages of developing our commercialization infrastructure in the United States and have no history of selling, marketing or distributing therapeutic products. In order to market any products that may be approved by the FDA, EMA or other comparable regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities, or make arrangements with third parties to perform these services. We have entered into the Avacopan Agreement with Vifor for development and commercialization of avacopan outside of the United States. We retain commercialization rights to avacopan in the United States. To the extent we rely on third parties such as Vifor for marketing and distributing our approved products, any revenue we receive will depend upon the efforts of third parties, which may not be successful and are only partially within our control and our product revenue is likely to be lower than if we directly marketed or sold our products. Future collaborators may fail to develop or effectively commercialize our drug candidates because they cannot obtain necessary regulatory approvals, development or commercialization is not commercially reasonable, they elect to pursue competitive products outside of the collaboration, or for other reasons. If we are unable to enter into arrangements with third parties to commercialize any approved products on acceptable terms or at all, we may not be able to successfully commercialize our future products or we will have to market these products ourselves, which will be expensive and require us to build our own commercial infrastructure, which we do not have experience doing. We cannot assure you we will be successful in any of these initiatives. If we are not successful in commercializing our future products, either on our own or through collaborations with third parties, any future product revenue will be materially adversely affected.

The development of new drugs is a highly risky undertaking which involves a lengthy process, and our drug discovery and development activities therefore may not result in products that are approved for marketing and sale by the applicable regulatory authorities on the time schedule we have planned, or at all, or result in substantial payments to us.

Many of our drug candidates are in the early stages of drug discovery or clinical trials and are prone to the risks of failure inherent in drug development. We will need to conduct significant additional preclinical studies and clinical trials for many of our drug candidates before we can demonstrate that such drug candidates are safe and effective to the satisfaction of the FDA, the EMA and other regulatory authorities. Preclinical studies and clinical trials are expensive and uncertain processes that take years to complete. For example, we incurred significant expenses related to the IND filing and the completed single ascending dose Phase I clinical trial for CCX915, our first generation CCR2 drug candidate, which did not advance into Phase II clinical trials because its pharmacokinetic, or PK, properties in humans did not meet our expectations. Failure can occur at any stage of the process, and we cannot assure you that any of our drug candidates will demonstrate safety and efficacy in clinical trials or result in commercially successful products. While we have filed integrated regulatory submissions in 2020 with the EMA and FDA for full (unconditional) regulatory approval of avacopan for the treatment of ANCA vasculitis, we can provide no assurance that we will receive such approval.

We cannot assure you that our ongoing clinical trials or any future clinical trial of any of our other drug candidates will be completed on schedule, or at all, or whether our planned clinical trials will start in a timely manner. The commencement of our planned clinical trials could be substantially delayed or prevented by a number of factors, including:

- delays or failures in obtaining sufficient quantities of the API and/or drug product;
- delays or failures in reaching agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites;
- delays or failures in obtaining institutional review board, or IRB, or ethics committee approval to conduct a clinical trial at a prospective site;
- the need to successfully complete, on a timely basis, preclinical safety pharmacology or toxicology studies;

- the limited number of, and competition for, suitable sites to conduct the clinical trials;
- the limited number of, and competition for, suitable patients for enrollment in the clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies; or
- obtaining regulatory authorizations to commence a trial.

The completion of our clinical trials could also be substantially delayed or prevented by a number of factors, including:

- changes to clinical trial protocols;
- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trials;
- failure of our third party vendors to timely or adequately perform their contractual obligations relating to the clinical trials or in accordance with regulatory requirements;
- inability or unwillingness of patients or medical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment;
- termination of the clinical trials by one or more clinical trial sites;
- unforeseen safety issues;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- subjects choosing an alternative treatment for the indication for which we are developing our drug candidates, or participating in competing clinical trials;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- lack of efficacy demonstrated during clinical trials;
- lack of adequate funding to continue the clinical trials;
- the need for unexpected discussions with the FDA, EMA or other foreign regulatory agencies regarding the scope or design of our clinical trials or the need to conduct additional trials;
- unforeseen delays by the FDA, EMA or other foreign regulatory agencies after submission of our results;
- a facility manufacturing our drug candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down; any changes to our manufacturing process that may be necessary or desired; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs or ethics committees of the institutions in which such trials are being conducted, the Data Safety Monitoring Board, or DSMB, for such trial or the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Any failure or significant delay in completing clinical trials for our drug candidates would harm the commercial prospects for our drug candidates and adversely affect our financial results.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to regulatory agencies and ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our drug candidates may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a drug candidate.

If we are required to suspend or discontinue clinical trials due to side effects or other safety risks, or if we are required to conduct studies on the long-term effects associated with the use of our drug candidates, our efforts to commercialize our products could be delayed or halted.

Our clinical trials may be suspended or terminated at any time for a number of safety-related reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that our drug candidates present an unacceptable safety risk to the clinical trial patients. In addition, IRBs or regulatory agencies may order the temporary discontinuation or termination of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, including if they present an unacceptable safety risk to patients. Administering any drug candidate to humans may produce undesirable side effects. The existence of undesirable side effects resulting from our drug candidates could cause us or regulatory authorities, such as the FDA, to interrupt, delay or halt clinical trials of our drug candidates and could result in the FDA or other regulatory agencies denying further development or approval of our drug candidates for any or all targeted indications.

Further, chemokine receptors and chemoattractant receptors are a novel class of targets. As a result, we may experience unforeseen adverse side effects with our existing and future drug candidates for such targets, including avacopan and CCX507. As of the date of this Annual Report on Form 10-K, nine of our drug candidates have been tested in human beings. Although we have not observed material safety concerns in prior studies of our drug candidates, later trials could reveal unforeseen adverse events. The safety PK results from preclinical studies may not be indicative of results observed in subsequent clinical trials. We have not completed studies on the long-term effects associated with the use of our drug candidates. Completion of studies of these long-term effects may be required for regulatory approval and would delay our introduction of our drug candidates into the market. These studies could also be required at any time after regulatory approval of any of our drug candidates. Absence of long-term data may also limit the approved uses of our products, if any, to short-term use. Some or all of our drug candidates may prove to be unsafe for human use.

Undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or other comparable regulatory authorities. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Given the serious nature of the conditions we are treating in our clinical trials, and the multiple concomitant medications including our active drug candidates that our patients are treated with, side effects (such as nausea, diarrhea, infections, hepatic enzyme elevations, and possible allergic reactions) have been reported in our clinical studies. While such disorders may be found to be not related to our drug candidates, such events may create a negative safety perception. Even if any of our drug candidates receives regulatory approval, as greater numbers of patients use a drug following its approval, an increase in the incidence or severity of side effects or the incidence of other post-approval problems that were not seen or anticipated during pre-approval clinical trials could result in a number of potentially significant negative consequences, including that regulatory authorities may withdraw their approval of the product, regulatory authorities may require the addition of labeling statements, such as “black box” warnings or contraindications, or impose additional safety monitoring or reporting requirements, we may be required to change the way the product is administered or conduct additional clinical trials, we may be required to implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients, we could be sued and held liable for harm caused to patients, and our reputation may suffer. Any of these events could substantially increase the costs and expenses of developing, commercializing and marketing any such drug candidates or could harm or prevent sales of any approved products.

Interim, "topline," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, in November 2019, we announced positive topline data from our ADVOCATE trial, and in 2020 we announced topline data from our AURORA and ACCOLADE trials, and we are currently conducting a more comprehensive review of the data from each of these trials.

We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our drug products may be harmed, which could harm our business, operating results, prospects or financial condition.

We rely on third parties to conduct all our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize any of our drug candidates.

We currently do not have the ability to independently conduct preclinical studies or clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as clinical research organizations, or CROs, to conduct clinical trials on our drug candidates. The third parties with which we contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our preclinical studies and clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with GCP requirements for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials.

In addition, the execution of preclinical studies and clinical trials, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. In most cases, these third parties may terminate their agreements with us upon 30 days' prior written notice of a material breach by us that is not cured within 30 days. Many of these agreements may also be terminated by such third parties under certain other circumstances, including our insolvency or our failure to comply with applicable laws. In general, these agreements require such third parties to reasonably cooperate with us at our expense for an orderly winding down of services of such third parties under the agreements. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCP, or for any other reason, we may need to enter into new arrangements with alternative third parties, which could be costly, and our clinical trials may be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the drug candidate being tested in such trials.

We will need additional financing and may be unable to raise capital on acceptable terms, or at all, when needed, which would force us to delay, reduce or eliminate our research and development programs and other operations or commercialization efforts.

We are advancing multiple drug candidates through discovery and development and will require substantial funds to conduct development, including preclinical studies and clinical trials, of our drug candidates. Commercialization of any drug candidate will also require substantial expenditures. Our ability to develop and commercialize our drug candidates will depend upon our ability to identify financing or collaboration arrangements and there can be no assurance that we will be successful in identifying or implementing any such arrangement.

As of December 31, 2020, we had approximately $461.5 million in cash, cash equivalents, restricted cash and investments, excluding an additional $60.0 million we may borrow under the amended and restated credit facility, or Restated Credit Facility, with Hercules Capital, Inc., or Hercules. We believe that our available cash, cash equivalents and investments will be sufficient to fund our anticipated level of operations for at least 12 months following our financial statement issuance date, March 1, 2021. Our future financing requirements will depend on many factors, some of which are beyond our control, including:

- the rate of progress and cost of our clinical trials, preclinical studies and other discovery and research and development activities;
- the timing of, and costs involved in, seeking and obtaining FDA and other regulatory approvals;
- the success of any strategic alliance with collaboration partners and potential future collaboration partners;
- the costs of preparing, filing, prosecuting, maintaining and enforcing any patent claims and other intellectual property rights, including litigation costs and the results of such litigation;
- our ability to enter into additional collaboration, licensing, government or other arrangements and the terms and timing of such arrangements;
- potential acquisition or in-licensing of other products or technologies; and
- the emergence of competing technologies or other adverse market developments.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies. We currently have no understandings, commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings, our credit facility, government grants and contracts and/or strategic collaborations. Additional financing may not be available to us when we need it or it may not be available on favorable terms, if at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs or our commercialization efforts. We may be required to enter into collaborative partnerships for one or more of our drug candidate programs at an earlier stage of development or on less favorable terms, which may require us to relinquish rights to some of our drug candidates that we would otherwise have pursued on our own.

The terms of our credit facility place restrictions on our operating and financial flexibility.

We have entered into the Restated Credit Facility with Hercules, which is secured by substantially all of our assets, excluding intellectual property, pursuant to which we may borrow up to an aggregate principal amount of $120.0 million, subject to certain terms and conditions. The outstanding principal balance under the credit facility was $25 million at December 31, 2020.

The credit facility also includes customary affirmative and negative covenants and events of default, the occurrence and continuance of which provide Hercules with the right to demand immediate repayment of all principal and unpaid interest under the credit facility, and to exercise remedies against us and the collateral securing the credit facility. These events of default include, among other things: (i) insolvency, liquidation, bankruptcy or similar events; (ii) failure to pay any debts due under the credit facility or other loan documents on a timely basis; (iii) failure to observe any covenant or secured obligation under the credit facility, which failure, in most cases, is not cured within 15 days; (iv) occurrence of an event that could reasonably be expected to have a material adverse effect; (v) material misrepresentations; (vi) occurrence of any default under any other agreement involving indebtedness in excess of $1,000,000 or the occurrence of a default under any agreement that could reasonably be expected to have a material adverse effect on us; and (vii) certain money judgments being entered against us or any portion of our assets are attached or seized.

Our ability to make scheduled payments on or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. If we desire to refinance our indebtedness, our ability to do so will depend on the capital and lending markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Any orphan drug designations we receive may not confer marketing exclusivity or other benefits.

In the United States, under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition. Such diseases and conditions are those that affect fewer than 200,000 individuals in the United States, or if they affect more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug available in the United States for these types of diseases or conditions will be recovered from sales of the drug. Orphan drug designation must be requested before submitting an NDA. If the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by that agency. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but it can lead to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers.

If a drug that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the drug is entitled to orphan drug marketing exclusivity for a period of seven years. Orphan drug marketing exclusivity generally prevents the FDA from approving another application, including a full NDA, to market the same drug or biological product for the same indication for seven years, except in limited circumstances, including if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines “same drug” as a drug that contains the same active chemical entity and is intended for the same use as the drug in question. A designated orphan drug may not receive orphan drug marketing exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Orphan drug marketing exclusivity rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (i) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (ii) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the MAA if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the EU may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

The FDA granted orphan drug designation for avacopan for the treatment of C3G and ANCA vasculitis, including granulomatosis with polyangiitis or Wegener's granulomatosis, microscopic polyangiitis, and Churg-Strauss syndrome. In November 2014, the European Commission granted orphan drug designation for avacopan for the treatment of granulomatosis with polyangiitis or Wegener's granulomatosis and microscopic polyangiitis, and, in June 2017, for the treatment of C3G. However, we cannot assure you that we will be able to obtain or maintain orphan drug exclusivity for avacopan, if it is approved for the treatment of C3G and/or ANCA vasculitis in any jurisdiction, in a timely manner or at all, or that a competitor will not obtain orphan drug exclusivity that could block the regulatory approval of avacopan for several years. If we are unable to obtain or maintain orphan drug exclusivity in the United States or the EU, our ability to generate sufficient revenues may be negatively affected. If a competitor is able to obtain orphan drug exclusivity that would block avacopan's regulatory approval, our ability to generate revenues would be significantly reduced, which would harm our business prospects, financial condition and results of operations.

We may form additional strategic alliances in the future with respect to our programs, and we may not realize the benefits of such alliances.

We may form additional strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties with respect to our programs that we believe will complement or augment our existing business. For example, we entered into collaboration and license agreements with Vifor for the development and commercialization of avacopan and CCX140. We face significant competition in seeking appropriate strategic partners or other alternative arrangements and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any current or future drug candidates and programs because our research and development pipeline may be insufficient, our drug candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our drug candidates and programs as having the requisite potential to demonstrate safety and efficacy. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. For example, Vifor has the right to terminate the Avacopan Agreement and the CCX140 Agreement at its convenience, in which case we would not receive payments under such agreements. Any delays in entering into new strategic partnership agreements related to our drug candidates could also delay the development and commercialization of our drug candidates and reduce their competitiveness even if they reach the market.

Key elements of our proprietary suite of drug discovery technologies, known as EnabaLink, including our RAM screening technology, are proprietary approaches to the discovery and development of new drug candidates and may not result in the discovery of any small molecule compounds of commercial value.

We must continue to identify and develop compounds that target the chemokine network and expand our portfolio of drug candidates. Research programs to identify new disease targets and drug candidates require substantial technical, financial and human resources. We have limited resources to study the more than 50 known chemokine ligands, as described in a February 2006 article in the New England Journal of Medicine, and approximately 25 identified chemokine receptors as described in a January 2014 publication by the nomenclature committee of the International Union of Pharmacology. Two structural biology papers published during 2016 in Nature describe crystal structures of two different chemokine receptors in complex with small molecule inhibitors and provides insight to the function and respective modulation through multiple binding pockets. We expect that this pivotal work will assist in the development of novel small inhibitors of chemokine receptors. EnabaLink represents a new approach to the development of new drug candidates and we cannot assure you that EnabaLink will result in the discovery of new drug candidates. EnabaLink has only resulted in a limited number of clinical and preclinical-stage programs to date, and we may not identify any therapeutic small molecule compounds of commercial value using EnabaLink or other commercially available drug discovery technologies.

If our Reverse Activation of Migration, or RAM, screening technology or any other screening technologies fail to identify highly specific “hits” that lead to the development of new drug candidates, our business may be materially and adversely affected. Our scientists may be unable to optimize the chemical “hits” identified by our RAM screening technology and develop the identified starting material into a candidate for further development that meets the desired product criteria. Our research and development programs may initially show promise in identifying chemokine receptors and their impact on the body’s immune system, yet fail to yield drug candidates that are suitable for preclinical and clinical development. We cannot assure you that our current efforts will be successful or that we will not abandon any of our efforts in the future related to a particular chemokine receptor or small molecule program.

We rely on third party contract manufacturing organizations to manufacture and supply our drug candidates for us. If one of our suppliers or manufacturers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers or manufacturers. We may also face delays in the development and commercialization of our drug candidates.

We currently have limited experience in, and we do not own facilities for, manufacturing our drug candidates. We rely upon third party contract manufacturing organizations to manufacture and supply larger quantities of these other drug candidates. The manufacture of pharmaceutical products in compliance with cGMP requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the drug candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced FDA cGMP requirements, other federal and state regulatory requirements, and foreign regulations. Raw materials for the synthesis of our API are sourced globally. If the manufacturers of our raw materials and pharmaceutical products were to encounter any difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, our ability to provide study drugs in our preclinical studies and clinical trials would be jeopardized. Any delay or interruption in the supply of preclinical study or clinical trial materials could delay the completion of our preclinical studies and clinical trials, increase the costs associated with maintaining our preclinical study and clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the studies and trials completely.

All manufacturers of our drug candidates must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our component materials may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers’ compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product supplied is compromised due to our manufacturers’ failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our drug candidates or entail higher costs or impair our reputation.

We currently rely on a single source supplier for API and drug product for each of our drug candidates. In the event that we and our suppliers cannot agree to the terms and conditions for them to provide some or all of our API clinical and commercial supply needs, or if any single source supplier terminates the agreement in response to a breach by us, or if a supplier is not able to timely provide us with API and drug product, we would not be able to manufacture the API on a commercial scale until a qualified alternative supplier is identified, which could also delay the development of, and impair our ability to commercialize, drug candidates. For example, public health epidemics, such as the ongoing coronavirus outbreak, may impact the ability of our existing or future suppliers to provide us with preclinical study or clinical trial materials.

Although alternative sources of supply exist, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange for alternative suppliers, which could have a material adverse effect on our business. New suppliers of any API would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing such ingredients. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs which may be passed on to us.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

As of December 31, 2020, we had 133 full-time employees. We will need to continue to expand our commercial, managerial, operational, financial and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our drug candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- build our sales, marketing and distribution capabilities;
- manage our clinical trials effectively;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors, collaborators, government agencies and other third parties;
- continue to improve our operational, financial and management controls, reporting systems and procedures; and
- identify, recruit, maintain, motivate and integrate additional employees.

We face substantial competition and our competitors may discover, develop or commercialize products faster or more successfully than us.

The biotechnology and pharmaceutical industries are highly competitive, and we face significant competition from companies in the pharmaceutical, biotechnology and other related markets that are researching and marketing products designed to address autoimmune diseases, inflammatory disorders, and cancer. Established pharmaceutical companies that currently sell or are developing drugs in our markets of interest include, but are not limited to, AbbVie, Alexion, Amgen, AstraZeneca, Aurinia, Bayer, Biogen, Elan, GlaxoSmithKline, Johnson & Johnson, Mallinckrodt, Merck, Merck Serono, Novartis, Pfizer, Travere, Roche/Genentech, Sanofi, Takeda and Teva. In addition, in some instances we may face competition from companies that sell generic versions of approved drugs that are part of the current SOC. Many or all of these established competitors are also involved in research and drug development regarding various chemokine receptors. Pharmaceutical and biotechnology companies which are known to be involved in chemokine and chemoattractant research and related drug development include, but are not limited to, Pfizer, GlaxoSmithKline, Bristol-Myers Squibb, Merck, Takeda, Sanofi, Incyte, Alexion, Allergan, Appellis, Omeros, InflaRx, X4 Pharmaceuticals, Mitsubishi Tanabe, Biolinerx, Akari Therapeutics and UCB Pharma, among others.

We are developing small molecule therapeutics that will compete with other drugs and alternative therapies that are currently marketed or are being developed to treat ANCA vasculitis, C3G, HS, LN and other renal disease, other autoimmune diseases, metabolic diseases, inflammatory disorders, and cancer. Similarly, other future drug candidates we are pursuing would compete against numerous existing and established drugs and potentially against other novel drugs and therapies that are currently in development. See “Item 1. Business—Competition.” We also anticipate that we will face increased competition in the future as new companies enter into our target markets and scientific developments surrounding the chemokine system continue to develop.

Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Large pharmaceutical companies in particular have extensive expertise in preclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors.

We may be subject to costly product liability claims related to our clinical trials and drug candidates and, if we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition.

Because we conduct clinical trials with human patients, we face the risk that the use of our drug candidates may result in adverse side effects to patients and to otherwise healthy volunteers in our clinical trials. We face even greater risks upon any commercialization of our drug candidates. Although we have product liability insurance for clinical trials for up to $10.0 million, our insurance may be insufficient to reimburse us for any expenses or losses we may suffer, and we will be required to increase our product liability insurance coverage for our advanced clinical trials that we plan to initiate. We do not know whether we will be able to continue to obtain product liability coverage and obtain expanded coverage on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. There is also a risk that third parties that we have agreed to indemnify could incur liability. An individual may bring a product liability claim against us if one of our drug candidates or products causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

- withdrawal of clinical trial volunteers, investigators, patients or trial sites;
- the inability to commercialize our drug candidates;
- decreased demand for our drug candidates;
- regulatory investigations that could require costly recalls or product modifications;
- loss of revenues;
- substantial costs of litigation;
- liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourselves;
- an increase in our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, if at all;
- the diversion of management’s attention from our business; and
- damage to our reputation and the reputation of our products.

Our business involves the use of hazardous materials and we and our third-party manufacturers must comply with environmental laws and regulations, which may be expensive and restrict how we do business.

Our third-party manufacturers’ activities and our own activities involve the controlled storage, use, handling and disposal of hazardous materials, including the components of our pharmaceutical products, test samples and reagents, biological materials and other hazardous compounds. We and our manufacturers are subject to federal, state and local and foreign laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials. Although we believe that our safety procedures for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other applicable authorities may curtail our use of these materials and/or interrupt our business operations. In addition, if an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines. The substantial unexpected costs we may incur could significantly harm our financial condition and results of operations.

Future financings may adversely affect our stockholders or impose additional restrictions on our assets or operations, which may harm our business.

If we raise additional capital by issuing equity securities or convertible debt securities, then our existing stockholders' ownership will be diluted and the terms of any new equity securities may have preferences over our common stock. If we raise additional capital through the issuance of debt securities, the debt will have rights senior to the holders of our common stock and may contain covenants that restrict our operational flexibility or impose liens or other restrictions on our assets, in addition to the restrictions imposed by our credit facility with Hercules. In addition, the terms of future financings may restrict our ability to raise additional capital, which would delay or prevent the further development or commercialization of our drug candidates. If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our current drug candidates, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the development of one or more of our drug candidates.

We are highly dependent on the services of our founder, President and Chief Executive Officer, Dr. Thomas J. Schall, and if we are not able to retain Dr. Schall or other members of our management or recruit additional management, clinical and scientific personnel, our business will suffer.

We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay area. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We are highly dependent on the principal members of our management and scientific staff. The loss of service of any of our management could harm our business. In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified additional management, commercial, clinical and scientific personnel. The competition for qualified personnel in the pharmaceutical industry is intense. Due to our limited resources, we may not be able to effectively attract and recruit additional qualified personnel. If we are not able to retain our management, particularly our founder, President and Chief Executive Officer, Dr. Schall, and 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 business. Although we have executed employment agreements with each member of our current executive management team, including Dr. Schall, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. In addition to the competition for personnel, the San Francisco Bay area in particular is characterized by a high cost of living. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

In addition, we have scientific and clinical advisors who assist us in formulating our product development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours.

We are required to maintain compliance with Section 404 of the Sarbanes-Oxley Act of 2002 or we may be subject to sanctions by regulatory authorities.

Section 404(a) of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal controls over financial reporting and provide a management report on the internal control over financial reporting. We have performed the system and process evaluation and testing required to comply with the management certification. We are also required to comply with auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002. If we do not properly implement the requirements of Section 404 with adequate compliance, and maintain such compliance, we may be subject to sanctions or investigation by regulatory authorities, such as the SEC or The Nasdaq Stock Market LLC, or Nasdaq. Any such action could adversely affect our financial results or investors' confidence in us and could cause our stock price to fall. If we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our consolidated financial statements may be materially misstated. If we or our independent registered public accounting firm identifies deficiencies in our internal controls that are deemed to be material weaknesses, we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources and could materially adversely affect our stock price.

We may be adversely affected by the economic environment.

Our ability to attract and retain collaboration partners or customers, invest in and grow our business and meet our financial obligations depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the United States and inflationary pressures. We cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

We are exposed to risks associated with reduced profitability and the potential financial instability of our collaboration partners or customers, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, our collaboration partners or customers may experience reductions in revenues, profitability and/or cash flow that could lead them to reduce their support of our programs or financing activities. If collaboration partners or customers are not successful in generating sufficient revenue or are precluded from securing financing, they may not be able to pay, or may delay payment of, accounts receivable that are owed to us. This, in turn, could adversely affect our financial condition and liquidity. In addition, if economic challenges in the United States result in fewer individuals pursuing or being able to afford our products once commercialized, our business, results of operations, financial condition and cash flows could be adversely affected.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs, adverse publicity, and fines or penalties. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our drug candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed.

Our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: FDA regulations, including those that require the reporting of true, complete and accurate information to the FDA; manufacturing standards we have established; federal and state healthcare fraud and abuse laws and regulations; and laws that require the reporting of true, complete and accurate financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These activities could also include the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change, by value, in its equity ownership over a three year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income and taxes may be limited. We previously determined that we had ownership changes, which limit our ability to use our then existing tax attributes. Future changes in our stock ownership, many of the causes of which are outside our control, could result in additional ownership changes. Any such ownership changes could further limit our ability to use net operating loss carryforwards and other pre-change tax attributes. Furthermore, under U.S. tax legislation enacted in 2017, the treatment of tax losses generated before December 31, 2017 has generally not changed but tax losses generated in calendar year 2018 and beyond may be used to offset only 80% of taxable income and carryforward indefinitely. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, such as the ongoing coronavirus outbreak, and other natural or manmade disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our corporate headquarters is located in California and certain clinical sites for our drug candidates, operations of our existing and future partners and suppliers are or will be located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant partners, suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural or manmade disaster.

The outbreak of the novel coronavirus disease 2019, or COVID-19, could adversely impact our business, manufacturing operations, preclinical studies and clinical trials.

In December 2019, a disease caused by a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and has spread to nearly every country and region in the world, including those in which we have active clinical trial sites or contract manufacturing sites. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19 and in accordance with direction from state and local government authorities, we have limited the number of essential staff in our corporate headquarters. As the COVID-19 pandemic continues to spread around the globe, we may experience disruptions that could severely impact our business, manufacturing operations, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as (i) clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, (ii) interruption of clinical trial subject visits and study procedures, or (iii) difficulties in collecting study data in accordance with clinical trial protocols due to patients' inability to travel or site closures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our drug candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials and interruption in global shipping that may affect the transport of clinical trial materials;
- increases in the costs of clinical trials due to the impact of COVID-19;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility or those of our outsourced service providers;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies or clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, staffing shortages, travel limitations, cyber security and data accessibility, or communication or mass transit disruptions;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- changes in local regulations as part of a response to COVID-19 which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States;
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States;
- delays or impacts on the successful commercial launch of our product candidates due to decreases in business travel or live customer interactions;

- interruption or delays to our discovery and development pipeline;
- continued volatility in our and other biopharmaceutical companies' shares of common stock, which may result in difficulties raising capital through sales of our common stock or equity linked to our common stock, to the extent needed, and the terms of sales may be on unfavorable terms or unavailable, which may impact our short-term and long-term liquidity; and
- interruption or delays to, or increased costs associated with, our planned move to our new corporate headquarters

The COVID-19 pandemic continues to rapidly evolve and as a result of the COVID-19 resurgence impacting certain sites where we have been conducting our AURORA trial, topline data from that trial was delayed until early in the fourth quarter of 2020. The extent to which the COVID-19 pandemic may further impact our business, including our manufacturing operations, preclinical studies, clinical trials and financial condition, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

To the extent the COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks described in "Item 1A. Risk Factors".

Risks Related to Intellectual Property

Our proprietary rights may not adequately protect our technologies and drug candidates. If we are unable to protect our drug candidates and our intellectual property rights, it may materially adversely affect our position in the market.

Our commercial success will depend on our ability to obtain patents and maintain adequate protection for our technologies, intellectual property and drug candidates in the United States and other countries. We cannot assure you that any of our patent applications will result in issued patents. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and future products are covered by valid and enforceable patents or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely impact our position in the market.

We apply for patents covering both our technologies and drug candidates, as we deem appropriate. However, we may fail to apply for patents on important technologies or drug candidates in a timely fashion, or at all. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies. Composition-of-matter patents on the chemical active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our patent applications covering composition-of-matter of our drug candidates will be considered patentable by the USPTO and courts in the United States or by the patent offices and courts in other countries, nor can we be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patent rights that we license from others, may be challenged in the courts or patent offices in the United States and abroad. Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action or similar proceedings in court or before patent offices in the United States or foreign jurisdictions for a given period after allowance or grant, during which time third parties can raise objections against such patents. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, all of which could limit our ability to stop others from using or commercializing similar or identical drug products, or limit the duration of the patent protection of our drug products and candidates.

Moreover, the patent positions of numerous biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. As a result, the validity and enforceability of our patents cannot be predicted with certainty. In addition, we cannot assure you that:

- we were the first to make the inventions covered by each of our issued patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies by inventing around our claims;
- any of our pending patent applications will result in issued patents;
- a third party will not challenge our proprietary rights or that a court will hold that our patents are valid and enforceable;
- any patents issued to us or our collaboration partners will provide us with any competitive advantages, or will not be challenged by third parties;
- we will develop additional proprietary technologies that are patentable; or
- the patents of others will not have an adverse effect on our business.

Changes in patent law in the United States or in other countries could diminish the value of patents in general, thereby impairing our ability to protect our drug products and candidates.

Our patent rights may be affected by developments or uncertainty in the United States' or other jurisdictions' patent statutes, patent case law, USPTO rules and regulations or the rules and regulations of other jurisdictions' patent offices.

There are a number of recent changes to United States patent laws that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law, including provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application is typically entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings including opposition, derivation, reexamination, inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. In addition, the United States Congress may pass additional patent reform legislation that is unfavorable to us.

The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future. Similarly, statutory or judicial changes to the patent laws of other countries may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents.

We may become subject to third parties' claims alleging infringement of patents and proprietary rights or seeking to invalidate our patents or proprietary rights, which would be costly, time-consuming and, if successfully asserted against us, delay or prevent the development and commercialization of our products.

Intellectual property litigation, and patent litigation in particular, is expensive, complex and lengthy and its outcome is difficult to predict. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We may be subject to third-party claims in the future against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third party's patents. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or drug candidate that is the subject of the suit. As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to redesign it, or to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly. For example, for hidradenitis suppurativa, or HS, InflaRx GmbH holds patents regarding methods of use to treat HS with agents that inhibit C5a activities. While we believe that these patents may not be enforceable, may be invalidated, or may be limited in scope, such patents could potentially affect the use of avacopan to treat HS. If we are unable to invalidate or challenge such patents for HS, we may need to obtain a license to commercialize avacopan in that indication. Such a license, if necessary, could require us to make royalty or other material payments to InflaRx GmbH.

Furthermore, 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 and can involve other factors such as expert opinion. Our analysis of these issues, including interpretation of the relevance or the scope of claims in a patent or a pending application, determining applicability of such claims to our proprietary technologies or drug candidates, predicting whether a third party's pending patent application will issue with claims of relevant scope, and determining 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 drug candidates. We do not always conduct independent reviews of pending patent applications and patents issued to third parties.

Additionally, patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain United States applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our drug candidates or the use of our drug candidates. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. As a result, we may be unaware of third-party patents that may be infringed by commercialization of our drug candidates, and cannot be certain that we were the first to file a patent application related to a drug candidate or proprietary technology. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims.

In addition to infringement claims against us, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding the patentability of our inventions relating to our drug candidates, and/or the enforceability, validity or scope of protection offered by our patents relating to our drug candidates. Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. Or, if third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine the priority of invention. We may also become involved in similar opposition proceedings in the European Patent Office regarding our intellectual property rights with respect to our products and technology.

The cost to us of any intellectual property litigation or other proceedings could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Discovery proceedings in the United States might lead to the disclosure of some of our proprietary confidential information. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may also absorb significant management and technical staff's time which may materially and adversely impact our financial position and results of operations.

Restrictions on our patent rights relating to our drug candidates may limit our ability to prevent third parties from competing against us.

Our success will depend, in part, on our ability to obtain and maintain patent protection for our drug candidates, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others. Composition-of-matter patents on APIs are generally considered to be the strongest form of intellectual property protection for pharmaceutical products as they apply without regard to any method of use. Entirely new individual chemical compounds, often referred to as new chemical entities, are typically entitled to composition-of-matter coverage. However, we cannot be certain that the current law will remain the same, or that our drug candidates will be considered novel and non-obvious by the USPTO and courts.

In addition to composition-of-matter patents and patent applications, we also have filed method-of-use patent applications. This type of patent protects the use of the product only for the specified method. However, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if these competitors do not actively promote their product for our targeted indication, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Patent applications in the United States and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we and the inventors of the issued patents and applications that we may in-license were the first to conceive of the inventions covered by such patents and pending patent applications or that we and those inventors were the first to file patent applications covering such inventions. Also, we have numerous issued patents and some patent applications pending before the USPTO and the patent protection may lapse before we manage to obtain commercial value from them, which might result in increased competition and materially affect our position in the market.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our employees were previously employed at universities or biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to commercialize, or prevent us from commercializing our drug candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Some of our intellectual property which is discovered through government funded programs is subject to federal regulation such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with foreign manufacturers.

Some of our existing drug candidates, including CCX140, and some of our research and development work were funded, at least in part, by the U.S. government and are therefore subject to certain federal regulations. For example, some of our research and development work on vaccine adjuvants and immunomodulation for biothreat applications was funded by government research grants. In addition, as noted on several of our patents, including U.S. Patent Nos. 7,884,110; 7,622,583; 7,776,877; 8,198,309 and 8.093,247, inventions covering various CCR9 and CCR2 inhibitors were supported at least in part by National Institutes of Health funding (U19-AI056690-01). Under the "march-in" provisions of the Bayh-Dole Act, the government may have the right under limited circumstances to require us to grant exclusive, partially exclusive or non-exclusive rights to third parties for intellectual property discovered through the government funded program. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the new invention or because action is necessary to alleviate health or safety needs of the public. Intellectual property discovered under the government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. Such intellectual property is also subject to a preference for U.S. industry, which may limit our ability to contract with foreign product manufacturers for products covered by such intellectual property. We plan to apply for additional U.S. government funding, and it is possible that we may discover compounds or drug candidates as a result of such funding. Intellectual property under such discoveries would be subject to the applicable provisions of the Bayh-Dole Act.

Risks Related to Government Regulation

The regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our drug candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, the EMA, the EU institutions (e.g., the European Commission) and the EU Member State Competent Authorities, as well as equivalent authorities and regulatory bodies in other countries, which regulations differ from country to country. We are not permitted to market our drug candidates in the United States until we receive approval of an NDA from the FDA and in the EU until we have received approval from the European Commission or EU Member State Competent Authorities. We have not submitted an application for or received regulatory approval for any of our drug candidates, except in the EU where we have applied to the EMA for a CMA, which we subsequently withdrew, for avacopan in the treatment of patients with ANCA vasculitis. Obtaining approval of an NDA, MAA or CMA can be an expensive, time-consuming and uncertain process. In addition, failure to comply with FDA, EMA and other applicable U.S., EU and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including:

- warning letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of approved products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production; and
- refusal to approve pending NDAs or supplements to approved NDAs, pending CMA or MAAs.

Prior to receiving approval to commercialize any of our drug candidates in the United States, the EU, or in other countries, we must demonstrate with substantial evidence from well controlled clinical trials, and to the satisfaction of the FDA, the EMA, and other regulatory authorities abroad, that such drug candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our drug candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA, and other regulatory authorities. Administering any of our drug candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials of our drug candidates and result in the FDA, the EMA, or other regulatory authorities denying approval of our drug candidates for any or all targeted indications.

Regulatory approval of an NDA or NDA supplement, or of a CMA, MAA, or of their respective extensions and variations, is not guaranteed, and the approval process is expensive and may take several years. The FDA and the EMA also have substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA or EMA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. The FDA or EMA can delay, limit or deny approval of a drug candidate for many reasons, including, but not limited to, the following:

- a drug candidate may not be deemed safe or effective;
- FDA or EMA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA or EMA might not approve our or our third-party manufacturer’s processes or facilities; or
- the FDA or EMA may change its approval policies or adopt new regulations.

If any of our drug candidates fails to demonstrate safety and efficacy in clinical trials or does not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by 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 employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The availability of adequate third-party coverage and reimbursement for newly approved drugs is uncertain, and failure to obtain adequate coverage and reimbursement from third-party payors could impede our ability to market any future products we may develop and could limit our ability to generate revenue.

There is significant uncertainty related to the third-party payor coverage and reimbursement of newly approved drugs. The commercial success of our future products in both domestic and international markets depends on whether such third-party coverage and reimbursement is available for our future products. Governmental payors, including Medicare and Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to manage their healthcare expenditures by limiting both coverage and the level of reimbursement of new drugs and, as a result, they may not cover or provide adequate reimbursement for our future products. These payors may not view our future products as cost-effective, and coverage and reimbursement may not be available to our customers or may not be sufficient to allow our future products to be marketed on a competitive basis. Third-party payors are exerting increasing influence on decisions regarding the use of, and coverage and reimbursement levels

for, particular treatments. Such third-party payors, including Medicare, are challenging the prices charged for medical products and services, and many third-party payors limit or delay coverage and reimbursement for newly approved healthcare products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could cause us to decrease the price we might establish for products, which could result in lower than anticipated product revenues. If the prices for our drug candidates decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.

We may market future products in international markets. In order to market our future products in the EEA and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicines that contain a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, and auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

In the EEA, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the EU from referencing the innovator’s data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator’s data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the EU’s regulatory authorities to be a new chemical entity and qualify for data exclusivity.

To meet unmet medical needs of patients and in the interest of public health, the EMA may grant, subject to certain specific obligations to be reviewed annually, a CMA, on the basis of less complete data than is normally required. To be eligible for a CMA, a medicinal product must belong to at least one of these categories: (i) be aimed at treating, preventing or diagnosing seriously debilitating or life-threatening diseases; (ii) be intended for use in emergency situations; or (iii) be designated as an orphan medicine. Further, a CMA may only be granted if the EMA finds that all the following requirements are met:

- the benefit-risk balance of the product is positive;
- it is likely that the applicant will be able to provide comprehensive data;
- unmet medical needs will be fulfilled; and
- the benefit to public health of the medicinal product's immediate availability on the market outweighs the risks due to the need for further data.

In 2016, the EMA launched its Priority Medicines, or PRIME, scheme. PRIME is a voluntary scheme aimed at enhancing the EMA’s support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. The scheme focuses on

medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options. These medicines are considered priority medicines by the EMA. To be accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data. The benefits of a PRIME designation include the appointment of a CHMP rapporteur, before submission of the MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process. Obtaining access to PRIME may not result in a materially faster development process, review or approval compared to conventional EMA procedures, nor does access to PRIME assure or increase the likelihood of EMA's grant of a marketing authorization.

We have had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file we may not receive necessary approvals to commercialize our products in any market.

Healthcare reform measures could hinder or prevent our drug candidates' commercial success.

In the United States, there have been and we expect there will continue to be a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenues and profitability and the future revenues and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in March 2010, the Affordable Care Act was signed into law. It contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which impacted existing government healthcare programs and resulted in the development of new programs. The Affordable Care Act, among other things:

- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs;
- increased the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70% (in 2021) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- mandated a further shift in the burden of Medicaid payments to the states.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. By way of example, in December 2017, the Tax Cuts and Jobs Act was enacted, which, among other things, removed penalties for not complying with the individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On November 10, 2020, the U.S. Supreme Court heard oral arguments over the constitutionality of the individual mandate and whether the rest of the Affordable Care Act can be severed if the mandate is unconstitutional. It is unclear how these decisions, subsequent appeals, if any, and other efforts to challenge, repeal or replace the Affordable Care Act will impact the Affordable Care Act and our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into

effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2029 unless additional Congressional action is taken. In January 2013, the ATRA was enacted, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently, there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our potential customers and accordingly, our financial operations.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact, particularly in light of the current presidential administration and U.S. Congress. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

- our ability to set a price we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability; and
- the availability of capital.

Further, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the recall and withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products or require safety surveillance and/or patient education. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and the drug approval process. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Even if we are able to commercialize one or more of our drug candidates, the drugs may become subject to unfavorable pricing regulations or third party reimbursement practices, which could harm our business.

Successful sales of our drug candidates, if approved, depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new drug acceptance.

Our ability to commercialize any drugs successfully also will depend in part on the extent to which coverage and reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country, but be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recover our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a drug is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for any drug that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approval. Obtaining reimbursement for our drugs may be difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any drug candidate that we successfully develop.

In the United States, no uniform policy of coverage and reimbursement for drugs exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our drugs on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our drugs.

If we obtain approval in one or more non-U.S. jurisdictions for our drug candidates, we will be subject to rules and regulations in those jurisdictions. In some non-U.S. jurisdictions, the reimbursement of drugs and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining regulatory approval of a drug candidate. In addition, market acceptance and sales of our drug candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our drug candidates and may be affected by existing and future health care reform measures.

If we fail to comply with healthcare laws and regulations, we could face investigations, substantial civil or criminal penalties and our business, operations and financial condition could be adversely affected. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse rules by both the federal government and the states in which we conduct our business. The laws and regulations that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either

the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute may result in significant civil monetary penalties or criminal fines and imprisonment. Violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;

- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government including the Medicare and Medicaid or other federal healthcare programs. For example, pharmaceutical companies have been prosecuted under the False Claims Act in connection with alleged "off-label" promotion of drugs, misstated government pricing information, or provision of free product or other items of value to customers, among other things. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose significant civil fines and penalties, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or 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 in order to have committed a violation;
- the federal Physician Payments Sunshine Act, which requires pharmaceutical companies to submit annual reports to CMS. In the annual reports, pharmaceutical companies must report information related to payments and other transfers of value to teaching hospitals, physicians, and, beginning in 2022, certain other health care professionals . Failure to submit required information, or failure to submit information in a timely, accurate and complete manner, may result in significant civil monetary penalties;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers or competitors; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by the government or, in some states, any payor including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance published 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 product pricing information.

In addition, certain states mandate that we comply with a state code of conduct, adopt a company code of conduct under state criteria, disclose marketing payments made to physicians and other healthcare providers, and/or report compliance information to the state authorities. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply in multiple jurisdictions with different compliance and reporting requirements increases the possibility that a pharmaceutical company may run afoul of one or more of the requirements.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the exclusion from participation in U.S. federal or state health care programs and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it or reach a settlement agreement, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Changes in and failures to comply with U.S. and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and financial performance.

We may be subject to U.S. federal and state and foreign health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. In the U.S., HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to the federal government, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission, or 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, 15 U.S.C. § 45(a). 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. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context.

In Europe, the European Union General Data Protection Regulation 2016/679, or GDPR, went into effect in May 2018 and introduces strict requirements for processing the personal data of European Union data subjects. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements. We are also subject to evolving EU laws on data export, as we may transfer personal data from the EU to other jurisdictions. Following Brexit, we will have to comply with the GDPR and the UK GDPR, each regime having the ability to fine up to the greater of €20 million/ £17 million or 4% of global turnover. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, e.g. how data transfers between EU member states. These changes will lead to additional costs and increase our overall risk. Achieving and sustaining compliance with applicable federal, state and foreign privacy and security laws may prove costly.

Risks Related to the Securities Markets and an Investment in Our Stock

There may not be a viable market for our common stock or the price of our common stock may be volatile, and stockholders may not be able to sell their shares at prices that are attractive to them.

There was no public market for our common stock prior to our initial public offering in February 2012, the trading volume of our common stock on the Nasdaq Global Select Market has been limited and there can be no assurance that an active and liquid trading market for our common stock will develop or be sustained. We cannot predict the extent to which investor interest in our company will lead to the development or maintenance of an active trading market on the Nasdaq Global Select Market or otherwise or how liquid that market might become. If an active public market does not develop or is not sustained, it may be difficult for stockholders to sell their shares of

common stock at prices that are attractive to them, or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or drugs, drug candidates or technologies by using our shares of common stock as consideration.

Stockholders may also be unable to sell their shares of common stock at prices that are attractive to them due to fluctuations in the market price of our common stock. The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile. Since the commencement of trading in connection with our initial public offering in February 2012, the publicly traded shares of our common stock have themselves experienced significant price and volume fluctuations. During the year ended December 31, 2020, the price per share for our common stock on the Nasdaq Global Select Market ranged from a low sale price of $30.72 to a high sale price of $65.43. This market volatility is likely to continue. These and other factors could reduce the market price of our common stock, regardless of our operating performance. In addition, the trading price of our common stock could change significantly, both over short periods of time and the longer term, due to many factors, including, but not limited to, those described elsewhere in this “Risk Factors” section and the following:

- results from, and any delays in, clinical trial programs relating to our drug candidates, including the ongoing and planned clinical trials for avacopan, CCX559, CCX507 and other drug candidates;
- announcements of regulatory approvals or disapprovals of our drug candidates, including avacopan, or delays in any regulatory agency review or approval processes;
- failure or discontinuation of any of our research programs;
- announcements relating to future collaborations;
- general economic conditions in the United States and abroad;
- acquisitions and sales of new products, technologies or business;
- delays in the commercialization of any of our drug candidates;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors;
- the issuance of new or changed securities analysts’ reports or recommendations regarding us, our competitors or our industry in general;
- actual and anticipated fluctuations in our quarterly operating results;
- disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new products by us or our competitors;
- manufacturing issues related to our drug candidates for clinical trials or future products for commercialization;
- market acceptance of our future products;
- deviations in our operating results from the estimates of analysts, or other analyst comments;
- third-party payor coverage and reimbursement policies;
- new legislation in the United States relating to the sale or pricing of pharmaceuticals;
- FDA, EMA or other U.S. or foreign regulatory actions affecting us or our industry;
- product liability claims or other litigation or public concern about the safety of our drug candidates or future drugs;
- our ability to obtain necessary intellectual property licenses;
- the outcome of any future legal actions to which we are party;
- sales of our common stock by our officers, directors or significant stockholders;
- additions or departures of key personnel; and
- other external factors, including natural disasters and other crises.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that have been often unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business.

The ownership of our common stock is highly concentrated, and these stockholders could delay or prevent a change of control.

As of December 31, 2020, our officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially owned approximately 69% of our outstanding common stock. Accordingly, these stockholders, acting as a group, have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with the interests of our other stockholders. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Future sales of our common stock or securities convertible or exchangeable for our common stock may depress our stock price.

Persons who were our stockholders prior to the sale of shares in our initial public offering continue to hold a substantial number of shares of our common stock that they are able to sell in the public market, subject in some cases to certain legal restrictions. If our stockholders or holders of our options or warrants sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline. As of December 31, 2020, we had 69,452,466 shares of common stock outstanding. Of these shares, approximately 46,834,230 are freely tradeable, without restriction, in the public market. In addition, approximately 22,618,236 of the outstanding shares of common stock are eligible for sale in the public market, subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, with respect to shares held by directors, executive officers and other affiliates. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans are 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 and, in any event, we have filed a registration statement permitting shares of common stock issued on exercise of options to be freely sold in the public market. If additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Certain of our directors and executive officers have established, programmed selling plans under Rule 10b5-1 of the Exchange Act, for the purpose of effecting sales of our common stock. Any sales of securities by these stockholders, or the perception that those sales may occur, including the entry into such programmed selling plans, could have a material adverse effect on the trading price of our common stock.

If we sell shares of our common stock in future financings, common stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our common stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. For example, in 2020, we completed an equity follow-on offering of 5,980,000 shares of our common stock for net proceeds of $325.7 million. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our drug candidates or future development programs;
- if any of our drug candidates receives regulatory approval, the level of underlying demand for these drug candidates and wholesalers' buying patterns;
- addition or termination of clinical trials or funding support;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under such arrangements, or the termination of such arrangements;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our drug candidates or those of our competitors; and
- our ability to secure new government contracts and allocation of our resources to or away from performing work under government contracts.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

We have broad discretion in the use of our cash and may not use it effectively.

Our management has broad discretion over the use of our cash. Because of the number and variability of factors that will determine our use of cash, stockholders may not agree with how we allocate or spend our cash. We may pursue collaborations or clinical trials that do not result in an increase in the market value of our common stock and that may increase our losses, or we may place our cash in investments that do not produce significant investment returns or that may lose value. Our failure to allocate and spend our cash effectively would have a material adverse effect on our financial condition and business and could cause our stock price to decline.

Provisions of our charter documents or Delaware law could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders, and could make it more difficult for our stockholders to change management.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include:

- a classified board of directors so that not all directors are elected at one time;
- a prohibition on stockholder action through written consent;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by the board of directors;
- an advance notice requirement for stockholder proposals and nominations;
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine; and
- a requirement of approval of not less than 66 2/3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our certificate of incorporation.

In addition, Delaware law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns or within the last three years has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Delaware law may discourage, delay or prevent a change in control of our company.

Our employment agreements with certain of our executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change of control of us, which could harm our financial condition or results.

Certain of our executive officers are parties to employment agreements providing for aggregate cash payments of up to approximately $4.4 million for severance and other benefits and acceleration of vesting of stock awards with an intrinsic value of $45.0 million as of December 31, 2020 in the event of a termination of employment in connection with a change of control of us. The accelerated vesting of options could result in dilution to our stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future, therefore capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

We have never declared or paid cash dividends on our capital stock. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. In addition, our ability to pay dividends is currently restricted by the terms of our credit facility with Hercules. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. Further, any future debt financing arrangement may contain additional terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. As of January 2021, we had research coverage by seven securities analysts. In the event one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

On January 31, 2020, the United Kingdom withdrew from the European Union, following its referendum in June 2016. The terms of the United Kingdom's withdrawal from the EU provide for a transitional period that ended on December 31, 2020. The United Kingdom ratified a trade and cooperation agreement governing its future with the EU. The agreement, which is being applied provisionally from January 1, 2021 until it is ratified by the European Parliament and the Council of the European Union, addresses trade, economic arrangements, law enforcement, judicial cooperation and a governance framework including procedures for dispute resolution, among other things. Because the agreement merely sets forth a framework in many respects and will require complex additional bilateral negotiations between the United Kingdom and the EU as both parties continue to work on the rules for implementation, significant uncertainty remains about the future relationship and the precise terms governing such relationship between the United Kingdom and the EU, including with respect to the laws and regulations that will apply as the United Kingdom determines which EU laws to replace or replicate. The withdrawal has also given rise to calls for the governments of other EU member states to consider withdrawal. These

developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our common stock.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our corporate headquarters are located in Mountain View, California, where we lease 35,755 square feet of office and laboratory space. The lease for the Mountain View facility will expire in June 2021. We believe that our existing facilities are adequate for our current needs, as the facility has sufficient laboratory space to house additional scientists to be hired as we expand.

In July 2019, we entered into a ten-year operating lease for a 96,463 square foot facility in San Carlos, California to replace our current headquarters located in Mountain View, California. Subject to landlord consent, we have the right to sublease the facility. After the initial lease term, we also have the option to extend the lease for five years.

Item 3. Legal Proceedings.

We are not currently a party to any legal proceedings.

Item 4. Mine Safety Disclosures.

Not Applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on the Nasdaq Global Select Market under the symbol "CCXI."

Holders of Common Stock

As of February 22, 2021, there were approximately 31 holders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors. In addition, our ability to pay dividends is currently restricted by the terms of our credit facility with Hercules.

Equity Compensation Plan Information

The following table summarizes securities available under our equity compensation plans as of December 31, 2020:

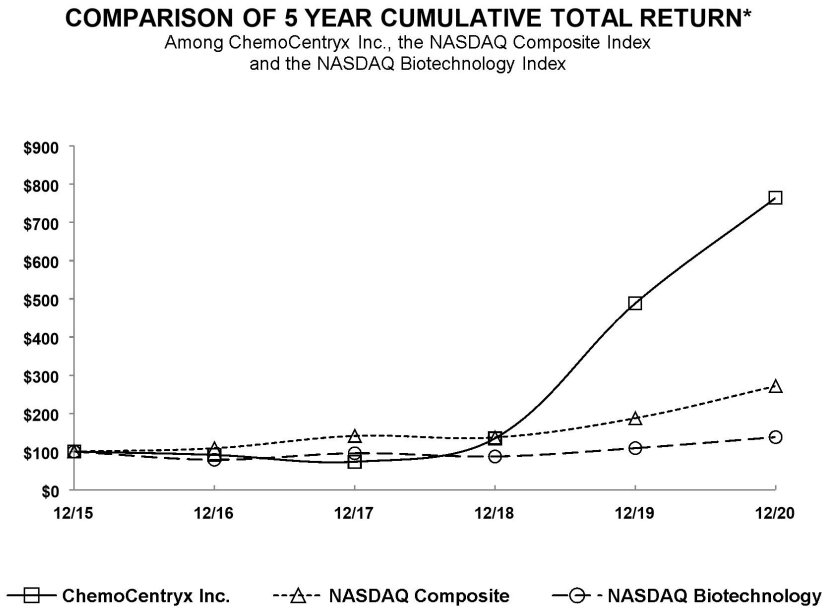
Plan Category	Shares Issuable Upon Exercise of Outstanding Options, Warrants and Rights(2)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights(3)	Number of Securities Available for Future Issuance(4)
Equity compensation plans approved by security holders: (1)	7,520,275	$ 14.61	4,014,314
Equity compensation plans not approved by security holders:	—	—	—
Total	7,520,275	$ 14.61	4,014,314

(1) Consists of our Amended and Restated 1997 Stock Option/Stock Issuance Plan, our Amended and Restated 2002 Equity Incentive Plan and our 2012 Equity Incentive Award Plan, our Non-Employee Director Compensation Policy and our Employee Stock Purchase Plan, or ESPP.
(2) Includes 7,114,225 shares subject to outstanding stock options and 406,050 shares subject to outstanding restricted stock units as of December 31, 2020.
(3) Calculated exclusive of outstanding restricted stock unit awards.
(4) Of these shares, 3,170,577 shares were available for stock option awards, restricted stock units and restricted stock awards, and 843,737 were available for the ESPP, in each case as of December 31, 2020.

Performance Graph

The information contained in this Performance Graph section shall not be deemed "soliciting material" or to be "filed" with the SEC, for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of ChemoCentryx, Inc. under the Securities Act of 1933, as amended, or the Exchange Act.

The following graph shows a comparison from December 31, 2015 (the date our common stock commenced trading on the Nasdaq Global Select Market) through December 31, 2020 of cumulative total return for our common stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index. Such returns are based on historical results and are not intended to suggest future performance. Data for the Nasdaq Composite Index and the Nasdaq Biotechnology Index assume reinvestment of dividends.



*$100 invested on 12/31/15 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

	12/15	12/16	12/17	12/18	12/19	12/20
ChemoCentryx Inc.	**100**	**91.36**	**73.46**	**134.69**	**488.27**	**764.44**
Nasdaq Composite	**100**	**108.87**	**141.13**	**137.12**	**187.44**	**271.64**
Nasdaq Biotechnology	**100**	**78.65**	**95.67**	**87.19**	**109.08**	**137.90**

Item 6. Selected Financial Data.

The following selected financial data have been derived from our audited financial statements. The information set forth below is not necessarily indicative of future results and should be read in conjunction with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 8. Financial Statements and Supplementary Data" included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2020	2019	2018	2017	2016
	(in thousands, except share and per share data)				
Consolidated Statements of Operations Data:					
Revenue:					
Collaboration and license revenue from related party	$ 64,392	$ 35,952	$ 42,875	$ 82,497	$ 11,435
Grant revenue	499	176	—	—	500
Total revenue	64,891	36,128	42,875	82,497	11,935
Operating expenses:					
Research and development	77,882	70,276	62,736	49,495	37,945
General and administrative	42,186	24,155	20,409	16,509	14,710
Total operating expenses	120,068	94,431	83,145	66,004	52,655
(Loss) income from operations	(55,177)	(58,303)	(40,270)	16,493	(40,720)
Interest income	2,464	4,963	3,528	1,370	757
Interest expense	(2,643)	(2,149)	(1,224)	(4)	—
Net (loss) income	$ (55,356)	$ (55,489)	$ (37,966)	$ 17,859	$ (39,963)
Net (loss) income per share, basic (1)	$ (0.84)	$ (0.98)	$ (0.76)	$ 0.37	$ (0.86)
Net (loss) income per share, diluted (1)	$ (0.84)	$ (0.98)	$ (0.76)	$ 0.36	$ (0.86)
Shares used to compute net (loss) income per share, basic	65,688,401	56,898,478	49,814,162	48,412,531	46,431,501
Shares used to compute net (loss) income per share, diluted	65,688,401	56,898,478	49,814,162	49,615,406	46,431,501

(1) See Note 2 within the notes to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for a description of the method used to compute basic and diluted net (loss) income per share.

	As of December 31,				
	2020	2019	2018	2017	2016
	(in thousands)				
Consolidated Balance Sheets Data:					
Cash, cash equivalents, restricted cash and investments(2)	$ 461,450	$ 203,320	$ 176,984	$ 135,220	$ 123,761
Accounts receivable(3)	169	176	2,058	51,090	30,205
Working capital	390,012	115,282	116,988	146,893	110,356
Total assets	518,899	209,083	183,310	189,328	155,872
Long-term debt, net	18,099	19,786	19,689	4,676	—
Accumulated deficit	(485,342)	(429,986)	(374,497)	(289,200)	(307,059)
Total stockholders' equity	385,613	66,000	14,738	79,267	49,889

(2) As of December 31, 2020 and 2019, amount included restricted cash of $1,080 which was held as collateral for stand-by letters of credit issued to our landlord in connection with the lease of our new facility in San Carlos, California. See "Note 8. Commitments" within the notes to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for additional information on this lease.

(3) Amounts include accounts receivable from related party of $32, $0, $2,058, $51,090 and $30,000 as of December 31, 2020, 2019, 2018, 2017, and 2016, respectively.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of financial condition and results of operations together with "Item 6. Selected Financial Data" and our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in "Item 1A. Risk Factors" of this Annual Report on Form 10-K.

Overview

ChemoCentryx is a biopharmaceutical company focused on the development and commercialization of new medications targeting inflammatory disorders, autoimmune diseases and cancer. Each of our drug candidates is designed to selectively block a specific chemoattractant receptor, leaving the rest of the immune system intact. Our drug candidates are small molecules, which are orally administered, and, if approved, could address unmet medical needs, including improved efficacy, and offer significant quality of life benefits. Since patients swallow a capsule or pill instead of having to visit a clinic for an infusion or undergo an injection, our drug candidates may improve patient compliance.

We are preparing for a potential commercial launch of avacopan, an orally-administered selective complement 5a receptor inhibitor, for the treatment of patients with anti-neutrophil cytoplasmic autoantibody-associated vasculitis, or ANCA vasculitis. In November 2019, we announced positive topline data from the pivotal Phase III ADVOCATE trial of avacopan for the treatment of patients with ANCA vasculitis. In September 2020, we announced that the FDA had accepted for review the avacopan New Drug Application, or NDA, for the treatment of ANCA vasculitis in the United States and had set July 7, 2021 as the Prescription Drug User Fee Act, or PDUFA, target goal date for the avacopan NDA. If the NDA is approved, we plan to commercialize avacopan in the United States on our own. We also plan to commercialize avacopan internationally through our kidney health alliance with Vifor Fresenius Medical Care Renal Pharma Ltd. and its affiliates and sublicensees, or collectively, Vifor. In November 2020, Vifor announced that the Marketing Authorisation Application, or MAA, for avacopan in the treatment of ANCA vasculitis was accepted for review (validated) by the European Medicines Agency, or EMA, for which a decision is expected in the second half of 2021.

Our pipeline includes the following programs:

Avacopan:

- We are also developing avacopan for the treatment of severe (Hurley Stage III) hidradenitis suppurativa, or HS. In October 2020, we announced positive topline data in severe HS patients from the Phase II AURORA trial of avacopan. We plan to advance avacopan into a Phase III clinical trial for the treatment of severe HS in the second half of 2021.
- In December 2020, we announced topline data from the Phase II ACCOLADE trial of avacopan for the treatment of patients with complement 3 glomerulopathy, or C3G. We plan to discuss the evidence of clinical benefit of avacopan in C3G with the FDA in 2021.
- Based on the renal improvement results observed with avacopan treatment in both the ADVOCATE trial in ANCA vasculitis and the ACCOLADE trial in C3G, as measured by an increase in estimated glomerular filtration rate, we plan to develop avacopan in additional complement-mediated renal indications such as lupus nephritis, or LN. We plan to initiate a registrational clinical trial of avacopan for the treatment of LN in the second half of 2021.

Immuno-Oncology

- CCX559 is our orally-administered inhibitor for programmed death protein 1/programmed death-ligand 1, or PD-1/PD-L1, which we are developing for the treatment of various cancers. We plan to initiate a Phase I clinical trial of CCX559 in the first half of 2021.

Our Strategy

The key elements to our commercial and scientific strategy are to:

- Obtain regulatory approval of avacopan for the treatment of ANCA vasculitis in the United States on our own, and support our international commercialization partner Vifor and its Japanese sublicensee Kissei Pharmaceutical, Co., Ltd., or Kissei, in their regulatory approval applications;
- Commercialize avacopan in the United States on our own, where we believe a company of our size can effectively compete in rare disease markets. If our avacopan NDA is approved by the FDA, we plan to deploy a specialty sales force primarily targeting that subset of nephrologists and rheumatologists treating ANCA vasculitis patients in the United States;
- Develop and commercialize avacopan for additional indications, including C3G, severe HS, and additional complement-mediated renal indications such as LN;
- Develop our other drug candidates and establish collaborations with pharmaceutical and biotechnology companies to further develop and market our drug candidates; and
- Discover and validate new drug candidates.

As of December 31, 2020, we had an accumulated deficit of $485.3 million. We expect to continue to incur net losses as we develop our drug candidates, expand clinical trials for our drug candidates currently in clinical development, expand our research and development activities, expand our systems and facilities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of FDA approval of our drug candidates. In addition, if a product is approved for commercialization, we will need to expand our organization. Significant capital is required to launch a product and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Recent Developments

In December 2019, a disease caused by a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and has spread to nearly every country and region in the world, including those in which we have active clinical trial sites or contract manufacturing sites. The length of the pandemic and its related restrictions and their consequences for us remain subject to a number of risks and uncertainties. We experienced a delay in topline clinical data from our ongoing AURORA trial to the fourth quarter of 2020 due to COVID-19 impacting certain sites where the trial was being conducted. We do not currently anticipate any material delays in our preparation for commercial readiness to launch avacopan for the treatment of ANCA vasculitis, if approved, nor are we currently anticipating any material disruption in our clinical drug supply as a result of the pandemic.

In February 2021, results from our Phase III ADVOCATE trial of avacopan for the treatment of patients with ANCA vasculitis were published as a peer reviewed journal article in NEJM.

In February 2021, Vifor and Kissei filed the Japanese NDA, or JNDA, for avacopan in the treatment of ANCA vasculitis with the Japanese Pharmaceuticals and Medical Device Agency, or PMDA.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements as well as the reported revenues and expenses during the reported periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in the Notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following critical accounting policies relating to revenue recognition, clinical trial expenses and stock-based compensation are most important to understanding and evaluating our reported financial results.

Revenue Recognition

Effective January 1, 2018, we adopted Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, or ASC 606, using the modified retrospective transition method. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

We enter into corporate collaborations under which we may obtain upfront license fees, research and development funding and development and regulatory and commercial milestone payments and royalty payments. Our performance obligations under these arrangements may include licenses of intellectual property, distribution rights, research and development services, delivery of manufactured product, and/or participation on joint steering committees.

Licenses of intellectual property: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from upfront license fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring proportional performance for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of proportional performance each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone payments: At the inception of each arrangement that includes development, regulatory or commercial milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price. ASC 606 suggests two alternatives to use when estimating the amount of variable consideration: the expected value method and the most likely amount method. Under the expected value method, an entity considers the sum of probability-weighted amounts in a range of possible consideration amounts. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. Whichever method is used, it should be consistently applied throughout the life of the contract; however, it is not necessary for us to use the same approach for all contracts. We expect to use the most likely amount method for development and regulatory milestone payments. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis. We recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of each such milestone and any related constraint, and if necessary, adjust our estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Commercial milestones and royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and in which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue when the related sales occur. To date, we have not recognized any royalty revenue resulting from our collaboration arrangements.

Up-front payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements. Amounts payable to us are recorded as accounts receivable when our right to consideration is unconditional.

Clinical Trial Accruals and Related Expenses

We accrue and recognize expenses for clinical trial activities performed by third parties, including clinical research organizations, or CROs, and clinical investigators, based upon estimates made as of the reporting date of the work completed over the life of the individual trial in accordance with agreements established with CROs and clinical trial sites. Some CROs invoice us on a monthly basis, while others invoice upon milestones achieved and the expense is recorded as services are rendered. We determine the estimates of clinical activities incurred at the end of each reporting period through discussion with internal personnel and outside service providers as to the progress or stage of completion of trials or services, as of the end of each reporting period, pursuant to contracts with numerous clinical trial centers and CROs and the agreed upon fee to be paid for such services. The significant factors considered in estimating accruals include the number of patients enrolled and the percentage of work completed to date. Costs of setting up clinical trial sites for participation in the trials that are paid for in advance are expensed over the estimated set-up period. While the set-up periods vary from one arrangement to another, such set-up periods generally take from two to six months. Such set-up activities include clinical site identification, local ethics committee submissions, regulatory submissions, clinical investigator kick-off meetings and pre-study site visits. Clinical trial site costs related to patient enrollments are accrued as patients are entered into the trial. Due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials.

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the employee's requisite service period on a straight line basis. The fair value of the stock options is estimated using the Black-Scholes valuation model. We recorded non-cash stock-based compensation expense of $22.9 million, $11.6 million and $10.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. At December 31, 2020 and 2019, we had $33.8 million and $18.4 million, respectively, of total unrecognized stock-based compensation expense, net of estimated forfeitures, related to employee stock options that will be recognized over a weighted-average period of 2.3 years and 2.5 years, respectively. We expect to continue to grant stock options in the future, and to the extent that we do, our actual stock-based compensation expense recognized in future periods will likely increase. Determining an estimate of the fair value of equity awards using the Black-Scholes valuation model requires that use of subjective assumptions related to expected stock price volatility, term, risk-free interest rate and dividend yield.

Results of Operations

Revenue

We have not generated any revenue from product sales. For the years ended December 31, 2020, 2019 and 2018, our revenues were derived from collaboration and license revenue related to the Avacopan Agreement and the CCX140 Agreement, in each case, as amended, and the related letter agreements. For the years ended December 31, 2020 and 2019, we also have grant revenue derived from the FDA Orphan Products Development grant to support the clinical development of avacopan for the treatment of patients with C3G.

Total revenues were as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Collaboration and license revenue from related party	$ 64,392	$ 35,952	$ 42,875
Grant revenue	499	176	—
Total revenue	$ 64,891	$ 36,128	$ 42,875
Dollar increase (decrease)	$ 28,763	$ (6,747)	
Percentage increase (decrease)	80%	-16%	

We use a cost-based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize. In applying the cost-based input method of revenue recognition, we measure actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. These costs consist primarily of third-party contract costs. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as we complete our performance obligations. The increase in total revenue from 2019 to 2020 was primarily due to the acceleration of revenue recognition of the transaction price associated with the CCX140 Agreement with Vifor. Following the decision to discontinue development of CCX140 in FSGS, $46.7 million of deferred revenue was recognized as contract revenue in the second quarter of 2020. This increase was partially offset by lower costs incurred due to the completion of the avacopan ADVOCATE Phase III pivotal trial in 2020. The decrease in revenue from 2018 to 2019 was primarily due to the full enrollment of the avacopan ADVOCATE Phase III pivotal trial in 2018. Revenue in 2020 and 2019 also included $499,000 and $176,000, respectively, of grant revenue from the FDA to support the clinical development of avacopan in patients with C3G.

Research and development expenses

Research and development expenses represent costs incurred to conduct basic research, discovery and development of novel small molecule therapeutics, development of our suite of proprietary drug discovery technologies, preclinical studies and clinical trials of our drug candidates. We recognize all research and development expenses as they are incurred. These expenses consist primarily of salaries and related benefits, including stock-based compensation, third-party contract costs relating to research, formulation, manufacturing, preclinical study and clinical trial activities, laboratory consumables, and allocated facility costs. Total research and development expenses, as compared to the prior years, were as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Research and development expenses	$ 77,882	$ 70,276	$ 62,736
Dollar increase	$ 7,606	$ 7,540	
Percentage increase	11%	12%	

The increase in research and development expenses from 2019 to 2020 was primarily attributable to patient enrollment of the avacopan AURORA Phase IIb clinical trial in patients with HS, professional fees associated with the preparation of our NDA submission for avacopan for the treatment of ANCA vasculitis and higher research and drug discovery expenses, including those associated with the development of CCX559, our orally-available small molecule checkpoint (PD-1/PD-L1) inhibitor. These increases were partially offset by decreases in expenses due to the completion of the avacopan ADVOCATE Phase III pivotal trial in 2020 and the CCX140 LUMINA-1 Phase II clinical trial in 2019.

The increase in research and development expenses from 2018 to 2019 was primarily attributable to (i) an increase in Phase II clinical study expense driven by patient enrollment of the avacopan AURORA trial in patients with HS and the two CCX140 LUMINA trials in patients with FSGS, and (ii) an increase in Phase I clinical study expense due to the initiation of the avacopan ancillary studies. These increases were partially offset by decreases in 2019 in research and drug discovery expenses and expenses for the avacopan ADVOCATE Phase III pivotal trial as the study was fully enrolled in 2018.

The following table summarizes our research and development expenses by stage of development (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Phase I	$ 405	$ 2,515	$ 1,168
Phase II	25,669	24,777	13,895
Phase III	28,017	29,495	32,876
Research and drug discovery	23,791	13,489	14,797
Total R&D	$ 77,882	$ 70,276	$ 62,736

We track development expenses that are directly attributable to our clinical development candidates by phase of clinical development. Such development expenses include third-party contract costs relating to formulation, manufacturing, preclinical studies and clinical trial activities. We allocate research and development salaries, benefits or indirect costs to our development candidates and we have included such costs in research and development expenses. All remaining research and development expenses are reflected in “Research and drug discovery” which represents early stage drug discovery programs. Such expenses include allocated employee salaries and related benefits, stock-based compensation, consulting and contracted services to supplement our in-house laboratory activities, laboratory consumables and allocated facility costs associated with these earlier stage programs.

At any given time, we typically have several active early stage research and drug discovery projects. Our internal resources, employees and infrastructure are not directly tied to any individual research or drug discovery project and are typically deployed across multiple projects. As such, we do not maintain information regarding these costs incurred for our early stage research and drug discovery programs on a project specific basis. We expect our research and development expenses to increase as we advance our development programs further and increase the number and size of our clinical trials. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. We or our partners may never succeed in achieving marketing approval for any of our drug candidates. The probability of success for each drug candidate may be affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability and commercial viability. Our strategy includes entering into additional partnerships with third parties for the development and commercialization of some of our independent drug candidates.

The successful development of our drug candidates is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each drug candidate and are difficult to predict for each product. Given the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of the current or future clinical trials of our drug candidates or if, or to what extent, we will generate revenues from the commercialization and sale of any of our drug candidates. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each drug candidate, as well as ongoing assessment as to each drug candidate’s commercial potential. We may need to

raise additional capital or may seek additional strategic alliances in the future in order to complete the development and commercialization of our drug candidates, including avacopan, CCX559 and CCX507.

General and administrative expenses

Total general and administrative expenses were as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
General and administrative expenses	$ 42,186	$ 24,155	$ 20,409
Dollar increase	$ 18,031	$ 3,746	
Percentage increase	75%	18%	

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation and travel expenses, in executive, finance, business and corporate development and other administrative functions. Other general and administrative expenses include allocated facility-related costs not otherwise included in research and development expenses, legal costs of pursuing patent protection of our intellectual property, and professional fees for auditing, tax, and legal services.

The increases from 2019 to 2020 and from 2018 to 2019 were primarily due to higher employee-related expenses, including those associated with our commercialization planning efforts, and higher professional fees.

We anticipate that our general and administrative expenses will increase substantially in the future primarily due to commercialization-related activities and personnel costs to support the anticipated launch of avacopan for the treatment of ANCA vasculitis in the United States.

Other income, net

Other income, net primarily consists of interest income earned on our marketable securities and interest expense for our long-term debt. Total other income, net as compared to prior years was as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Interest income	$ 2,464	$ 4,963	$ 3,528
Interest expense	(2,643)	(2,149)	(1,224)
Total other income, net	$ (179)	$ 2,814	$ 2,304
Dollar increase (decrease)	$ (2,993)	$ 510	
Percentage increase (decrease)	-106%	22%	

The change from total other income, net for 2019 to total other expense, net for 2020 was primarily due to lower interest income from our investment portfolio in a low interest rate environment during the current COVID-19 pandemic and increased interest expense due to additional borrowings under the loan and security agreement, or Credit Facility, with Hercules Capital, Inc., or Hercules, and the amended and restated loan and security agreement, or Restated Credit Facility, with Hercules, partially offset by higher interest income from higher cash and investment balances.

The increase in total other income, net from 2018 to 2019 was primarily due to increased interest income resulting from higher cash and investment balances and rate of return on the investment portfolio, partially offset by increased interest expense due to additional borrowings under Credit Facility.

Liquidity and Capital Resources

As of December 31, 2020, we had approximately $461.5 million in cash, cash equivalents, restricted cash and investments. The following table shows a summary of our cash flows for each of the three years ended December 31, 2020, 2019 and 2018 (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Cash provided by (used in)			
Operating activities	$ (81,143)	$ (70,123)	$ 16,436
Investing activities	$ (282,360)	$ (12,526)	$ (53,068)
Financing activities	$ 356,621	$ 94,820	$ 24,700

Operating activities. Net cash used in operating activities was $81.1 million for the year ended December 31, 2020, compared to $70.1 million for the same period in 2019. This increase was primarily due to higher operating expenses and changes in working capital items. The change in operating activities from 2018 to 2019 was primarily due to a higher net loss in the 2019 period and changes in working capital items driven by the receipt of a $50.0 million milestone payment in connection with the Avacopan Agreement, a $10.0 million upfront commitment under the Avacopan Amendment, a $10.0 million of aggregate payments under the June 2018 Avacopan Letter Agreement and the CCX140 Letter Agreement and a $11.5 million payment for CCX140 development funding by Vifor in the 2018 period.

Investing activities. Net cash provided by or used in investing activities for periods presented primarily relate to the purchase, sale and maturity of investments used to fund the day-to-day needs of our business, as well as purchases or property and equipment. We invested the majority of our net proceeds received from the June 2020 equity follow-on offering and the March 2019 issuance of common stock under an equity distribution agreement in short and long term investments. The use of cash in investing activities in all periods presented also includes the investment of funds received under the Avacopan Agreement and CCX140 Agreement, in each case, as amended, and the related letter agreements. We expect cash used in investing activities in the first half of 2021 to continue to increase as we build out our new headquarters in San Carlos, California. See “Note 8. Commitments” for a detailed discussion.

Financing activities. Net cash provided by financing activities was $356.6 million for the year ended December 31, 2020, compared to $94.8 million for the year ended December 31, 2019. Net cash provided by financing activities for the year ended December 31, 2020 included net proceeds of $325.7 million from the issuance of common stock from our June 2020 equity follow-on offering and $4.4 million received under the Restated Credit Facility. Net cash provided by financing activities for the year ended December 31, 2019 included net proceeds of $73.3 million from the issuance of common stock under an equity distribution agreement. For the year ended December 31, 2018, net cash provided by financing activities included $15.0 million received under the Credit Facility. Net cash provided by financing activities for the years presented also included proceeds from the exercise of stock options and stock purchases from contributions to our 2012 Employee Stock Purchase Plan, and cash used for tendered ChemoCentryx, Inc. common stock to satisfy employee tax withholding requirements upon vesting of restricted stock units.

As of December 31, 2020, we had borrowed $20.0 million under the Credit Facility with Hercules. In January 2020, we entered into the Restated Credit facility with Hercules, which provides for borrowings of up to an additional $100.0 million in three tranches, subject to certain terms and conditions. As of December 31, 2020, we had borrowed $5.0 million under the Restated Credit Facility. See “Note 7. Long-term Debt” in the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information regarding our borrowings.

As of December 31, 2020, we had approximately $461.5 million in cash, cash equivalents, restricted cash and investments. We believe that our available cash, cash equivalents, restricted cash and investments will be sufficient to fund our anticipated level of operations and capital expenditures for at least 12 months following our financial statement issuance date, March 1, 2021. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

Our future capital requirements are difficult to forecast and will depend on many factors, including:

- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the initiation, progress, timing and completion of preclinical studies and clinical trials for our drug candidates and potential drug candidates, including any delays as a result of the COVID-19 pandemic on our business, preclinical studies or clinical trials;
- the number and characteristics of drug candidates that we pursue;
- the progress, costs and results of our clinical trials;
- the outcome, timing and cost of regulatory approvals;
- delays that may be caused by changing regulatory approvals;
- the cost and timing of hiring new employees to support continued growth;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the cost and timing of procuring clinical and commercial supplies of our drug candidates;
- the cost and timing of establishing sales, marketing and distribution capabilities; and
- the extent to which we acquire or invest in businesses, products or technologies.

Contractual Obligations and Commitments

The following is a summary of our long-term contractual cash obligations as of December 31, 2020 (in thousands):

	Payments Due by Period				
	Total	Less than One Year	1-3 Years	3-5 Years	More than 5 Years
Long-term debt (1)	$ 25,000	$ 6,389	$ 18,019	$ 592	$ —
Aggregate interest obligation (2)	4,807	1,955	2,488	364	—
Operating lease (3)	80,280	5,210	14,832	15,653	44,585
Purchase obligations (4)	7,162	7,136	26	—	—
Total contractual obligations	$ 117,249	$ 20,690	$ 35,365	$ 16,609	$ 44,585

(1) These amounts represent the future principal payments, excluding the end of the term charge, of the Credit Facility and the Restated Credit Facility we entered into with Hercules. See “Note 7. Long-term Debt” in the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

(2) These amounts represent the estimated interest for our outstanding debt obligations that are payable in cash and the end of term charge, excluding non-cash amortization of debt discount. See “Note 7. Long-term Debt” in the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

(3) These amounts represent minimum lease payments under the lease agreements for the facilities in San Carlos, California and Mountain View, California. See “Note 8. Commitments” in the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

(4) Purchase obligations include firm purchase commitments related to commercial manufacturing arrangements.

We enter into contracts in the normal course of business with CROs for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements (as defined by applicable SEC regulations) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources, except warrants and stock options.

Recent Accounting Pronouncements

See “Note 2. Summary of Significant Accounting Policies” in the Notes to Consolidated Financial Statements of this Annual Report on Form 10-K for a full description of recently issued accounting pronouncements, including the respective expected dates of adoption and effects on our consolidated financial position and results of operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. To minimize the risk in the future, we intend to maintain our portfolio of cash equivalents and short-term investments in a variety of securities, including commercial paper, money market funds, government and non-government debt securities and corporate obligations. Because of the short-term maturities of our cash equivalents and marketable securities, we do not believe that an increase or decrease in interest rates would have any significant impact on the realized value of our marketable securities.

We are affected by market risk exposure primarily through the effect of changes in interest rates on amounts payable under the Credit Facility and Restated Credit Facility. At December 31, 2020, borrowings under the Credit Facility totaled $20.0 million with an interest rate of 8.05%. Advances under the Credit Facility bear an interest rate equal to the greater of (i) 8.05% plus the prime rate as reported from time to time in The Wall Street Journal, or Prime Rate, minus 4.75%, and (ii) 8.05%. We are obligated to make interest-only payments on our borrowings under the Credit Facility through July 1, 2021, at which point we will then be obligated to repay the principal balance and interest on the advances in equal monthly installments after the interest-only period and continuing through December 1, 2022.

In addition, borrowings under the Restated Credit Facility totaled $5.0 million at December 31, 2020 with an interest rate equal to the greater of (i) 8.50% plus the Prime Rate minus 5.25%, and (ii) 8.50%, which may be reduced upon the Company achieving certain cumulative net avacopan revenue levels. We are obligated to make interest-only payments on our borrowings under the Restated Credit Facility through September 1, 2022, at which point we will then be obligated to repay the principal balance and interest on the advances in equal monthly installments after the interest-only period and continuing through February 1, 2024. If the total amounts outstanding under the Credit Facility and the Restated Credit Facility remained at this level for an entire year and the interest rates increased by 1%, our annual interest expense would increase by an additional $250,000. See “Note 7. Long-term Debt” in the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information regarding our borrowings.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements and the reports of our independent registered public accounting firm are included in this Annual Report on Form 10-K on pages F-1 through F-34 and are incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2020, management, with the participation of our Disclosure Committee, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act 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 the Chief Executive Officer and the Chief Financial and Administrative Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective. Based on this evaluation, our Chief Executive Officer and Chief Financial and Administrative Officer concluded that, as of December 31, 2020, the design and operation of our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles, or GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial and Administrative Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2020 based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO (the 2013 Framework). Based on our evaluation under the criteria set forth in Internal Control - Integrated Framework issued by the COSO, our management concluded our internal control over financial reporting was effective as of December 31, 2020.

Our independent registered public accounting firm, Ernst & Young LLP, has audited our Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K and has issued an attestation report on our internal control over financial reporting as of December 31, 2020, which appears below.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2020, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. As a result of the COVID-19 pandemic, including the related stay-at-home and shelter-in-place orders mandated by state and local governments in which we operate, many of our employees have been working remotely since March 2020. As part of our Company's transition to a temporary remote workforce, we took precautionary actions to re-evaluate our financial reporting process to provide assurance that we could report our financial results accurately and timely. We will continue to monitor and assess new potential impacts of the COVID-19 pandemic, including those related to any stay-at-home and shelter-in-place requirements, on the design and operating effectiveness of our internal controls going forward.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be contained in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with our 2021 Annual Meeting of Stockholders, or the Definitive Proxy Statement, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2020, under the headings “Election of Directors,” “Corporate Governance,” “Our Executive Officers,” and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees which is available on our website at www.chemocentryx.com. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics, and is intended to qualify as a “code of ethics” within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation.

Information required by this item will be contained in our Definitive Proxy Statement under the heading “Executive Compensation and Other Information,” and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information under the heading “Equity Compensation Plan Information” in Part II, Item 5, “Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities” is incorporated herein by reference. Additional information required by this item will be contained in our Definitive Proxy Statement under the heading “Security Ownership of Certain Beneficial Owners and Management” and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this item will be contained in our Definitive Proxy Statement under the headings “Certain Relationships and Related Party Transactions,” “Board Independence” and “Committees of the Board of Directors” and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Information required by this item will be contained in our Definitive Proxy Statement under the heading “Independent Registered Public Accountants’ Fees,” and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as part of this Annual Report on Form 10-K:

1. Financial Statements.

The following consolidated financial statements of ChemoCentryx, Inc., together with the reports thereon of Ernst & Young LLP, an independent registered public accounting firm, are included in this Annual Report on Form 10-K:

2. Financial Statement Schedules.

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits.

A list of exhibits is set forth on the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K, and is incorporated herein by reference.

Item 16. Form 10-K Summary.

None.

ChemoCentryx, Inc.

Consolidated Financial Statements
As of December 31, 2020 and 2019
and for each of the three years in the period ended December 31, 2020

Contents

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of ChemoCentryx, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ChemoCentryx, Inc. (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated March 1, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued Clinical Trial Expenses

Description of the Matter

The Company's total accrued costs for research and development expenses were $11.1 million at December 31, 2020, which included accruals related to clinical trials of $5.3 million. As discussed in Note 2 to the consolidated financial statements, the Company accrues and expenses clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with clinical research organizations and clinical trial sites. The accrual for these costs is determined by management's assessment of services completed through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services, as well as observation of services completed, and the agreed-upon fees to be paid for such services.

Auditing accrued clinical trial expenses is complex due to significant judgments and estimates made by management in determining the time period over which services will be performed and the level of effort expended in each period. The financial terms of the agreements with contract research organizations ("CROs") are subject to negotiation and amendment and may require re-assessment of the estimates.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of relevant controls that addressed the identified risks related to the Company's process of recording accrued clinical trial expenses.

To test the accrued clinical trial expenses, our audit procedures included, among others, testing the accuracy and completeness of the inputs used in management's analysis to determine costs incurred. We also inspected the terms and conditions of material vendor contracts and change orders and compared these to the calculations management used in determining the level of effort completed pursuant to these agreements. We evaluated the estimated services incurred by third parties by understanding the terms and timeline of significant projects, evaluating management's estimated percentage of work performed and costs incurred, and obtaining external confirmation of key terms and conditions for a sample of contracts. We also met with internal clinical personnel that oversee the clinical trials to understand the status of significant contract research and development activities.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2000.

Redwood City, California
March 1, 2021

Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors of ChemoCentryx, Inc.

Opinion on Internal Control over Financial Reporting

We have audited ChemoCentryx, Inc.'s internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, ChemoCentryx, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and our report dated March 1, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Redwood City, California
March 1, 2021

CHEMOCENTRYX, INC.

Consolidated Balance Sheets

(In thousands, except share and par value data)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 32,297	$ 39,179
Short-term investments	404,273	133,607
Accounts receivable, other	137	176
Accounts receivable from related party	32	—
Prepaid expenses and other current assets	4,831	1,400
Total current assets	441,570	174,362
Property and equipment, net	25,160	2,154
Long-term investments	23,800	29,454
Operating lease right-of-use assets	26,911	1,704
Other assets	1,458	1,409
Total assets	$ 518,899	$ 209,083
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 12,875	$ 1,532
Accrued and other current liabilities	19,794	19,806
Long-term debt, current	6,302	—
Deferred revenue from related party	12,587	37,742
Total current liabilities	51,558	59,080
Long-term debt, net	18,099	19,786
Non-current deferred revenue from related party	24,000	63,095
Non-current lease liabilities	38,671	566
Other non-current liabilities	958	556
Total liabilities	133,286	143,083
Commitments (Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized; 69,452,466 and 60,234,784 shares issued and outstanding at December 31, 2020 and 2019, respectively	69	60
Additional paid-in capital	870,788	495,624
Note receivable	(16)	(16)
Accumulated other comprehensive income	114	318
Accumulated deficit	(485,342)	(429,986)
Total stockholders' equity	385,613	66,000
Total liabilities and stockholders' equity	$ 518,899	$ 209,083

See accompanying notes.

CHEMOCENTRYX, INC.

Consolidated Statements of Operations

(In thousands, except per share data)

	Year Ended December 31,		
	2020	2019	2018
Revenue:			
Collaboration and license revenue from related party	$ 64,392	$ 35,952	$ 42,875
Grant revenue	499	176	—
Total revenue	64,891	36,128	42,875
Operating expenses:			
Research and development	77,882	70,276	62,736
General and administrative	42,186	24,155	20,409
Total operating expenses	120,068	94,431	83,145
Loss from operations	(55,177)	(58,303)	(40,270)
Other income (expense):			
Interest income	2,464	4,963	3,528
Interest expense	(2,643)	(2,149)	(1,224)
Total other income (expense), net	(179)	2,814	2,304
Net loss	$ (55,356)	$ (55,489)	$ (37,966)
Net loss per common share			
Basic and diluted net loss per common share	$ (0.84)	$ (0.98)	$ (0.76)
Shares used to compute basic and diluted net loss per common share	65,688	56,898	49,814

See accompanying notes.

CHEMOCENTRYX, INC.

Consolidated Statements of Comprehensive Loss

(In thousands)

	Year Ended December 31,		
	2020	2019	2018
Net loss	$ (55,356)	$ (55,489)	$ (37,966)
Unrealized gain (loss) on available-for-sale securities	(204)	516	(79)
Comprehensive loss	$ (55,560)	$ (54,973)	$ (38,045)

See accompanying notes.

CHEMOCENTRYX, INC.

Consolidated Statements of Stockholders' Equity

(In thousands, except share data)

	Common Stock		Additional Paid-In	Note	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Receivable	Income (Loss)	Deficit	Equity
Balance as of December 31, 2017	48,837,060	$ 49	$ 368,553	$ (16)	$ (119)	$ (289,200)	$ 79,267
Net loss	—	—	—	—	—	(37,966)	(37,966)
Adoption of accounting standards (Note 2)	—	—	—	—	—	(47,331)	(47,331)
Unrealized loss on investments	—	—	—	—	(79)	—	(79)
Issuance of common stock under equity incentive and employee stock purchase plans	1,912,703	2	10,690	—	—	—	10,692
Repurchased shares upon vesting of restricted stock units for tax withholdings	(97,525)	—	(678)	—	—	—	(678)
Employee stock-based compensation	—	—	9,971	—	—	—	9,971
Compensation expense related to options granted to consultants	—	—	862	—	—	—	862
Balance as of December 31, 2018	50,652,238	51	389,398	(16)	(198)	(374,497)	14,738
Net loss	—	—	—	—	—	(55,489)	(55,489)
Unrealized gain on investments	—	—	—	—	516	—	516
Issuance of common stock through Equity Distribution Agreement, net of issuance costs (Note 11)	6,491,196	6	73,270	—	—	—	73,276
Issuance of common stock under equity incentive and employee stock purchase plans	3,216,876	3	22,631	—	—	—	22,634
Repurchased shares upon vesting of restricted stock units for tax withholdings	(125,526)	—	(1,313)	—	—	—	(1,313)
Employee stock-based compensation	—	—	11,349	—	—	—	11,349
Compensation expense related to options granted to consultants	—	—	289	—	—	—	289
Balance as of December 31, 2019	60,234,784	60	495,624	(16)	318	(429,986)	66,000
Net loss	—	—	—	—	—	(55,356)	(55,356)
Unrealized loss on investments	—	—	—	—	(204)	—	(204)
Issuance of common stock upon follow-on offering, net of issuance costs (Note 11)	5,980,000	6	325,648	—	—	—	325,654
Issuance of common stock under equity incentive and employee stock purchase plans	3,330,141	3	30,313	—	—	—	30,316
Repurchased shares upon vesting of restricted stock units for tax withholdings	(92,459)	—	(3,709)	—	—	—	(3,709)
Employee stock-based compensation	—	—	20,948	—	—	—	20,948
Compensation expense related to options granted to consultants	—	—	1,964	—	—	—	1,964
Balance as of December 31, 2020	69,452,466	$ 69	$ 870,788	$ (16)	$ 114	$ (485,342)	$ 385,613

See accompanying notes.

CHEMOCENTRYX, INC.

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2020	2019	2018
Operating activities			
Net loss	$ (55,356)	$ (55,489)	$ (37,966)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Stock-based compensation	22,912	11,638	10,833
Depreciation of property and equipment	797	550	512
Non-cash lease expense	1,970	1,092	—
Non-cash interest (income) expense, net	1,490	(1,499)	(1,071)
Changes in assets and liabilities:			
Accounts receivable, other	39	(176)	—
Accounts receivable from related party	(32)	2,058	49,032
Prepaids and other current assets	(2,492)	719	(668)
Other assets	(49)	61	(31)
Accounts payable	2,982	188	(434)
Operating lease liabilities	10,270	(1,114)	—
Other liabilities	576	5,573	4,158
Deferred revenue from related party	(64,250)	(33,724)	(7,929)
Net cash (used in) provided by operating activities	(81,143)	(70,123)	16,436
Investing activities			
Purchases of property and equipment, net	(15,409)	(790)	(838)
Purchases of investments	(445,671)	(211,973)	(192,480)
Sales of investments	—	4,967	—
Maturities of investments	178,720	195,270	140,250
Net cash used in investing activities	(282,360)	(12,526)	(53,068)
Financing activities			
Proceeds from issuance of common stock	325,654	73,276	—
Proceeds from exercise of stock options and employee stock purchase plan	30,318	22,857	10,467
Employees' tax withheld and paid for restricted stock units	(3,709)	(1,313)	(678)
Borrowings under credit facility agreement, net of issuance costs	4,358	—	14,911
Net cash provided by financing activities	356,621	94,820	24,700
Net increase (decrease) in cash, cash equivalents and restricted cash	(6,882)	12,171	(11,932)
Cash, cash equivalents and restricted cash at beginning of period	40,259	28,088	40,020
Cash, cash equivalents and restricted cash at end of period	$ 33,377	$ 40,259	$ 28,088
Supplemental disclosures of cash flow information			
Cash paid for interest	$ 1,947	$ 1,735	$ 748
Right-of-use assets obtained in exchange for lease obligations (1)	$ 27,177	$ 2,796	$ —
Purchases of property and equipment, net recorded in accounts payable and accrued liabilities	$ 8,394	$ 378	$ —

(1) Amounts for the year ended December 31, 2019 include the transition adjustment of $1,301 for the adoption of Accounting Standards Codification (ASC) Topic 842 *Leases* (ASC 842).

See accompanying notes.

CHEMOCENTRYX, INC.

Notes to Consolidated Financial Statements
December 31, 2020

1. Description of Business

ChemoCentryx, Inc. (the Company) commenced operations in 1997. The Company is a biopharmaceutical company focused on the development and commercialization of new medications targeting inflammatory disorders, autoimmune diseases and cancer. The Company's principal operations are in the United States and it operates in one segment.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States (GAAP). The consolidated financial statements include the Company's accounts and those of its wholly owned subsidiaries, ChemoCentryx Ireland Limited and ChemoCentryx Limited. The operations of ChemoCentryx Ireland Limited and ChemoCentryx Limited have been immaterial to date. All intercompany amounts have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from these estimates.

Cash Equivalents and Investments

The Company considers all highly liquid investments with an original maturity at the date of purchase of three months or less to be cash equivalents. The Company limits its concentration of risk by diversifying its investments among a variety of issuers. All investments are classified as available for sale and are recorded at fair value based on quoted prices in active markets or based upon other observable inputs, with unrealized gains and losses excluded from earnings and reported in other comprehensive income (loss). Purchase premiums and discounts are recognized in interest income using the interest method over the terms of the securities. Realized gains and losses and unrealized declines in fair value that are attributed to credit-related factors are reflected in the statement of operations. The cost of securities sold is based on the specific-identification method.

Fair Value of Financial Instruments

The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, short-term investments, accounts receivable and accounts payable, approximate their fair value due to their short maturities.

2. Summary of Significant Accounting Policies (continued)

Fair value is considered to be the price at which an asset could be exchanged or a liability transferred (an exit price) in an orderly transaction between knowledgeable, willing parties in the principal or most advantageous market for the asset or liability. Where available, fair value is based on or derived from observable market prices or other observable inputs. Where observable prices or inputs are not available, valuation models are applied. The valuation techniques involve management estimation and judgment, the degree of which is dependent on the price transparency for the instruments or market and the instruments' complexity.

Concentration of Credit Risk

The Company invests in a variety of financial instruments and, by its policy, limits the amount of credit exposure with any one issuer, industry or geographic area.

For the years ended December 31, 2020, 2019 and 2018, 99.2%%, 99.5% and 100%, respectively, of the Company's total revenue was derived from the Company's collaboration with Vifor (International) Ltd., and/or its affiliates, or collectively, Vifor. Accounts receivable are typically unsecured and are concentrated in the pharmaceutical industry and government sector. Accordingly, the Company may be exposed to credit risk generally associated with pharmaceutical companies and government funded entities. The Company has not historically experienced any significant losses due to concentration of credit risk.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which range from five to seven years. Tenant improvements are depreciated over the lesser of the estimated useful life or the remaining life of the lease at the time the asset is placed into service.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its respective fair value. To date, the Company has not recorded any impairment losses.

2. Summary of Significant Accounting Policies (continued)

Leases

Effective January 1, 2019, the Company adopted ASC 842 using the modified retrospective approach. Amounts presented prior to the adoption of ASC 842 have not been adjusted and continue to be reported in accordance with the Company's historical accounting under previous lease guidance, ASC Topic 840, Leases (ASC 840). The Company determines if an arrangement includes a lease at inception. Operating leases are included in operating lease right-of-use (ROU) assets, accrued and other current liabilities and other non-current liabilities on the Company's Condensed Consolidated Balance Sheets. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The Company uses the incremental borrowing rate based on the information available at lease commencement date in determining the present value of future payments. The operating lease ROU asset also excludes lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise any such options. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. The Company has elected not to apply the recognition requirements for short-term leases. For lease agreements with lease and non-lease components, the Company generally accounts for them separately.

Revenue Recognition

Effective January 1, 2018, the Company adopted ASC Topic 606, *Revenue from Contracts with Customers* (ASC 606) using the modified retrospective transition method. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into corporate collaborations under which it may obtain upfront license fees, research and development funding and development and regulatory and commercial milestone payments and royalty payments. The Company's performance obligations under these arrangements may include licenses of intellectual property, distribution rights, research and development services, delivery of manufactured product, and/or participation on joint steering committees.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from upfront license fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring proportional performance for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of proportional performance each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

2. Summary of Significant Accounting Policies (continued)

Milestone payments: At the inception of each arrangement that includes development, regulatory or commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. There are two alternatives to use when estimating the amount of variable consideration: the expected value method and the most likely amount method. Under the expected value method, an entity considers the sum of probability-weighted amounts in a range of possible consideration amounts. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. Whichever method is used, it should be consistently applied throughout the life of the contract; however, it is not necessary for the Company to use the same approach for all contracts. The Company expects to use the most likely amount method for development and regulatory milestone payments. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis. The Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of each such milestone and any related constraint, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Commercial milestones and royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and in which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue when the related sales occur. To date, the Company has not recognized any royalty revenue resulting from its collaboration arrangements.

Up-front payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional.

Upon adoption of ASC 606 under the modified retrospective transition method, the Company recognized the cumulative effect of initially applying the new revenue standard of $47.3 million as an adjustment to the opening balance of accumulated deficit and an increase in deferred revenue.

Revenue from government and private agency grants is recognized as the related research and development expenses are incurred and to the extent that funding is approved.

Research and Development Expenses

All research and development expenses are recognized as incurred. Research and development expenses include, but are not limited to, salaries and related benefits, including stock-based compensation, third-party contract costs relating to research, formulation, manufacturing, preclinical study and clinical trial activities, laboratory consumables and allocated facility costs.

Clinical Trial Accruals

Clinical trial costs are a component of research and development expenses. The Company accrues and expenses clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with clinical research organizations and clinical trial sites. The Company determines the estimates through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

Nonrefundable advance payments for goods and services that will be used or rendered in future research and development activities, are deferred and recognized as expense in the period that the related goods are delivered or services are performed.

2. Summary of Significant Accounting Policies (continued)

Stock-Based Compensation

The Company measures stock-based compensation cost at the grant date based on the fair value of the award, and recognizes the expense over the award's vesting periods on a straight-line basis. The fair value of a stock option is estimated using the Black-Scholes valuation model, which requires that, at the date of grant, assumptions are made with respect to the expected life of the option, the volatility of the fair value of the Company's common stock, the risk-free interest rate and the expected dividend yield of the Company's common stock. The fair value of a restricted stock unit (RSU) and restricted stock award (RSA) is valued at the closing price of the Company's common stock on the date of the grant. Because stock compensation expense is based on awards ultimately expected to vest, it has been reduced by an estimate for future forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

On January 1, 2019 the Company adopted Accounting Standards Update (ASU) No. 2018-07, *Compensation – Stock Compensation* (Topic 718), which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The measurement of nonemployee stock-based compensation is fixed at the grant date. Prior to the adoption of ASU No. 2018-07, the measurement of nonemployee stock-based compensation was subject to periodic adjustment as the underlying equity instruments vested.

Comprehensive Loss

Comprehensive loss comprises net loss and other comprehensive income (loss). For the periods presented, other comprehensive income (loss) consists of unrealized gains (losses) on the Company's available-for-sale securities. For the year ended December 31, 2019, amounts reclassified from accumulated other comprehensive income (loss) to net loss for unrealized gains on available-for-sale securities were not significant, and were recorded as part of other income, net in the Consolidated Statements of Operations. For the years ended December 31, 2020 and 2018, there were no sales of investments, and therefore there were no reclassifications.

Income Taxes

The Company uses the liability method for income taxes, whereby deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are provided when the expected realization for the deferred tax assets does not meet the more-likely-than-not criteria.

The Company accounts for uncertain tax positions in the financial statements when it is not more likely than not that the position will be sustained upon examination by the tax authorities. Such tax positions must initially and subsequently be measured at the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the tax authority assuming full knowledge of the position and relevant facts. The Company's policy is to recognize any interest and penalties related to unrecognized tax benefits in income tax expense.

2. Summary of Significant Accounting Policies (continued)

Net Loss Per Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents.

Diluted net loss per share is computed by dividing net loss attributable to common stockholders by the sum of the weighted-average number of common shares outstanding and dilutive common stock equivalent shares outstanding for the period. The Company's potentially dilutive common stock equivalent shares, which include incremental common shares issuable upon (i) the exercise of outstanding stock options and warrants, (ii) vesting of RSUs and RSAs, and (iii) the purchase from contributions to the 2012 Employee Stock Purchase Plan (the ESPP) (calculated based on the treasury stock method), are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following potentially dilutive securities were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Options to purchase common stock, including purchases from contributions to ESPP	7,118	9,304	10,731
Restricted stock units	406	369	440
Restricted stock awards	14	31	27
Warrants to purchase common stock(1)	150	150	150
	7,688	9,854	11,348

(1) In 2012, the Company issued a warrant with a ten-year term to purchase 150,000 shares of its common stock at an exercise price of $20.00 per share.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standard Board (FASB) issued ASU 2016-13, *Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments*. The new standard replaces the incurred loss impairment methodology under the current standard with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The Company is required to use a forward-looking expected credit loss model for accounts receivable and other financial instruments. Credit losses relating to available-for-sale debt securities will also be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. The new standard was effective for the Company on January 1, 2020. The Company's adoption on January 1, 2020 did not have a material impact on the 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 consolidated financial statements as a result of future adoption.

3. Cash Equivalents, Restricted Cash and Investments

Cash, Cash Equivalents and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash shown in the Consolidated Statements of Cash Flows (in thousands):

	December 31,	
	2020	2019
Cash and cash equivalents	$ 32,297	$ 39,179
Restricted cash included in Other assets	1,080	1,080
Total cash, cash equivalents and restricted cash	$ 33,377	$ 40,259

Restricted cash as of December 31, 2020 and 2019 was held as collateral for a stand-by letter of credit issued by the Company to its landlord in connection with the lease of the Company's facility in San Carlos, California. See "Note 8. Commitments" for additional information on this lease.

Cash Equivalents and Investments

The amortized cost and fair value of cash equivalents and investments at December 31, 2020 and 2019 were as follows (in thousands):

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market fund	$ 30,139	$ —	$ —	$ 30,139
U.S. treasury securities	176,625	60	—	176,685
Government-sponsored agencies	12,500	—	—	12,500
Commercial paper	140,364	—	—	140,364
Asset-backed securities	25,706	23	—	25,729
Corporate debt securities	72,764	38	(7)	72,795
Total available-for-sale securities	$ 458,098	$ 121	$ (7)	$ 458,212
Classified as:				
Cash equivalents				$ 30,139
Short-term investments				404,273
Long-term investments				23,800
Total available-for-sale securities				$ 458,212

3. Cash Equivalents, Restricted Cash and Investments (continued)

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market fund	$ 30,353	$ —	$ —	$ 30,353
U.S. treasury securities	40,245	47	—	40,292
Commercial paper	12,429	—	—	12,429
Asset-backed securities	25,436	50	—	25,486
Corporate debt securities	84,605	225	(4)	84,826
Total available-for-sale securities	$ 193,068	$ 322	$ (4)	$ 193,386
Classified as:				
Cash equivalents				$ 30,325
Short-term investments				133,607
Long-term investments				29,454
Total available-for-sale securities				$ 193,386

Cash equivalents in the tables above exclude cash of $2.2 million and $8.9 million as of December 31, 2020 and 2019, respectively. All available-for-sale securities held as of December 31, 2020 had contractual maturities of less than two years. There have been no significant realized gains or losses on available-for-sale securities for the periods presented. The Company applies the specific identification method to determine the cost basis of the securities sold. No available-for-sale securities held as of December 31, 2020 have been in a continuous unrealized loss position for more than 12 months. As of December 31, 2020, unrealized losses on available-for-sale investments are not attributed to credit risk. The Company believes that it is more-likely-than-not that investments in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. The Company believes that an allowance for credit losses is unnecessary because the unrealized losses on certain of the Company's marketable securities are due to market factors. To date, the Company has not recorded any impairment charges on marketable securities.

4. Fair Value Measurements

The Company determines the fair value of financial assets and liabilities using three levels of inputs as follows:

Level 1—Inputs which include quoted prices in active markets for identical assets and 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.

4. Fair Value Measurements (continued)

Recurring Fair Value Measurements

The Company's financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows as of December 31, 2020 and 2019 (in thousands):

	December 31, 2020			
Description	Level 1	Level 2	Level 3	Total
Money market fund	$ 30,139	$ —	$ —	$ 30,139
U.S. treasury securities	—	176,685	—	176,685
Government-sponsored agencies	—	12,500	—	12,500
Commercial paper	—	140,364	—	140,364
Asset-backed securities	—	25,729	—	25,729
Corporate debt securities	—	72,795	—	72,795
Total assets	$ 30,139	$ 428,073	$ —	$ 458,212

	December 31, 2019			
Description	Level 1	Level 2	Level 3	Total
Money market fund	$ 30,353	$ —	$ —	$ 30,353
U.S. treasury securities	—	40,292	—	40,292
Commercial paper	—	12,429	—	12,429
Asset-backed securities	—	25,486	—	25,486
Corporate debt securities	—	84,826	—	84,826
Total assets	$ 30,353	$ 163,033	$ —	$ 193,386

During the year ended December 31, 2020 there were no transfers between Level 1 and Level 2 financial assets. When the Company uses observable market prices for identical securities that are traded in less active markets, the Company classifies its marketable debt instruments as Level 2. When observable market prices for identical securities are not available, the Company prices its marketable debt instruments using non-binding market consensus prices that are corroborated with observable market data; quoted market prices for similar instruments; or pricing models, such as a discounted cash flow model, with all significant inputs derived from or corroborated with observable market data. Non-binding market consensus prices are based on the proprietary valuation models of pricing providers or brokers. These valuation models incorporate a number of inputs, including non-binding and binding broker quotes; observable market prices for identical or similar securities; and the internal assumptions of pricing providers or brokers that use observable market inputs and, to a lesser degree, unobservable market inputs. The Company corroborates non-binding market consensus prices with observable market data using statistical models when observable market data exists. The discounted cash flow model uses observable market inputs, such as LIBOR-based yield curves, currency spot and forward rates, and credit ratings.

Other Fair Value Measurements

The carrying amount and estimated fair value of financial instruments not recorded at fair value at December 31, 2020 and 2019 were as follows (in thousands):

	December 31, 2020		December 31, 2019	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Long-term debt, net (1)	$ 24,401	$ 25,332	$ 19,786	$ 20,253

(1) Carrying amounts of long-term debt were net of unamortized debt discounts of $599 and $214 as of December 31, 2020 and 2019, respectively.

4. Fair Value Measurements (continued)

The fair value of the Company's long-term debt is estimated using the net present value of future debt payments, discounted at an interest rate that is consistent with market interest rates, which is a Level 2 input.

5. Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31,	
	2020	2019
Lab equipment	$ 6,098	$ 6,747
Computer equipment and software	738	1,865
Furniture and fixtures	381	552
Tenant improvements	24,826	1,607
	32,043	10,771
Less: accumulated depreciation	(6,883)	(8,617)
	$ 25,160	$ 2,154

6. Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following (in thousands):

	December 31,	
	2020	2019
Research and development related	$ 11,062	$ 13,100
Compensation related	5,498	3,608
Consulting and professional services	1,690	1,094
Current portion of operating lease liability	845	1,503
Other	699	501
	$ 19,794	$ 19,806

7. Long-term Debt

In December 2017, the Company entered into a Loan and Security Agreement with Hercules Capital, Inc. (Hercules), pursuant to which term loans in an aggregate principal amount of up to $50.0 million (as amended, the Credit Facility) were available to the Company. As of December 31, 2020, the Company had borrowed $20.0 million under the Credit Facility, with an interest rate of 8.05% per annum, and the remaining available amount had expired. Advances under the Credit Facility bear an interest rate equal to the greater of either (i) 8.05% plus the prime rate as reported from time to time in The Wall Street Journal (the Prime Rate) minus 4.75%, and (ii) 8.05%. The Company will make interest-only payments through July 1, 2021, and will then repay the principal balance and interest on the advances in equal monthly installments continuing through December 1, 2022. The Company will pay an end of term charge of $1.3 million in December 2022.

7. Long-term Debt (continued)

On January 8, 2020, the Company entered into an Amended and Restated Loan and Security Agreement (the Amended Loan Agreement) with Hercules, which amended and restated the agreement between the parties, and pursuant to which an additional term loan in an aggregate principal amount of up to $100.0 million (the Restated Credit Facility) is available to the Company at its discretion in three tranches. The first tranche of the Restated Credit Facility of up to $40.0 million was available to the Company through December 15, 2020, of which $20.0 million became available upon submission of the avacopan New Drug Application (NDA) for the treatment of patients with anti-neutrophil cytoplasmic auto-antibody associated vasculitis (ANCA vasculitis). The second tranche of up to an additional $30.0 million would be available to the Company through December 15, 2021 upon NDA approval of avacopan for the treatment of ANCA vasculitis. The third tranche of up to an additional $30.0 million would be available through December 15, 2022, subject to certain conditions.

Under the Restated Credit Facility, the Company borrowed $5.0 million from the first tranche with an interest rate of 8.50% per annum as of December 31, 2020. Advances under the Restated Credit Facility bear an initial interest rate equal to the greater of either (i) 8.50% plus the Prime Rate minus 5.25%, and (ii) 8.50%, which may be reduced upon the Company achieving certain cumulative net avacopan revenue levels. For advances under the Restated Credit Facility, the Company will make interest only payments through September 1, 2022 and will then repay the principal balance and interest on the advances in equal monthly installments through February 1, 2024. Upon satisfaction of certain conditions, the interest-only payment period and the principal balance repayment period may be extended. In addition, the Company will pay an end of term charge of 7.15% of the aggregate amount of the advances under the Restated Credit Facility.

The Company paid a commitment fee of 1% of the advances made by Hercules, with a minimum charge of $162,500 for the Credit Facility and a minimum charge of $520,000 for the Restated Credit Facility. Also, the Company reimbursed Hercules for costs incurred related to the Restated Credit Facility. These charges were recorded as discounts to the carrying value of the loan and are amortized over the term of the loan using the effective interest method.

In addition, the Company may prepay advances under the Restated Credit Facility, in whole or in part, at any time, subject to a prepayment charge that ranges from 1.0% to 2.0%, depending on the timing of the prepayment. The Restated Credit Facility is secured by substantially all of the Company's assets, excluding intellectual property. The Restated Credit Facility also includes customary loan covenants, with which the Company was in compliance for all periods presented.

In connection with the Restated Credit Facility, the Company also entered into a Right to Invest Agreement with Hercules, pursuant to which Hercules shall have the right to participate, in an amount up to $3.0 million, in any subsequent equity financing broadly marketed to multiple investors in an amount greater than $30.0 million. Hercules purchased $1.0 million of the Company's common stock during the June 2020 equity follow-on offering. See "Note 11. Stockholders' Equity" for additional information.

7. Long-term Debt (continued)

As of December 31, 2020, the Company had outstanding borrowings under the Amended Loan Agreement of $24.4 million, net of discounts of $0.6 million. Future minimum principal payments, which exclude the end of term charge, as of December 31, 2020 are as follows (in thousands):

	Amounts
Year ending December 31:	
2021	$ 6,389
2022	14,666
2023	3,353
2024	592
Total minimum payments	25,000
Less: amount representing debt discount	(599)
Present value of remaining debt payments	24,401
Less: current portion	(6,302)
Non-current portion	$ 18,099

8. Commitments

Operating Leases

In May 2004, the Company entered into a noncancelable operating lease for its current office and primary research facility located in Mountain View, California. In May 2019, the Company entered into a third amendment to the lease agreement for the same facility to extend the term of the lease through April 2021. In July 2020, the Company entered into a letter agreement to further extend the lease term through June 2021.

In July 2019, the Company entered into a ten-year operating lease for a 96,463 square foot facility in San Carlos, California to replace its current headquarters located in Mountain View, California. Upon execution of the lease agreement, the Company provided the landlord an approximately $1.1 million security deposit in the form of a letter of credit. The lease commenced in June 2020 and is anticipated to expire in February 2031 with an option to extend the lease for five years. The lease extension option was not considered in the ROU asset or the lease liability as the Company did not consider it reasonably certain the option would be exercised. Monthly rent payments are anticipated to begin in March 2021. Following a six month period of discounted rent, the Company will pay an initial annual base rent at a rate of approximately $6.5 million, which is subject to scheduled 3% annual increases, plus certain operating expenses.

The Company was provided a tenant improvement allowance of $15.4 million plus an additional allowance of $4.8 million for the same. The additional allowance will be repaid by the Company as additional rent in equal monthly payments at a rate of 7% per annum through the initial term of the lease. As of December 31, 2020, the Company received a tenant improvement allowance of $9.3 million. The Company has the right to sublease the facility, subject to landlord consent.

8. Commitments (continued)

The balance sheet classification of the Company's operating lease assets and liabilities was as follows (in thousands):

	December 31, 2020	December 31, 2019
Balance Sheet		
Assets:		
Operating lease right-of-use assets	$ 26,911	$ 1,704
Liabilities:		
Operating lease liabilities:		
Accrued and other current liabilities (1)	$ 845	$ 1,503
Non-current lease liabilities	38,671	566

(1) Includes current portion of operating lease liabilities.

The component of lease costs, which was included in operating expenses in the Company's Consolidated Statements of Operations, was as follows (in thousands):

	Year Ended December 31, 2020	2019	2018
Operating lease cost	$ 4,648	$ 1,295	$ 1,072

For the years ended December 31, 2020 and 2019, cash paid for amounts included in the measurement of lease liabilities was $1.7 million, excluding the $9.3 million tenant improvement allowance received, and $1.3 million, respectively. These amounts were included in net cash used in operating activities in the Company's Consolidated Statements of Cash Flows.

Future minimum lease payments under all noncancelable operating leases as of December 31, 2020, are as follows (in thousands):

	Operating leases
Year ending December 31:	
2021	$ 5,210
2022	7,316
2023	7,516
2024	7,721
2025	7,932
Thereafter	44,585
Total minimum payments	80,280
Less: interest	(30,296)
Less: future tenant improvement reimbursements	(10,468)
Present value of lease liabilities	$ 39,516

As of December 31, 2020, the weighted-average remaining lease term was 10.0 years and the weighted-average operating discount rate used to determine the operating lease liability was 9.5%.

9. Related Party Transactions

Vifor

Vifor held 9,194,085 shares of the Company's common stock as of December 31, 2020. The Company has collaboration agreements with Vifor: the Avacopan Agreements and the CCX140 Agreements (each as described below). See "Note 2. Summary of Significant Accounting Policies – Concentration of Credit Risk" for additional information on accounts receivable balance due from Vifor.

Avacopan Agreements

In May 2016, the Company entered into an exclusive collaboration and license agreement with Vifor pursuant to which the Company granted Vifor exclusive rights to commercialize avacopan in Europe and certain other markets (the Avacopan Agreement). Avacopan is the Company's lead drug candidate for the treatment of patients with ANCA vasculitis and other rare diseases. The Avacopan Agreement also provided Vifor with an exclusive option to negotiate during 2016 a worldwide license agreement for one of the Company's other drug candidates, CCX140, an orally-administered inhibitor of the chemokine receptor known as CCR2. In connection with the Avacopan Agreement, the Company received a non-refundable upfront payment of $85.0 million, comprising $60.0 million in cash and $25.0 million in the form of an equity investment to purchase 3,333,333 shares of the Company's common stock at a price of $7.50 per share.

In February 2017, Vifor and the Company expanded the Vifor territories under the Avacopan Agreement to include all markets outside the United States and China (the Avacopan Amendment). In connection with this February 2017 amendment, the Company received a $20.0 million upfront payment for the expanded rights. In June 2018, Vifor and the Company further expanded the Vifor territories under the Avacopan Agreement to provide Vifor with exclusive commercialization rights in China (the Avacopan Letter Agreement, and together with the Avacopan Agreement and the Avacopan Amendment, the Avacopan Agreements). The Company retains control of ongoing and future development of avacopan (other than country-specific development in the licensed territories) and all commercialization rights to avacopan in the United States. In consideration for the Avacopan Letter Agreement, the Company received a $5.0 million payment for the expanded rights.

Upon achievement of certain regulatory and commercial milestones with avacopan, the Company will receive additional payments of up to $460.0 million under the Avacopan Agreements. In addition, the Company will receive royalties, with rates ranging from the low teens to the mid-twenties, on future potential net sales of avacopan by Vifor in the licensed territories. In December 2017, the Company achieved a $50.0 million regulatory milestone when the European Medicines Agency (EMA) validated the Company's conditional marketing authorization (CMA) application for avacopan for the treatment of ANCA vasculitis.

The Company identified the following material promises under the Avacopan Agreements: (1) the license related to avacopan; (2) the development and regulatory services for the submission of the marketing authorization application (MAA); and (3) an exclusive option to negotiate a worldwide license agreement for CCX140, which expired in 2016. The Company considered that the license has standalone functionality and is capable of being distinct. However, the Company determined that the license is not distinct from the development and regulatory services within the context of the agreement because Vifor is dependent on the Company to execute the development and regulatory activities in order for Vifor to benefit from the license. As such, the license is combined with the development and regulatory services into a single performance obligation. The exclusive option related to CCX140 is a separate performance obligation and the Company determined that its transaction price is not material. As such, the transaction price under this arrangement is allocated to the license and the development and regulatory services.

9. Related Party Transactions (continued)

As of December 31, 2020, the transaction price of $153.0 million comprises the following:

- $78.0 million upfront payment under the May 2016 Avacopan Agreement. Of the total $85.0 million upfront payment received under the May 2016 Avacopan Agreement, $7.0 million was allocated to the issuance of 3,333,333 shares of the Company's common stock valued at $2.10 per share, the closing stock price on the effective date of the agreement, May 9, 2016. The remaining $78.0 million was allocated to the transaction price under this arrangement;
- $20.0 million upfront payment under the February 2017 Avacopan Amendment;
- $50.0 million regulatory milestone payment achieved upon the validation of the Company's CMA application by the EMA, for avacopan for the treatment of ANCA vasculitis in December 2017; and
- $5.0 million non-refundable upfront payment under the Avacopan Letter Agreement.

The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company determined that the combined performance obligation will be performed over the duration of the contract, which began on the effective date of May 9, 2016 and ends upon completion of development and regulatory services. The Company uses a cost-based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize. The Company believes this is the best measure of progress because other measures do not reflect how the Company transfers its performance obligation to Vifor. In applying the cost-based input method of revenue recognition, the Company measures actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. These costs consist primarily of third-party contract costs. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligations.

Avacopan Commercial Supply Agreement

In October 2020, the Company entered into a Manufacturing and Supply Agreement with Vifor (the Avacopan Commercial Supply Agreement). Under the Avacopan Commercial Supply Agreement, the Company will supply and sell avacopan drug product to Vifor for commercial use outside of the United States. Vifor will purchase avacopan drug product at a certain percentage mark up to the Company's cost of goods, in accordance with the Avacopan Agreements. Vifor's purchase of avacopan drug product is subject to certain binding forecast periods. The Avacopan Commercial Supply Agreement will expire upon the termination of the Avacopan Agreements or under certain circumstances as specified in the agreement. In connection with the Avacopan Commercial Supply Agreement, the Company also entered into a letter agreement with Vifor, pursuant to which the $6.2 million previously received from Vifor under the CCX140 Agreement (discussed below) is creditable to Vifor's purchase of avacopan drug product. No revenue was recognized during the year ended December 31, 2020 under the Avacopan Commercial Supply Agreement.

For the years ended December 31, 2020, 2019 and 2018, the Company recognized $13.0 million, $29.5 million and $37.1 million of collaboration and license revenue under the Avacopan Agreements, respectively.

CCX140 Agreements

In December 2016, the Company entered into a second collaboration and license agreement with Vifor pursuant to which the Company granted Vifor exclusive rights to commercialize CCX140 (the CCX140 Agreement) in markets outside the United States and China. CCX140 is an orally-administered inhibitor of the chemokine receptor known as CCR2. The Company retains marketing rights in the United States and China, while Vifor has commercialization rights in the rest of the world. Pursuant to the CCX140 Agreement, the Company is responsible for the clinical development of CCX140 in rare renal diseases and is reimbursed for Vifor's equal share of such development cost. Under the terms of the CCX140 Agreement, the Company received a non-refundable upfront payment of $50.0 million in 2017.

9. Related Party Transactions (continued)

In June 2018, the Company and Vifor entered into a letter agreement to expand Vifor's rights to include the right to exclusively commercialize CCX140 in China (the CCX140 Letter Agreement). In connection with the CCX140 Letter Agreement, the Company received a non-refundable payment of $5.0 million. The Company and Vifor also entered into an amendment to the CCX140 Agreement (the CCX140 Amendment, and together with the CCX140 Agreement and the CCX140 Letter Agreement, the CCX140 Agreements) to clarify the timing of certain payments with respect to development funding of the CCX140 program by Vifor, and the Company received a non-refundable payment of $11.5 million. The Company retains control of ongoing and future development of CCX140 (other than country-specific development in the licensed territories), and all commercialization rights to CCX140 in the United States.

The Company identified the following material promises under the CCX140 Agreements: (1) the license related to CCX140; and (2) the development and regulatory services for the submission of the MAA. The Company considered that the license has standalone functionality and is capable of being distinct. However, the Company determined that the license is not distinct from the development and regulatory services within the context of the agreement because Vifor is dependent on the Company to execute the development and regulatory activities in order for Vifor to benefit from the license. As such, the license is combined with the development and regulatory services into a single performance obligation.

As of December 31, 2020, the transaction price of $66.5 million comprises the following:

- $50.0 million upfront payment under the CCX140 Agreement;
- $11.5 million of CCX140 development funding by Vifor; and
- $5.0 million non-refundable upfront payment under the CCX140 Letter Agreement.

The Company determined that the combined performance obligation will be performed over the duration of the contract, which began on the effective date of December 22, 2016 and ends upon completion of development services. The Company uses a cost-based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize. The Company believes this is the best measure of progress because other measures do not reflect how the Company transfers its performance obligation to Vifor. In applying the cost-based input method of revenue recognition, the Company measures actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. These costs consist primarily of third-party contract costs. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligations.

In May 2020, the Company announced topline data from a 46 patient Phase II dose-ranging trial in the orphan kidney disorder, primary Focal Segmental Glomerulosclerosis (FSGS), called the LUMINA-1 trial. In the study, CCX140 did not demonstrate a meaningful reduction in proteinuria relative to the control group after 12 weeks of blinded treatment. As such, CCX140 will not be further developed in FSGS. As a result, the Company reduced the total anticipated FSGS budgeted costs and the corresponding transaction price related to development funding under the CCX140 Agreement by $47.2 million and recognized $46.7 million of contract revenue during the three months ended June 30, 2020. In addition, $6.2 million of deferred revenue previously received from Vifor under the CCX140 Agreements is creditable against Vifor's purchases of avacopan drug product under the Avacopan Commercial Supply Agreement. Vifor retains an option to solely develop and commercialize CCX140 in more prevalent forms of chronic kidney disease (CKD). Should Vifor later exercise the CKD option, the Company would receive co-promotion rights for CKD in the United States.

For the years ended December 31, 2020, 2019 and 2018, the Company recognized $51.4 million, $6.4 million and $5.8 million of collaboration and license revenue under the CCX140 Agreements, respectively. As of December 31, 2020, deferred revenue under the CCX140 Agreement was $0.8 million, representing the Company's remaining estimated performance obligation under these agreements.

9. Related Party Transactions (continued)

The following table presents the contract assets and liabilities for all of the Company's revenue contracts as of the following dates (in thousands):

	December 31,	
	2020	2019
Contract asset:		
Accounts receivable	$ 32	$ —
Contract liability:		
Deferred revenue	(36,587)	(100,837)

During the years ended December 31, 2020, 2019 and 2018, the Company recognized the following revenue as a result of changes in the contract asset and the contract liability balances (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Revenue recognized in the period from:			
Amount included in contract liability at the beginning of the period	$ 64,250	$ 35,781	$ 39,815
Performance obligations satisfied (or partially satisfied) in previous periods	$ (40,647)	$ (2,251)	$ (3,357)

10. Government Grant

In September 2019, the Company was awarded a two-year $1.0 million grant from the orphan drug office of the U.S. Food and Drug Administration to support the clinical development of avacopan in patients with the rare kidney disease complement 3 glomerulopathy. For the years ended December 31, 2020 and 2019, the Company recognized $0.5 million and $0.2 million of grant revenue, respectively. As of December 31, 2020 and 2019, the Company recorded $0.1 million and $0.2 million as accounts receivable, respectively.

11. Stockholders' Equity

Equity Incentive Plans

In May 2002, the stockholders approved the Amended and Restated 1997 Stock Option/Stock Issuance Plan (the 1997 Plan) and in September 2002, the stockholders approved the 2002 Equity Incentive Plan (the 2002 Plan). In February 2012, the stockholders approved the 2012 Equity Incentive Award Plan (the 2012 Plan). As of December 31, 2020, a total of 17,440,000 shares of the Company's common stock were reserved for issuance under the 2012 Plan. In addition, the number of shares available for issuance under the 2012 Plan will be annually increased by an amount equal to the lesser of: 2,000,000 shares; 4% of the outstanding shares of the Company's common stock as of the last day of the Company's immediately preceding fiscal year; or an amount determined by the Company's Board of Directors. In November 2020, the Board of Directors approved an increase to the number of shares reserved for issuance under the 2012 Plan by 2,000,000 shares effective January 1, 2021. Collectively, the 1997 Plan, the 2002 Plan and the 2012 Plan are known as the Stock Plans.

11. Stockholders' Equity (continued)

Restricted Stock

Restricted Stock Awards (RSAs) and Restricted Stock Units (RSUs) are independent of stock option grants and are not transferrable, and are subject to forfeiture if recipients terminate their service to the Company prior to the release of the vesting restrictions. RSUs granted to employees generally vest over a period of three years. RSUs and RSAs granted to its nonemployee directors vest over a one-year period, or over a three-year period in the case of an initial grant pursuant to the Company's Non-Employee Director Compensation Policy (Directors Plan). In the case of a change in control, RSUs and RSAs granted to nonemployee directors will vest in full. RSUs are also granted to nonemployee with performance conditions and the related compensation expense is recognized when the performance condition is deemed probable to be achieved. RSUs and RSAs are valued at the closing price of the Company's common stock on the date of grant. During the years ended December 31, 2019 and 2018, the weighted-average grant date fair value for restricted stock granted was $11.54 and $11.32, respectively. The total fair value of restricted stock vested during the years ended December 31, 2020, 2019 and 2018 was $11.4 million, $3.1 million and $2.4 million, respectively.

The activity for restricted stock is summarized as follows:

	Shares	Weighted-Average Grant-Date Fair Value
Balance at December 31, 2019	399,823	$ 10.54
Granted	280,360	49.26
Vested	(248,486)	13.32
Canceled	(11,667)	10.95
Unvested at December 31, 2020	420,030	$ 34.73

As of December 31, 2020, there was $6.4 million of unrecognized compensation expense associated with unvested employee restricted stock, which is expected to be recognized over a weighted-average period of 1.5 years.

Stock Options

Under the Stock Plans, incentive stock options may be granted by the Board of Directors to employees at exercise prices of not less than 100% of the fair value at the date of grant. Nonstatutory options may be granted by the Board of Directors to employees, officers, and directors of the Company or consultants at exercise prices of not less than 85% of the fair value of the common stock on the date of grant. The fair value at the date of grant is determined by the Board of Directors. Under the Stock Plans, options may be granted with different vesting terms from time to time, but not to exceed 10 years from the date of grant. Outstanding options generally vest over four years, with 25% of the total grant vesting on the first anniversary of the option grant date and 1/36th of the remaining grant vesting each month thereafter.

11. Stockholders' Equity (continued)

The following table summarizes stock option activity and related information under the Company's Stock Plans:

	Available for Grant	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance at December 31, 2019	2,192,545	9,287,901	$ 9.44		
Shares authorized	2,000,000	—			
Granted (1)	(1,267,668)	987,308	49.52		
Exercised (2)	92,459	(3,019,410)	9.70		
Forfeited and expired (3)	153,241	(141,574)	23.97		
Outstanding at December 31, 2020	3,170,577	7,114,225	$ 14.61	6.53	$ 336,617,882
Vested and expected to vest, net of estimated forfeiture at December 31, 2020		6,886,096	$ 14.16	6.46	$ 328,929,110
Exercisable at December 31, 2020		4,491,790	$ 8.52	5.42	$ 239,880,734

(1) The difference between shares granted in the number of shares available for grant and outstanding options represents the RSUs and RSAs granted for the period.
(2) Shares presented as available for grant represents shares repurchased for tax withholding upon vesting of RSUs.
(3) The difference between shares forfeited and expired in the number of shares available for grant and outstanding options represents the RSUs canceled during the period.

The aggregate intrinsic value represents the value of the Company's closing stock price on the last trading day of the period in excess of the weighted-average exercise price multiplied by the number of options outstanding or exercisable. Total intrinsic value of options exercised was $123.3 million, $48.4 million and $9.8 million during 2020, 2019 and 2018, respectively. As of December 31, 2020, there was $33.8 million of unrecognized compensation expense, net of estimated forfeitures, associated with outstanding employee stock options, which is expected to be recognized over an estimated weighted-average period of 2.3 years.

As of December 31, 2020, stock options outstanding were as follows:

	Options Outstanding	
Exercise Price Range	Shares	Weighted-Average Contractual Life
$3.29 - $5.95	711,839	5.38
$6.08 - $6.62	963,248	5.48
$6.66 - $8.19	1,267,114	4.45
$8.29 - $10.82	331,926	7.45
$10.86	733,395	7.17
$10.91 - $10.93	27,492	7.64
$11.02	955,222	8.12
$11.56 - $13.89	764,764	7.75
$13.94 - $46.52	847,357	6.19
$46.59 - $62.39	511,868	9.43
	7,114,225	6.53

11. Stockholders' Equity (continued)

Employee Stock Purchase Plan

In February 2012, the stockholders approved the ESPP. As of December 31, 2020, a total of 1,700,000 shares of the Company's common stock were reserved for issuance under the ESPP. In addition, the number of shares available for issuance under the ESPP may be annually increased on the first day of each fiscal year during the term of the ESPP, beginning with the 2012 fiscal year, by an amount equal to the lesser of: 300,000 shares; 1% of outstanding shares of the Company's common stock; or an amount determined by the Company's Board of Directors. The ESPP provides for an aggregate limit of 3,000,000 shares of common stock that may be issued under the ESPP during the term of the ESPP. In November 2020, the Board of Directors approved an increase to the number of shares reserved for issuance under the ESPP by 300,000 shares effective January 1, 2021.

The Company issued 79,161, 71,653 and 88,784 shares under the ESPP in 2020, 2019 and 2018, respectively. As of December 31, 2020, 843,737 shares were available for issuance under the ESPP. As of December 31, 2020, there was $0.2 million of unrecognized compensation expense, net of estimated forfeitures, associated with the ESPP, which is expected to be recognized over an estimated weighted-average period of 0.4 years.

Stock Awards Granted to Employees

Employee stock-based compensation expense recognized is calculated based on awards ultimately expected to vest and reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Total employee stock-based compensation expense recognized associated with restricted stock, stock options, and the ESPP, was as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Research and development	$ 7,815	$ 4,530	$ 3,632
General and administrative	13,133	6,819	6,339
Total	$ 20,948	$ 11,349	$ 9,971

Valuation Assumptions

Fair value of options granted under the Stock Plans and purchases under the Company's ESPP were estimated at grant or purchase dates using a Black-Scholes option valuation model. The Black-Scholes valuation model requires that assumptions are made with respect to various factors, including the expected volatility of the fair value of the Company's common stock. The Company has based its expected volatility on the average historical volatilities of public entities having similar characteristics including: industry, stage of life cycle, size, and financial leverage. The weighted-average expected term of options was calculated using the simplified method as prescribed by accounting guidance for stock-based compensation. This decision was based on the lack of relevant historical data due to the Company's limited historical experience.

11. Stockholders' Equity (continued)

The fair values of the employee stock options granted under the Company's Stock Plans and the option component of the shares purchased under the ESPP during 2020, 2019 and 2018 were estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Employee Stock Options			Employee Stock Purchase Plan		
	2020	2019	2018	2020	2019	2018
Dividend yield	0%	0%	0%	0%	0%	0%
Volatility	87.4%	71.3%	67.8%	118.4%	56.4%	73.8%
Weighted-average expected life (in years)	6.0	6.0	6.0	0.5	0.5	0.5
Risk-free interest rate	0.66%	2.28%	2.66%	0.13%	1.87%	2.33%
Weighted-average grant date fair value	$ 35.71	$ 7.54	$ 6.22	$ 25.93	$ 4.10	$ 3.73

Stock Awards to Nonemployees

During 2020, 2019 and 2018, the Company granted to consultants options to purchase 21,400, 82,011 and 28,534 shares of common stock, respectively. In addition, during 2020, 66,000 shares of RSUs were granted to consultants, of which 35,000 were with performance vesting conditions.

Total stock-based compensation expense recognized associated with restricted stock and stock options granted to nonemployees was as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Research and development	$ 1,892	$ 186	$ 862
General and administrative	72	103	—
Total	$ 1,964	$ 289	$ 862

Valuation Assumptions

Stock-based compensation expense associated with stock options granted to nonemployees is recognized as the stock options vest.

The estimated fair values of the stock options granted are calculated at each reporting date using the Black-Scholes option-pricing model, with the following assumptions:

	Year Ended December 31,		
	2020	2019	2018
Dividend yield	0%	0%	0%
Volatility	87%	68-87%	67-68%
Weighted-average expected life (in years)	6.0	5.5-6.0	5.7-9.9
Risk-free interest rate	0.84%	1.6-2.2%	2.7-3.0%

Equity Distribution Agreement

In December 2018, the Company entered into an Equity Distribution Agreement (EDA), pursuant to which the Company may offer and sell, from time to time, shares of the Company's common stock, par value $0.001 per share, having an aggregate offering price of up to $75.0 million. For the year ended December 31, 2019, the Company sold 6,491,196 shares of its common stock pursuant to its EDA for net proceeds of $73.3 million. These sales fully exhausted the amount available under the EDA. Accordingly, no further sales will be made under the EDA.

11. Stockholders' Equity (continued)

Equity Follow-On Offering

In June 2020, the Company completed an equity follow-on offering of 5,980,000 shares of its common stock at a public offering price of $58.00 per share. The Company received net proceeds of approximately $325.7 million, after deducting underwriting discounts, commissions and offering expenses.

12. 401(k) Plan

In October 1997, the Company established the ChemoCentryx 401(k) Plan and Trust (the 401(k) Plan). Employees may contribute, up to the percentage limit imposed by the Internal Revenue Code of 1986, as amended, an amount of their salary each calendar year until termination of their employment with the Company. The Company may elect to make matching contributions, as per the Plan; however, no matching contributions were made in the years ended December 31, 2020, 2019 and 2018.

13. Income Taxes

The Company's loss before tax is only attributable to U.S. operations. The components of the income tax (benefit) expense are as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Current (benefit from) provision for income taxes:			
Federal	$ —	$ —	$ —
State	—	—	—
Total current (benefit from) provision for income taxes	—	—	—
Deferred (benefit from) provision for income taxes:	—	—	—
Federal	—	—	—
State	—	—	—
Total deferred tax (benefit from) provision for income taxes	—	—	—
(Benefit from) provision for income taxes	$ —	$ —	$ —

A reconciliation of the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,		
	2020	2019	2018
Federal statutory income tax rate	(21.0%)	(21.0%)	(21.0%)
Permanent items	2.1	1.3	1.6
Excess tax benefit for stock-based compensation	(40.9)	(13.3)	(2.8)
Tax credits	(13.4)	(38.3)	(3.5)
Change in valuation allowance	70.4	70.3	24.5
Non-deductible executive compensation	2.7	1.0	0.6
Other	0.1	—	0.6
(Benefit from) provision for income taxes	—%	—%	—%

13. Income Taxes (continued)

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets consist of the following (in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 120,347	$ 76,033
Tax credits	49,229	39,625
Amortization of deferred stock compensation - non-qualified	4,165	5,172
Reserves and accruals	1,770	1,528
Deferred revenue	7,684	20,312
Depreciation and amortization	—	15
Lease liability	8,299	434
Gross deferred tax assets	191,494	143,119
Less: valuation allowance	(183,948)	(142,761)
Total deferred tax assets	7,546	358
Deferred tax liabilities:		
Property, Plant and Equipment	(1,894)	—
Right of use asset	(5,652)	(358)
Total deferred tax liabilities	(7,546)	(358)
Net deferred tax assets	$ —	$ —

The Company concluded that it is more likely than not that its deferred tax assets would not be realized. Accordingly, the total deferred tax assets have been fully offset by a valuation allowance. The Company's valuation allowance increased by approximately $41.2 million and $39.9 million in 2020 and 2019, respectively.

At December 31, 2020, the Company had federal and state net operating loss carryforwards of approximately $489.7 million and $225.7 million, respectively. The federal net operating loss carryforwards will begin to expire in 2032. Due to tax reform, federal net operating loss carryforwards generated in 2018 and forward no longer have an expiration date. The state net operating loss carryforwards will begin to expire in 2028.

As of December 31, 2020, the Company has federal and state research and development credit carryforwards of $14.2 million and $12.2 million, respectively. The federal research and development credits will begin to expire in 2021 if not utilized. California research and development credits can be carried forward indefinitely. The Company also has federal Orphan Drug credits of $52.6 million as of December 31, 2020. Such orphan drug credit will begin to expire in 2034 if not utilized.

Utilization of the net operating loss and credit carryforwards may be subject to annual limitation due to historical or future ownership percentage change rules provided by the Internal Revenue Code of 1986, and similar state provisions. The annual limitation may result in the expiration of certain net operating loss and credit carryforwards before their utilization.

13. Income Taxes (continued)

A reconciliation of the Company's unrecognized tax benefits for the years ended December 31, 2020, 2019 and 2018, is as follows (in thousands):

	Unrecognized Income Tax Benefits
Balance as of December 31, 2018	$ 9,714
Additions for current tax positions	3,455
Additions for prior tax positions	16,007
Balance as of December 31, 2019	29,176
Additions for current tax positions	1,317
Releases	(29)
Balance as of December 31, 2020	$ 30,464

As of December 31, 2020 and 2019, the Company had approximately $30.5 million and $29.2 million, respectively, of unrecognized tax benefits, none of which would currently affect the Company's effective tax rate if recognized due to the Company's deferred tax assets being fully offset by a valuation allowance. In 2020, unrecognized tax benefits increased due to uncertainty associated with the Company's claim of 2020 federal and California research and development and orphan drug credits. In 2020, unrecognized tax benefits decreased due to expiration of federal research and development credit. The Company is not aware of any items that will significantly increase or decrease its unrecognized tax benefits in the next 12 months.

If applicable, the Company would classify interest and penalties related to uncertain tax positions in income tax expense. Through December 31, 2020, there has been no interest expense or penalties related to unrecognized tax benefits.

For U.S. federal and California income tax purposes, the statute of limitations remains open for the years beginning 2017 and 2016, respectively, except for the carryforward of net operating losses and research and development credits generated in prior years.

14. Selected Quarterly Financial Data (unaudited)

Selected quarterly results from operations for the years ended December 31, 2020 and 2019 are as follows (in thousands except per share amounts):

	2020 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenue	$ 6,008	$ 49,440	$ 5,085	$ 4,358
Net income (loss)	$ (21,687)	$ 20,267	$ (24,060)	$ (29,876)
Basic net income (loss) per share	$ (0.35)	$ 0.32	$ (0.35)	$ (0.43)
Diluted net income (loss) per share	$ (0.35)	$ 0.29	$ (0.35)	$ (0.43)

	2019 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenue	$ 8,327	$ 7,173	$ 10,581	$ 10,047
Net loss	$ (11,949)	$ (15,150)	$ (12,862)	$ (15,528)
Basic and diluted net loss per share	$ (0.23)	$ (0.26)	$ (0.22)	$ (0.26)

The four quarters of net earnings per share may not add to the total year because of differences in the weighted-average numbers of shares outstanding during the quarters and the year.

15. Subsequent Event

In February 2021, Vifor, through its Japanese sublicensee Kissei Pharmaceutical, Co., Ltd., filed the Japanese NDA (JNDA) for avacopan in the treatment of ANCA vasculitis with the Japanese Pharmaceuticals and Medical Device Agency. The acceptance of the JNDA resulted in the Company's achievement of a $10.0 million regulatory milestone from Vifor.

EXHIBIT INDEX

Exhibit Number		Description
3.1(1)		Amended and Restated Certificate of Incorporation.
3.2(16)		Amended and Restated Bylaws.
4.1(2)		Form of Common Stock Certificate.
4.2(3)		Form of Common Stock Warrant.
4.3(3)		Form of Series B Preferred Stock Warrant.
4.4(17)		Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
10.1#(1)		Amended and Restated 1997 Stock Option/Stock Issuance Plan and form of agreement thereunder.
10.2#(1)		Amended and Restated 2002 Equity Incentive Plan and forms of agreements thereunder.
10.3#(1)		2012 Equity Incentive Award Plan and form of agreement thereunder.
10.4#(1)		2012 Employee Stock Purchase Plan.
10.5#(1)		2012 Cash Incentive Plan.
10.6#(1)		Form of Indemnification Agreement.
10.7#(18)		Amended and Restated Non-Employee Director Compensation Policy.
10.8#(5)		Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2012 Equity Incentive Award Plan.
10.9#(6)		Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2012 Equity Incentive Award Plan.
10.10#(3)		Amended and Restated Employment Agreement, effective as of January 1, 2008, by and between the Registrant and Thomas J. Schall, Ph.D.
10.11#(3)		Amended and Restated Employment Agreement, effective as of January 1, 2008, by and between the Registrant and Markus J. Cappel, Ph.D.
10.12#(3)		Amended and Restated Employment Agreement, effective as of January 1, 2008, by and between the Registrant and Susan M. Kanaya.
10.13#		Employment Agreement, effective as of December 28, 2020, by and between the Registrant and Tausif Butt.
10.14(3)		Standard Industrial/Commercial Multi-Tenant Lease, dated April 20, 2004, by and between Portola Land Company and the Registrant.
10.15(7)		First Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated August 16, 2012, by and between Portola Land Company and the Registrant.
10.16(10)		Second Amendment to Lease, dated April 13, 2017, by and between Google Inc. and the Registrant.
10.17(15)		Third Amendment to Lease, dated May 1, 2019, by and between Google Inc. and the Registrant.
10.18(20)		Lease Extension Letter, dated July 1, 2020, by and between Google Inc. and the Registrant.

10.19(14)		Lease Agreement, dated July 31, 2019, by and between the Registrant and ARE-SAN FRANCISCO NO. 63, LLC.
10.20†(8)		Product Development and Commercialization Agreement, effective as of August 22, 2006, by and between the Registrant and Glaxo Group Limited.
10.21†(3)		Amendment No. 1 to Product Development and Commercialization Agreement, effective as of September 30, 2007, by and between the Registrant and Glaxo Group Limited.
10.22†(3)		Amendment No. 2 to Product Development and Commercialization Agreement, effective as of October 6, 2008, by and between the Registrant and Glaxo Group Limited.
10.23†(3)		Amendment No. 3 to Product Development and Commercialization Agreement, effective as of August 22, 2009, by and between the Registrant and Glaxo Group Limited.
10.24†(3)		Amendment No. 4 to Product Development and Commercialization Agreement, effective as of February 26, 2010, by and between the Registrant and Glaxo Group Limited.
10.25†(3)		Amendment No. 5 to Product Development and Commercialization Agreement, effective as of November 15, 2010, by and between the Registrant and Glaxo Group Limited.
10.26†(9)		Collaboration and License Agreement, dated as of May 9, 2016, by and between the Registrant and Vifor (International) Ltd.
10.27(9)		Stock Purchase Agreement, dated as of May 9, 2016, by and between the Registrant and Vifor (International) Ltd.
10.28(6)		Collaboration and License Agreement, dated as of December 22, 2016, by and between the Registrant and Vifor (International) Ltd.
10.29†(4)		Letter Agreement dated as of February 13, 2017 between the Registrant and Vifor (International) Ltd.
10.30†(10)		Amendment to Collaboration and License Agreement, effective as of May 22, 2017 between the Registrant and Vifor Fresenius Medical Care Renal Pharma Ltd.
10.31(12)		Letter Agreement dated as of June 6, 2018 between the Registrant and Vifor (International) Ltd. Regarding Grant of Rights to CCX168 in China.
10.32(12)		Letter Agreement dated as of June 6, 2018 between the Registrant and Vifor (International) Ltd. Regarding Grant of Rights to CCX140 in China.
10.33†(12)		Amendment to Collaboration and License Agreement, effective as of June 6, 2018 between the Registrant and Vifor Fresenius Medical Care Renal Pharma Ltd.
10.34†		Manufacturing and Supply Agreement, effective as of October 29, 2020 between the Registrant and Vifor Fresenius Medical Care Renal Pharma Ltd.
10.35(11)		Loan and Security Agreement, dated as of December 28, 2017, by and between the Registrant and Hercules Capital, Inc.
10.36(13)		Amendment No. 1 to Loan and Security Agreement, dated as of December 13, 2018, by and between the Registrant and Hercules Capital, Inc.
10.37†(18)		Amended and Restated Loan and Security Agreement, dated as of January 8, 2020, by and between the Registrant and Hercules Capital, Inc.
10.38(18)		Right to Invest Agreement, dated as of January 8, 2020, by and between the Registrant and Hercules Capital, Inc.

10.39†(19)		Master Manufacturing Services Agreement, dated as of March 18, 2020, by and between the Registrant and Patheon Pharmaceuticals Inc.
10.40†(19)		Product Agreement, dated as of May 8, 2020, by and between the Registrant and Patheon Pharmaceuticals Inc.
10.41†(20)		Commercial Manufacturing Agreement, dated as of August 26, 2020, by and between the Registrant and Hovione LLC.
21.1		Subsidiaries of the Registrant.
23.1		Consent of independent registered public accounting firm.
31.1		Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2		Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1		Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2		Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS		Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH		Inline XBRL Taxonomy Extension Schema Document
101.CAL		Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF		Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB		Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE		Inline XBRL Taxonomy Extension Presentation Linkbase Document
104		Cover Page Interactive Data File (embedded within the Inline XBRL document)

(1) Filed with Amendment No. 3 to the Registrant's Registration Statement on Form S-1 on January 23, 2012 (Registration No. 333-177332), and incorporated herein by reference.
(2) Filed with Amendment No. 4 to the Registrant's Registration Statement on Form S-1 on February 6, 2012 (Registration No. 333-177332), and incorporated herein by reference.
(3) Filed with the Registrant's Registration Statement on Form S-1 on October 14, 2011 (Registration No. 333-177332), and incorporated herein by reference.
(4) Filed with the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017, filed with the SEC on May 10, 2017, and incorporated herein by reference.
(5) Filed with the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2014, filed with the SEC on August 8, 2014, and incorporated herein by reference.
(6) Filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on March 14, 2017, and incorporated herein by reference.
(7) Filed with the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2012, filed with the SEC on November 13, 2012, and incorporated herein by reference.
(8) Filed with Amendment No. 2 to Registrant's Registration Statement on Form S-1 on January 6, 2012 (Registration No. 333-177332), and incorporated herein by reference.
(9) Filed with the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2016, filed with the SEC on August 9, 2016, and incorporated herein by reference.
(10) Filed with the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017, filed with the SEC on August 8, 2017, and incorporated herein by reference.
(11) Filed with the Registrant's Current Report on Form 8-K filed on January 4, 2018, and incorporated herein by reference.

(12) Filed with the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018, filed with the SEC on August 9, 2018, and incorporated herein by reference.
(13) Filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 11, 2019, and incorporated herein by reference.
(14) Filed with the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2019, filed with the SEC on November 4, 2019, and incorporated herein by reference.
(15) Filed with the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019, filed with the SEC on August 5, 2019, and incorporated herein by reference.
(16) Filed with the Registrant's Current Report on Form 8-K filed on March 19, 2019, and incorporated herein by reference.
(17) Filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 10, 2020, and incorporated herein by reference.
(18) Filed with the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020, filed with the SEC on May 11, 2020, and incorporated herein by reference.
(19) Filed with the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020, filed with the SEC on August 10, 2020, and incorporated herein by reference.
(20) Filed with the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, filed with the SEC on November 9, 2020, and incorporated herein by reference.
# Indicates management contract or compensatory plan.
† Portions of this exhibit have been omitted pursuant to Item 601 (b)(10)(iv) of Regulation S-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

CHEMOCENTRYX, INC.

Date: March 1, 2021

By: /s/ Thomas J. Schall, Ph.D.
Thomas J. Schall, Ph.D.
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Thomas J. Schall, Ph.D. Thomas J. Schall, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2021
/s/ Susan M. Kanaya Susan M. Kanaya	Executive Vice President, Chief Financial and Administrative Officer and Secretary (Principal Financial Officer)	March 1, 2021
/s/ Pui San Kwan Pui San Kwan	Vice President, Finance (Principal Accounting Officer)	March 1, 2021
/s/ Thomas A. Edwards Thomas A. Edwards	Director	March 1, 2021
/s/ Joseph M. Feczko, M.D. Joseph M. Feczko, M.D.	Director	March 1, 2021
/s/ Rita Jain, M.D. Rita Jain, M.D.	Director	March 1, 2021
/s/ Henry A. McKinnell, Jr., Ph.D. Henry A. McKinnell, Jr., Ph.D.	Director	March 1, 2021
/s/ Geoffrey M. Parker Geoffrey M. Parker	Director	March 1, 2021
/s/ James L. Tyree James L. Tyree	Director	March 1, 2021

Exhibit 4.4

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

ChemoCentryx, Inc. (we, us and our) has one class of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended: our common stock.

Description of Common Stock

General

The following summary of the terms of our common stock is based upon our amended and restated certificate of incorporation and amended and restated bylaws. The summary is not complete, and is qualified in its entirety by reference to our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to this Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our amended and restated certificate of incorporation, our amended and restated bylaws and the applicable provisions of the General Corporation Law of the State of Delaware (DGCL) for additional information.

Under our certificate of incorporation, the total number of shares of all classes of stock that we have authority to issue is 210,000,000 shares, consisting of 200,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share.

Common Stock

Voting rights

Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, and do not have cumulative voting rights.

Dividend rights

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive dividends, if any, as and when declared by our board of directors.

Liquidation rights

In the event of any liquidation, dissolution or winding-up of our affairs, holders of common stock will be entitled to share ratably in our assets that are remaining after payment or provision for payment of all of our debts and obligations and after liquidation payments to holders of outstanding shares of preferred stock, if any.

Rights and preferences

Holders of common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights,

preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock, which we may designate in the future.

Fully paid and nonassessable

The outstanding shares of our common stock are fully paid and nonassessable.

Anti-Takeover Effects of Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware Law

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our charter documents provide that a special meeting of stockholders may be called only by our chairperson of the board of directors, Chief Executive Officer or President, or by the board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

Election and Removal of Directors

Our board of directors is divided into three classes. The directors in each class serve for a three-year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the DGCL, which prohibits persons deemed "interested stockholders" from engaging in a "business combination" with a publicly-held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least 66 2/3% of our then outstanding common stock.

The provisions of the DGCL, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Listing

Our common stock is listed for trading on the Nasdaq Global Select Market under the symbol "CCXI."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

December 23, 2020

Tausif “Tosh” Butt

Dear Tosh:

On behalf of ChemoCentryx, Inc. (“**ChemoCentryx**” or the “**Company**”), I am pleased to offer you employment as Executive Vice President, Chief Operating Officer. In this position, you will report to Thomas Schall, President and Chief Executive Officer, and will work from our office in Mountain View, California.

Compensation & Benefits

Your initial annual base salary will be $575,000.00, less applicable deductions and withholdings, which will be paid semi-monthly in accordance to the Company’s normal payroll procedures. As an exempt employee, you will be required to work the Company’s normal business hours and additional hours as required by the nature of your work assignments, and you will not be entitled to payment of overtime. You are also eligible for certain employee benefits available generally to employees of ChemoCentryx pursuant to the terms of such benefit plans. You should note that ChemoCentryx may modify salaries, benefits, duties, titles, reporting relationships, and work locations from time to time at its discretion.

You will be eligible to participate in the ChemoCentryx Corporate Bonus plan, and your target award opportunity is 50% of your gross annual salary in effect during the bonus year (the “**Annual Bonus**”). Actual payment of the Annual Bonus will be based upon factors including, but not limited to, individual and Company performance and compliance with Company policies and procedures. During your first partial year of employment, your Annual Bonus target amount will be prorated based on your date of hire. You must be an active ChemoCentryx employee in good standing (*e.g.* not subject to an active compliance investigation, verbal counseling, any written warning, or a performance improvement plan) as of the date of any Annual Bonus is paid in order to earn the bonus. The Company will have the sole discretion to determine whether and to what extent the applicable corporate and individual goals and other bonus criteria have been achieved, and the amount of any awarded Annual Bonus.

Subject to and following approval by the Company’s Board of Directors (the “**Board**”) or a committee thereof, the Company shall grant you an option to purchase 87,000 shares of the Company’s common stock (subject to stock splits and similar adjustments) with a per share exercise price equal to the per share fair market value of the Company’s common stock on the date of grant (as determined by the Board or a committee thereof as of the date of grant) (the “**Option**”) pursuant to the Company’s 2012 Equity Incentive Plan (the “**Plan**”). The Option will be governed in full by the terms and conditions of the Plan and your individual grant agreement, including the service-based vesting schedule and requirements set forth therein.

You will receive a one-time $335,000.00 sign-on bonus/advance, subject to all applicable taxes, payable within your first thirty days of employment, subject to your continued employment with the Company through the payment date. You will earn the sign-on bonus/advance if you remain continuously employed with the Company for 12 months. If you resign your employment with ChemoCentryx for any reason prior

to completing 12 months of continuous service or the Company terminates your employment for Cause (in Exhibit C) prior to your completing 12 months of continuous service, you will be required to repay the gross amount of the sign-on bonus/advance, and it will be become due and payable by you to ChemoCentryx on your last day of employment.

Relocation

You acknowledge and agree that you shall relocate to the San Francisco Bay Area by no later than June 2022. In addition, you will have the added benefit of a one-time lump sum relocation bonus of $175,000.00, less applicable taxes, payable within the first thirty days of your relocation, subject to your continued employment with the Company through the payment date. The bonus will be paid to you as an advance, prior to its being earned. You will earn the relocation bonus if you remain continuously employed with the Company for 12 months following the date the relocation bonus is paid to you. If you resign your employment with ChemoCentryx for any reason prior to the 12-month anniversary of such payment date or the Company terminates your employment for Cause prior to such date, you will be required to repay the gross amount of the relocation bonus, and it will be become due and payable by you to ChemoCentryx on your last day of employment.

Commencing on the first month following your relocation to the San Francisco Bay Area and continuing for up to 18 months thereafter (the "**Housing Allowance Payment Period**"), you shall be eligible to receive a housing allowance of $12,500 per month, less applicable taxes. These housing allowance payments will be paid to you as an advance, prior to being earned. You will earn such housing allowance payments if you remain continuously employed with the Company during the Housing Allowance Payment Period. If you resign your employment with ChemoCentryx for any reason prior to the end of the Housing Allowance Payment Period or the Company terminates your employment for Cause prior to such date, you will be required to repay the gross amount of each housing allowance payment paid to you to date, and such balance will be become due and payable by you to ChemoCentryx on your last day of employment.

Policies/Confidential Information

As a condition of your employment you will abide by the Company's policies and procedures, including but not limited to the policies set forth in the Company's Employee Handbook, as may be in effect from time to time. You will be required to sign an acknowledgement that you have read and will comply with the policies contained in the Employee Handbook. You also must read, sign, and comply with the Company's Employee Confidential Information and Inventions Assignment Agreement (the "**Confidential Information Agreement**"), attached here as ***Exhibit A***. In your work for the Company, you are expected not to make unauthorized use or disclosure of any confidential or proprietary information or materials, including trade secrets, of any former employer or other third party to whom you have an obligation of confidentiality. By signing this letter, you represent that you are able to perform your job duties within these guidelines, and you are not in unauthorized possession of any confidential documents or other property of any former employer or other third party. You further represent that you have disclosed to the Company in writing any agreement you may have with any third party (*e.g.*, a former employer) which may conflict with or limit your ability to perform your duties to the Company.

At-Will Employment; Severance

ChemoCentryx is pleased about your joining and looks forward to a beneficial and fruitful relationship. Nevertheless, you should be aware that your employment is not for a specified period of time, it is terminable at-will by either party. This means that you may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying us. Likewise, the Company may terminate your employment at any time, with or without Cause, and with or without advance notice, simply by notifying you.

If, at any time, the Company terminates your employment for Cause (as defined in ***Exhibit C***), or if either party terminates your employment as a result of your death or disability, or you resign for any reason, you will receive your base salary accrued through your last day of employment, as well as any unused vacation (if applicable) accrued through your last day of employment. Under these circumstances, you will not be entitled to any other form of compensation from the Company, including any severance benefits.

If, at any time other than on or within 12 months following the effective date of a Change in Control (as defined in ***Exhibit C***), the Company terminates your employment without Cause, and other than as a result of your death or disability, and provided such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "**Separation from Service**"), then subject to your obligations below, you shall be entitled to receive the following severance benefits (collectively, the "**Non-CIC Severance Benefits**"):

(i) a cash amount equal to twelve (12) months of your then current base salary, less all applicable withholdings and deductions, paid over such twelve (12) month period, on the schedule described below (the "**Salary Continuation**");

(ii) if you timely elect continued coverage under COBRA for yourself and your covered dependents under the Company's group health plans following such termination or resignation of employment, then the Company shall pay the COBRA premiums necessary to continue your health insurance coverage in effect for yourself and your eligible dependents on the termination date until the earliest of (A) the close of the twelve (12) month period following the termination of your employment, (B) the expiration of your eligibility for the continuation coverage under COBRA, or (C) the date when you become eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment (such period from the termination date through the earliest of (A) through (C), the "**COBRA Payment Period**"). If you become eligible for coverage under another employer's group health plan or otherwise cease to be eligible for COBRA during the period provided in this clause, you must immediately notify the Company of such event, and all payments and obligations under this clause shall cease; and

(iii) acceleration of the service-based vesting of the Option and any other equity grants you may hold as of the date of termination, to the extent then outstanding, unvested and, if applicable, unexercised or unsettled, as to the number of shares subject to such equity grants that would have vested in accordance with the applicable service-based vesting schedule as if you had been in service for an additional twelve (12) months as of your termination date (based upon full months of service).

If, (1) at any time on or within 12 months following the effective date of a Change in Control (as defined in ***Exhibit C***), (2) (i) the Company terminates your employment without Cause, and other than as a result of your death or disability, or (ii) you terminate your employment with the Company for Good Reason (as defined in ***Exhibit C***), and (3) such termination constitutes a Separation from Service, then subject to your obligations below, you shall be entitled to receive the following severance benefits (collectively, the "**CIC Severance Benefits**" and together with the Non-CIC Severance Benefits, the "**Severance Benefits**"):

(i) a lump sum cash payment consisting of an amount equal to twelve (12) months of your then current base salary, less all applicable withholdings and deductions (the "**Lump Sum Salary Payment**");

(ii) a lump sum cash payment consisting of an amount equal to your target Annual Bonus, with such bonus determined assuming all applicable performance objectives were obtained at target levels for the applicable year (the "**Lump Sum Bonus Payment**");

(iii) payment of your COBRA premiums as described above during the COBRA Payment Period, subject to the terms set forth above; and

(iv) acceleration of the service-based vesting of the Option and any other equity grants you may hold as of the date of termination, to the extent then outstanding, unvested and, if applicable, unexercised or unsettled, such that you will be deemed fully vested as to the service-based vesting requirement thereof as of your termination date.

Notwithstanding the foregoing, if any of the Company's applicable health benefits are self-funded as of the date of your Separation from Service or the Company cannot provide the foregoing COBRA benefits in a manner that is compliant with applicable law, then, instead of providing the COBRA premiums in the manner described in either clause (ii) of the Non-CIC Severance Benefits or clause (iii) of the CIC Severance Benefits, the Company will instead pay to you the applicable amount as a taxable monthly payment for the COBRA Payment Period (or any remaining portion thereof). You will be solely responsible for all matters relating to continuation of coverage under COBRA, including, without limitation, the election of such coverage and, except to the extent the Company pays COBRA premiums on your behalf, the timely payment of premiums.

Your receipt of any such Severance Benefits is conditioned upon (a) your continuing to comply with your obligations under your Confidential Information Agreement; and (b) your delivering to the Company an effective, general release of claims in favor of the Company in a form acceptable to the Company (the "**Release**") within 60 days following your termination date. The Salary Continuation, if applicable, will be paid in equal installments on the Company's regular payroll schedule and will be subject to applicable tax withholdings; provided, however, that no payments will be made prior to the date on which the Release is effective. Within 60 days following your Separation from Service (but in no event later than March 15 of the year following the year in which the Separation from Service occurred), and subject to the Release becoming effective on or prior to such date, the Company will pay you in a lump sum the Salary Continuation or the Lump Sum Salary Payment and Lump Sum Bonus Payment, as applicable, and other applicable Severance Benefits that you would have received on or prior to such date under the original schedule but for the delay while waiting for the effectiveness of the Release, with the balance of the Salary Continuation, if applicable, and other applicable Severance Benefits being paid as originally scheduled. In no event will you be entitled to both the Non-CIC Severance Benefits and the CIC Severance Benefits. For the avoidance of doubt, the vesting acceleration set forth in the Severance Benefits will not apply to any equity award(s) to the extent vesting thereof is subject to the satisfaction of any performance-based metrics (other than remaining in continuous service with the Company or certain of its affiliates). Any vesting acceleration and other vesting terms of any such performance-based equity awards, if any, will be governed by the terms of the equity plan under which they are granted and the terms and conditions set forth in the award agreements governing such awards.

Additional Tax Matters

The provisions relating to Code Section 409A and Code Section 280G each as defined and set forth in ***Exhibit C*** hereto are incorporated herein by reference and form part of this letter.

Dispute Resolution

To aid in the rapid and economical resolution of disputes that may arise between us, you and the Company agree that any and all disputes, claims, or demands in any way arising from or relating to this offer letter agreement, your employment with the Company, or the termination of your employment with the Company, including but not limited to any statutory claims, shall be resolved, to the fullest extent permitted by law, pursuant to the Federal Arbitration Act, 9 U.S.C. § 1-16, by final, binding and confidential arbitration in San Francisco, California conducted before a single arbitrator by JAMS, Inc. ("**JAMS**") or its successor, under the then-applicable JAMS rules. You acknowledge that by agreeing to this arbitration procedure, you and the Company waive the right to resolve any such dispute, claim or demand through a trial by jury or judge or by administrative proceeding. In addition, all claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair

Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law to be submitted to mandatory arbitration and are not preempted by the Federal Arbitration Act (collectively, the “**Excluded Claims**”). In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration. You will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration under this agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be available under applicable law in a court proceeding; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator’s essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS’ arbitration fees. Nothing in this offer letter is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

Miscellaneous

Federal immigration law requires that we verify your right to work legally in the United States and your employment at ChemoCentryx is contingent upon satisfactory proof of your right to work legally in the United States. On the back of the Form I-9, you will find ‘Lists of Acceptable Documents’ that both identify and establish employment eligibility. Please bring in either one document from List A or one document from list B and list C on your first day of work. These document(s) must be provided to us no later than three business days after your date of hire or your employment relationship with ChemoCentryx may be terminated.

ChemoCentryx also participates in E-Verify. All newly-hired employees are queried through this electronic system established by the Department of Homeland Security (DHS) and the Social Security Administration (SSA) to verify their identity and employment eligibility. If you will not be present at a ChemoCentryx office location on your first day of employment, please contact Human Resources for instructions.

This letter, together with its exhibits, forms your complete and exclusive agreement with the Company concerning the subject matter hereof. The employment terms in this letter supersede any other representations or agreements made to you by any party, whether oral or written. The terms of this agreement cannot be changed (except with respect to those changes expressly reserved to the Company’s discretion in this letter) without a written agreement signed by you and a duly authorized officer of the Company. This agreement is to be governed by the laws of the state of California without reference to conflicts of law principles. In case any provision contained in this agreement shall, for any reason, be held invalid or unenforceable in any respect, such invalidity or unenforceability shall not affect the other provisions of this agreement, and such provision will be reformed, construed and enforced so as to render it valid and enforceable consistent with the general intent of the parties insofar as possible under applicable law. With respect to the enforcement of this agreement, no waiver of any right hereunder shall be effective unless it is in writing. For purposes of construction of this agreement, any ambiguity shall not be construed against either party as the drafter. This agreement may be executed in more than one counterpart, and signatures transmitted via facsimile or PDF shall be deemed equivalent to originals.

Your employment at ChemoCentryx is contingent upon satisfactory completion of professional references, drug test and background checks. You agree to assist as needed and to complete any documentation at the Company’s request to meet these conditions. If you wish to accept employment at ChemoCentryx under the terms contained above, please sign and date this letter and the Confidential Information Agreement by December 28, 2020, and return to the Senior Vice President, Human Resources. This offer of employment will terminate if it is not accepted, signed, and returned by this date.

We look forward to you joining ChemoCentryx and to a productive and enjoyable work relationship.

Very best regards,

/s/ Kari Leetch
Kari E. Leetch
Senior Vice President, Human Resources

Understood and Accepted:

/s/ Tausif Butt — December 28, 2020
Employee Signature — Date

February 23, 2021
Start Date

Enclosures
Exhibit A – Employee Confidential Information and Inventions Assignment Agreement
Exhibit B – State Specific Notifications/Modification (As Applicable)
Exhibit C – Definitions and Additional Tax Matters

EXHIBIT A

CHEMOCENTRYX, INC.

EMPLOYEE CONFIDENTIAL INFORMATION AND INVENTION ASSIGNMENT AGREEMENT

In consideration of my employment or continued employment by **CHEMOCENTRYX, INC.** ("***Employer***"), and its subsidiaries, parents, affiliates, successors and assigns (together with Employer, "***Company***"), the compensation paid to me now and during my employment with Company, and Company's agreement to provide me with access to its Confidential Information (as defined below), I enter into this Employee Confidential Information and Invention Assignment Agreement with Employer (the "***Agreement***"). Accordingly, in consideration of the mutual promises and covenants contained herein, Employer (on behalf of itself and Company) and I agree as follows:

1. Confidential Information Protections.

1.1 **Recognition of Company's Rights; Nondisclosure**. My employment by Company creates a relationship of confidence and trust with respect to Confidential Information (as defined below) and Company has a protectable interest in the Confidential Information. At all times during and after my employment, I will hold in confidence and will not disclose, use, lecture upon, or publish any Confidential Information, except as required in connection with my work for Company, or as approved by an officer of Company. I will obtain written approval by an officer of Company before I lecture on or submit for publication any material (written, oral, or otherwise) that discloses and/or incorporates any Confidential Information. I will take all reasonable precautions to prevent the disclosure of Confidential Information. Notwithstanding the foregoing, pursuant to 18 U.S.C. Section 1833(b), I will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (1) is made in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (2) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. I agree that Company information or documentation to which I have access during my employment, regardless of whether it contains Confidential Information, is the property of Company and cannot be downloaded or retained for my personal use or for any use that is outside the scope of my duties for Company.

1.2 **Confidential Information**. "***Confidential Information***" means any and all confidential knowledge or data of Company, and includes any confidential knowledge or data that Company has received, or receives in the future, from third parties that Company has agreed to treat as confidential and to use for only certain limited purposes. By way of illustration but not limitation, Confidential Information includes (a) trade secrets, inventions, ideas, processes, formulas, software in source or object code, data, technology, know-how, designs and techniques, and any other work product of any nature, and all Intellectual Property Rights (defined below) in all of the foregoing (collectively, "***Inventions***"), including all Company Inventions (defined in Section 2.1); (b) information regarding research, development, new products, business and operational plans, budgets, unpublished financial statements and projections, costs, margins, discounts, credit terms, pricing, quoting procedures, future plans and strategies, capital-raising plans, internal services, suppliers and supplier information; (c) information about customers and potential customers of Company, including customer lists, names, representatives, their needs or desires with respect to the types of products or services offered by Company, and other non-public information; (d) information about Company's business partners and their services, including names, representatives, proposals, bids, contracts, and the products and services they provide; (e) information regarding personnel, employee lists, compensation, and employee skills; and (f) any other non-public information that a competitor of Company could use to Company's competitive disadvantage. However, Company agrees that I am free to use information that I knew prior to my employment with Company or that is, at the time of use, generally known in the trade or industry through no breach of this Agreement by me. Company further agrees that this Agreement does not limit my right to discuss my employment or unlawful acts in Company's workplace, including but not limited to sexual harassment, or report possible violations of law or regulation with any federal, state or local government agency, or to discuss the terms and conditions of my employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act, or to the extent that such disclosure is protected under the applicable provisions of law or regulation, including but not limited to "whistleblower" statutes or other similar provisions that protect such disclosure, to the extent any such rights are not permitted by applicable law to be the subject of nondisclosure obligations.

1.3 **Term of Nondisclosure Restrictions**. I will only use or disclose Confidential Information as provided in this Section 1 and I agree that the restrictions in Section 1.1 are intended to continue indefinitely, even after my employment by Company ends. However, if a time limitation on my obligation not to use or disclose Confidential Information is required under applicable law, and the Agreement or its restriction(s) cannot otherwise be enforced, Company and I agree that the two year period after the date my employment ends will be the time limitation relevant to the contested restriction; ***provided,***

however, that my obligation not to disclose or use trade secrets that are protected without time limitation under applicable law shall continue indefinitely.

1.4 **No Improper Use of Information of Prior Employers and Others**. During my employment by Company, I will not improperly use or disclose confidential information or trade secrets, if any, of any former employer or any other person to whom I have an obligation of confidentiality, and I will not bring onto Company's premises any unpublished documents or property belonging to a former employer or any other person to whom I have an obligation of confidentiality unless that former employer or person has consented in writing.

2. Assignments of Inventions.

2.1 **Definitions**. The term (a) **"*Intellectual Property Rights*"** means all past, present and future rights of the following types, which may exist or be created under the laws of any jurisdiction in the world: trade secrets, Copyrights, trademark and trade name rights, mask work rights, patents and industrial property, and all proprietary rights in technology or works of authorship (including, in each case, any application for any such rights and any rights to apply for any such rights, as well as all rights to pursue remedies for infringement or violation of any such rights); (b) "***Copyright***" means the exclusive legal right to reproduce, perform, display, distribute and make derivative works of a work of authorship (for example, a literary, musical, or artistic work) recognized by the laws of any jurisdiction in the world; (c) "***Moral Rights***" means all paternity, integrity, disclosure, withdrawal, special and similar rights recognized by the laws of any jurisdiction in the world; and (d) "***Company Inventions***" means any and all Inventions (and all Intellectual Property Rights related to Inventions) that are made, conceived, developed, prepared, produced, authored, edited, amended, reduced to practice, or learned or set out in any tangible medium of expression or otherwise created, in whole or in part, by me, either alone or with others, during my employment by Company, and all printed, physical, and electronic copies, and other tangible embodiments of Inventions.

2.2 **Unassigned or Nonassignable Inventions.** I recognize that this Agreement will not be deemed to require assignment of any Invention that I developed entirely on my own time without using Company's equipment, supplies, facilities, trade secrets or Confidential Information, except for those Inventions that either (i) relate to Company's actual or anticipated business, research or development, or (ii) result from or are connected with work performed by me for Company ("***Nonassignable Inventions***"). In addition, this Agreement does not apply to any Invention which qualifies fully for protection from assignment to Company under any specifically applicable state law, regulation, rule or public policy, as more specifically described in Exhibit B for employees working in certain states (collectively, the "***Specific Inventions Law***").

2.3 **Prior Inventions**.

(a) On the signature page to this Agreement is a list describing any Inventions that (i) are owned by me or in which I have an interest and that were made or acquired by me prior to my date of first employment by Company, and (ii) may relate to Company's business or actual or demonstrably anticipated research or development, and (iii) are not to be assigned to Company ("***Prior Inventions***"). If no such list is attached, I represent and warrant that no Inventions that would be classified as Prior Inventions exist as of the date of this Agreement.

(b) I agree that if I use any Prior Inventions and/or Nonassignable Inventions in the scope of my employment, or if I include any Prior Inventions and/or Nonassignable Inventions in any product or service of Company, or if my rights in any Prior Inventions and/or any Nonassignable Inventions may block or interfere with, or may otherwise be required for, the exercise by Company of any rights assigned to Company under this Agreement (each, a "***License Event***"), (i) I will immediately notify Company in writing, and (ii) unless Company and I agree otherwise in writing, I hereby grant to Company a non-exclusive, perpetual, transferable, fully-paid, royalty-free, irrevocable, worldwide license, with rights to sublicense through multiple levels of sublicensees, to reproduce, make derivative works of, distribute, publicly perform, and publicly display in any form or medium (whether now known or later developed), make, have made, use, sell, import, offer for sale, and exercise any and all present or future rights in, such Prior Inventions and/or Nonassignable Inventions. To the extent that any third parties have any rights in or to any Prior Inventions or any Nonassignable Inventions, I represent and warrant that such third party or parties have validly and irrevocably granted to me the right to grant the license stated above. For purposes of this paragraph, "***Prior Inventions***" includes any Inventions that would be classified as Prior Inventions, whether or not they are listed on the signature page to this Agreement.

2.4 **Assignment of Company Inventions**. I hereby assign to Employer all my right, title, and interest in and to any and all Company Inventions other than Nonassignable Inventions and agree that such assignment includes an assignment of all Moral Rights. To the extent such Moral Rights cannot be assigned to Employer and to the extent the following is allowed by the laws in any country where Moral Rights exist, I hereby unconditionally and irrevocably waive the enforcement of such Moral Rights, and all claims and causes of action of any kind against Employer or related to Employer's customers, with respect to such rights. I further agree that neither my successors-in-interest nor legal heirs retain any Moral Rights in

any Company Inventions. Nothing contained in this Agreement may be construed to reduce or limit Company's rights, title, or interest in any Company Inventions so as to be less in any respect than that Company would have had in the absence of this Agreement.

2.5 **Obligation to Keep Company Informed**. During my employment by Company, I will promptly and fully disclose to Company in writing all Inventions that I author, conceive, or reduce to practice, either alone or jointly with others. At the time of each disclosure, I will advise Company in writing of any Inventions that I believe constitute Nonassignable Inventions; and I will at that time provide to Company in writing all evidence necessary to substantiate my belief. Subject to Section 2.3(b), Company agrees to keep in confidence, not use for any purpose, and not disclose to third parties without my consent, any confidential information relating to Nonassignable Inventions that I disclose in writing to Company.

2.6 **Government or Third Party**. I agree that, as directed by Company, I will assign to a third party, including without limitation the United States, all my right, title, and interest in and to any particular Company Invention.

2.7 **Ownership of Work Product**. I acknowledge that all original works of authorship that are made by me (solely or jointly with others) within the scope of my employment and that are protectable by Copyright are "works made for hire," pursuant to United States Copyright Act (17 U.S.C., Section 101).

2.8 **Enforcement of Intellectual Property Rights and Assistance**. I will assist Company, in every way Company requests, including signing, verifying and delivering any documents and performing any other acts, to obtain and enforce United States and foreign Intellectual Property Rights and Moral Rights relating to Company Inventions in any jurisdictions in the world. My obligation to assist Company with respect to Intellectual Property Rights relating to Company Inventions will continue beyond the termination of my employment, but Company will compensate me at a reasonable rate after such termination for the time I actually spend on such assistance. If Company is unable for any reason, after reasonable effort, to secure my signature on any document needed in connection with the actions specified in this paragraph, I hereby irrevocably designate and appoint Employer and its duly authorized officers and agents as my agent and attorney in fact, which appointment is coupled with an interest, to act for and on my behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of this Agreement with the same legal force and effect as if executed by me. I hereby waive and quitclaim to Company any and all claims, of any nature whatsoever, which I now or may hereafter have for infringement of any Intellectual Property Rights assigned to Employer under this Agreement.

2.9 **Incorporation of Software Code**. I agree not to incorporate into any Inventions, including any Company software, or otherwise deliver to Company, any software code licensed under the GNU General Public License, Lesser General Public License, or any other license that, by its terms, requires or conditions the use or distribution of such code on the disclosure, licensing, or distribution of any source code owned or licensed by Company, **except** in strict compliance with Company's policies regarding the use of such software or as directed by Company.

3. **Records**. I agree to keep and maintain adequate and current records (in the form of notes, sketches, drawings and in any other form that is required by Company) of all Confidential Information developed by me and all Company Inventions made by me during the period of my employment at Company, which records will be available to and remain the sole property of Employer at all times.

4. **Duty of Loyalty During Employment**. During my employment by Company, I will not, without Company's written consent, directly or indirectly engage in any employment or business activity that is directly or indirectly competitive with, or would otherwise conflict with, my employment by Company.

5. **No Solicitation of Employees, Consultants or Contractors**. To the extent permitted by applicable law, I agree that during my employment and for the one year period after the date my employment ends for any reason, including but not limited to voluntary termination by me or involuntary termination by Company, I will not, as an officer, director, employee, consultant, owner, partner, or in any other capacity, either directly or through others (except on behalf of Company) solicit, induce, encourage any person known to me to be an employee, consultant, or independent contractor of Company to terminate his, her or its relationship with Company.

6. **Reasonableness of Restrictions**. I have read this entire Agreement and understand it. I agree that (a) this Agreement does not prevent me from earning a living or pursuing my career, and (b) the restrictions contained in this Agreement are reasonable, proper, and necessitated by Company's legitimate business interests. I represent and agree that I am entering into this Agreement freely, with knowledge of its contents and the intent to be bound by its terms. If a court finds this Agreement, or any of its restrictions, are ambiguous, unenforceable, or invalid, Company and I agree that the court will read the Agreement as a whole and interpret such restriction(s) to be enforceable and valid to the maximum extent allowed by law. If the court declines to enforce this Agreement in the manner provided in this Section and/or Section

12.2, Company and I agree that this Agreement will be automatically modified to provide Company with the maximum protection of its business interests allowed by law, and I agree to be bound by this Agreement as modified.

7. **No Conflicting Agreement or Obligation**. I represent that my performance of all the terms of this Agreement and as an employee of Company does not and will not breach any agreement to keep in confidence information acquired by me in confidence or in trust prior to my employment by Company. I have not entered into, and I agree I will not enter into, any written or oral agreement in conflict with this Agreement.

8. **Return of Company Property**. When I cease to be employed by Company, I will deliver to Company any and all materials, together with all copies thereof, containing or disclosing any Company Inventions, or Confidential Information. I will not copy, delete, or alter any information contained upon my Company computer or Company equipment before I return it to Company. In addition, if I have used any personal computer, server, or e-mail system to receive, store, review, prepare or transmit any Company information, including but not limited to, Confidential Information, I agree to provide Company with a computer-useable copy of all such information and then permanently delete such information from those systems; and I agree to provide Company access to my system as reasonably requested to verify that the necessary copying and/or deletion is completed. I further agree that any property situated on Company's premises and owned by Company, including disks and other storage media, filing cabinets or other work areas, is subject to inspection by Company's personnel at any time during my employment, with or without notice. Prior to leaving, I hereby agree to: provide Company any and all information needed to access any Company property or information returned or required to be returned pursuant to this paragraph, including without limitation any login, password, and account information; cooperate with Company in attending an exit interview; and complete and sign Company's termination statement if required to do so by Company.

9. **Legal and Equitable Remedies**. I agree that (a) it may be impossible to assess the damages caused by my violation of this Agreement or any of its terms, (b) any threatened or actual violation of this Agreement or any of its terms will constitute immediate and irreparable injury to Company, and (c) Company will have the right to enforce this Agreement by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that Company may have for a breach or threatened breach of this Agreement. If Company enforces this Agreement through a court order, I agree that the restrictions of Section 5 will remain in effect for a period of 12 months from the effective date of the order enforcing the Agreement.

10. **Notices**. Any notices required or permitted under this Agreement will be given to Company at its headquarters location at the time notice is given, labeled "Attention Chief Executive Officer," and to me at my address as listed on Company payroll, or at such other address as Company or I may designate by written notice to the other. Notice will be effective upon receipt or refusal of delivery. If delivered by certified or registered mail, notice will be considered to have been given five business days after it was mailed, as evidenced by the postmark. If delivered by courier or express mail service, notice will be considered to have been given on the delivery date reflected by the courier or express mail service receipt.

11. **Publication of This Agreement to Subsequent Employer or Business Associates of Employee**. If I am offered employment, or the opportunity to enter into any business venture as owner, partner, consultant or other capacity, while the restrictions in Section 5 of this Agreement are in effect, I agree to inform my potential employer, partner, co-owner and/or others involved in managing the business I have an opportunity to be associated with, of my obligations under this Agreement and to provide such person or persons with a copy of this Agreement. I agree to inform Company of all employment and business ventures which I enter into while the restrictions described in Section 5 of this Agreement are in effect and I authorize Company to provide copies of this Agreement to my employer, partner, co-owner and/or others involved in managing the business I have an opportunity to be associated with and to make such persons aware of my obligations under this Agreement.

12. **General Provisions**.

12.1 **Governing Law; Consent to Personal Jurisdiction**. This Agreement will be governed by and construed according to the laws of the state or commonwealth in which I primarily work. I expressly consent to the personal jurisdiction and venue of the state and federal courts located in the state or commonwealth in which Company's headquarters are located for any lawsuit filed there against me by Company arising from or related to this Agreement**.**

12.2 **Severability**. If any portion of this Agreement is, for any reason, held to be invalid, illegal or unenforceable, such invalidity, illegality or unenforceability will not affect the other provisions of this Agreement, and this Agreement will be construed as if such provision had never been contained in this Agreement. If any portion of this Agreement is, for any

reason, held to be excessively broad as to duration, geographical scope, activity or subject, it will be construed by limiting and reducing it, so as to be enforceable to the extent allowed by the then applicable law.

12.3 **Successors and Assigns**. This Agreement is for my benefit and the benefit of Company and its and their successors, assigns, parent corporations, subsidiaries, affiliates, and purchasers, and will be binding upon my heirs, executors, administrators and other legal representatives.

12.4 **Survival**. This Agreement will survive the termination of my employment, regardless of the reason, and the assignment of this Agreement by Company to any successor in interest or other assignee.

12.5 **Employment At-Will**. I understand and agree that nothing in this Agreement will change my at-will employment status or confer any right with respect to continuation of employment by Company, nor will it interfere in any way with my right or Company's right to terminate my employment at any time, with or without cause or advance notice.

12.6 **Waiver**. No waiver by Company of any breach of this Agreement will be a waiver of any preceding or succeeding breach. No waiver by Company of any right under this Agreement will be construed as a waiver of any other right. Company will not be required to give notice to enforce strict adherence to all terms of this Agreement.

12.7 **Export**. I agree not to export, reexport, or transfer, directly or indirectly, any U.S. technical data acquired from Company or any products utilizing such data, in violation of the United States export laws or regulations.

12.8 **Counterparts**. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

12.9 **Advice of Counsel**. **I ACKNOWLEDGE THAT, IN EXECUTING THIS AGREEMENT, I HAVE HAD THE OPPORTUNITY TO SEEK THE ADVICE OF INDEPENDENT LEGAL COUNSEL, AND I HAVE READ AND UNDERSTOOD ALL OF THE TERMS AND PROVISIONS OF THIS AGREEMENT. THIS AGREEMENT WILL NOT BE CONSTRUED AGAINST ANY PARTY BY REASON OF THE DRAFTING OR PREPARATION OF THIS AGREEMENT.**

12.10 **Entire Agreement**. The obligations in Sections 1 and 2 (except Section 2.2 and Section 2.7) of this Agreement will apply to any time during which I was previously engaged, or am in the future engaged, by Company as a consultant if no other agreement governs nondisclosure and assignment of inventions during such period. This Agreement is the final, complete and exclusive agreement of the parties with respect to the subject matter of this Agreement and supersedes and merges all prior discussions between us, ***provided***, ***however***, if, prior to execution of this Agreement, Company and I were parties to any agreement regarding the subject matter hereof, that agreement will be superseded by this Agreement prospectively only. No modification of or amendment to this Agreement will be effective unless in writing and signed by the party to be charged. Any subsequent change or changes in my duties, salary or compensation will not affect the validity or scope of this Agreement.

This Agreement will be effective as of the date signed by the Employee below.

EMPLOYER:	**EMPLOYEE:**
(Signature)	(Signature)
(Printed Name)	(Printed Name)
(Title)	(Date Signed)

PRIOR INVENTIONS

1. **Prior Inventions Disclosure**. Except as listed in Section 2 below, the following is a complete list of all Prior Inventions:

☐ No Prior Inventions.

☐ See below:

_____

_____

_____

☐ Additional sheets attached.

2. Due to a prior confidentiality agreement, I cannot complete the disclosure under Section 1 above with respect to the Prior Inventions generally listed below, the intellectual property rights and duty of confidentiality with respect to which I owe to the following party(ies):

Excluded Invention	Party(ies)	Relationship

☐ Additional sheets attached.

EXHIBIT B

STATE SPECIFIC NOTIFICATIONS/MODIFICATIONS (AS APPLICABLE)

For Employees Working in California Only

THIS IS TO NOTIFY you in accordance with Section 2870 of the California Labor Code that the Agreement between you and Company does not require you to assign, or offer to assign, any of your rights in an invention to Company if you developed the invention entirely on your own time without using Company's equipment, supplies, facilities, or trade secret information except for those inventions that either:

1. Relate at the time of conception or reduction to practice of the invention to Company's business, or actual or demonstrably anticipated research or development; or

2. Result from any work performed by you for Company.

To the extent a provision in the foregoing Agreement purports to require you to assign an invention otherwise excluded from being required to be assigned as described above, the provision is against the public policy of this state and is unenforceable.

EXHIBIT C

CERTAIN DEFINITIONS AND ADDITIONAL TAX MATTERS

Definitions

For purposes of the offer letter to which this Exhibit C is attached (this "**Agreement**"), "**Cause**" shall mean that, in the reasonable determination of the Company, you: (i) have committed an act of fraud, embezzlement or intentional dishonesty in connection with your employment, or have intentionally committed some other illegal act that has, or may be reasonably expected to have, a material adverse impact on the Company or any successor or parent subsidiary thereof; (ii) have been convicted of, or entered a plea of "guilty" or "no contest" to, a felony, or to any crime involving moral turpitude, which causes or may reasonably be expected to cause substantial economic injury or substantial injury to the reputation of the Company or any successor or parent or subsidiary thereof; (iii) have made any unauthorized use or disclosure of confidential information or trade secrets of the Company or any successor or parent or subsidiary thereof that has, or may reasonably be expected to have, a material adverse impact on such entity; (iv) have materially breached a Company policy, materially breached the provisions of this Agreement, or have committed any other intentional misconduct that has, or may be reasonably expected to have, a material adverse impact on the Company or any successor or parent or subsidiary thereof; or (v) have intentionally refused or intentionally failed to act in accordance with any lawful and proper direction or order of the Board or the appropriate individual to whom you report; provided such direction is not materially inconsistent with your customary duties and responsibilities or applicable law.

For purposes of this Agreement, "**Change in Control**" shall mean and include each of the following:

(i) the acquisition, directly or indirectly, by any "person" or "group" (as those terms are defined in Sections 3(a)(9), 13(d), and 14(d) of the Securities Exchange Act of 1934, as amended, and the rules thereunder) of "beneficial ownership" (as determined pursuant to Rule 13d-3 under the Securities Exchange Act of 1934, as amended) of securities entitled to vote generally in the election of directors ("**voting securities**") of the Company that represent fifty percent (50%) or more of the combined voting power of the Company's then outstanding voting securities, other than:

(A) an acquisition by a trustee or other fiduciary holding securities under any employee benefit plan (or related trust) sponsored or maintained by the Company or any person controlled by the Company or by any employee benefit plan (or related trust) sponsored or maintained by the Company or any person controlled by the Company,

(B) an acquisition of voting securities by the Company or a corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of the stock of the Company,

(C) an acquisition of voting securities pursuant to a transaction described in subsection (ii) below that would not constitute a Change in Control under subsection (ii), or

Notwithstanding the foregoing, the following event shall not constitute an "acquisition" by any person or group for purposes of this section: an acquisition of the Company's securities by the Company that causes the Company's voting securities beneficially owned by a person or group to represent fifty percent (50%) or more of the combined voting power of the Company's then outstanding voting securities; *provided, however,* that if a person or group shall become the beneficial owner of fifty percent (50%) or more of the combined voting power of the Company's then outstanding voting securities by reason or share acquisitions by the Company as described above and shall, after such share acquisitions by the Company, become the beneficial owner of any additional voting securities of the Company, then such acquisition shall constitute a Change in Control; or

(ii) the consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company's asserts in a single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(A) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or

owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "**Successor Entity**")) directly or directly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and

(B) after which no person or group beneficially owns voting securities representing fifty percent (50%) or more of the combined voting power of the Successor Entity; *provided, however*, that no person or group shall be treated for purposes of this Section 1(d)(iii)(B) as beneficially owning fifty percent (50%) or more of combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction.

For purposes of (i) above, the calculation of voting power shall be made as if the date of the acquisition were a record date for a vote of the Company's stockholders, and for purposes of (ii) above, the calculation of voting power shall be made as if the date of the consummation of the transaction were a record date for a vote of the Company's stockholders.

Notwithstanding the foregoing, a transaction shall not constitute a Change in Control if it is a transaction effected primarily for the purpose of financing the Company with cash (as determined by the Board in its discretion and without regard to whether such transaction is effectuated by a merger, equity financing or otherwise). If required for compliance with Section 409A of the Internal Revenue Code of 1986, as amended, and the treasury regulations thereunder ("**Code Section 409A**"), in no event will a Change in Control be deemed to have occurred if such transaction is not also a "change in the ownership of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder). The Board shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control of the Company has occurred pursuant to the above definition, and the date of the occurrence of the Change in Control and any incidental matters thereto.

For purposes of this Agreement, "**Good Reason**" shall mean the occurrence of any of the following events or conditions without your written consent and without Cause:

(i) a material diminution in your authority, duties or responsibilities;

(ii) a material diminution in the authority, duties or responsibilities of the supervisor to whom you are required to report:

(iii) a material diminution in your base compensation, unless such a reduction is imposed across-the-board to [senior management]/[similarly situated employees] of the Company;

(iv) a material change in the principal geographic location at which you must perform your duties (and the Company and you agree that any involuntary relocation of your principal place of business to a location that increases your one-way commute by more than forty (40) miles would constitute a material change); provided, however, that a material change in the principal geographic location at which you must perform your duties will in no event be deemed to include (a) a change due to the lifting or imposition of any required or permitted remote work due to the impact of COVID-19 or another pandemic in connection with which similar restrictions apply and/or (b) your relocation to the San Francisco Bay Area as contemplated by this Agreement; or

(v) any other action or inaction that constitutes a material breach by the Company of its obligations to you under this Agreement.

You must provide written notice to the Board of the occurrence of any of the foregoing events or conditions without your written consent and without Cause within ninety (90) days of the occurrence of such event or condition. The Company shall have a period of thirty (30) days to cure such event or condition after receipt of written notice of such event from you and if such action is not cured by the Company within such cure period, you must resign due to such uncured event or condition within thirty (30) days following expiration of such Company cure period. For purposes of this definition, all references to the Company shall include any acquiring, resulting or successor party in a Change in Control (or ultimate parent or affiliate thereof).

409A

It is intended that all of the severance benefits and other payments payable under this letter satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this letter will be construed to the greatest extent possible as consistent with those provisions; provided, however, that to the extent such an exemption is not available, such severance benefits and other

payments are intended to comply with the requirements of Code Section 409A to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly. Any severance benefit or other payment that may be classified as a "short-term deferral" within the meaning of Code Section 409A will be deemed short-term deferral, even if it may also qualify for an exemption from Code Section 409A. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), your right to receive any installment payments under this letter (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this letter, if you are deemed by the Company at the time of your Separation from Service to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be "nonqualified deferred compensation" under Code Section 409A, then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Code Section 409A, such payments shall not be provided to you prior to the earliest of (i) the expiration of the six-month period measured from the date of your Separation from Service with the Company, (ii) the date of your death or (iii) such earlier date as permitted under Code Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this paragraph shall be paid in a lump sum to you, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred. Except as otherwise expressly provided herein, to the extent any expense reimbursement or the provision of any in-kind benefit under the this letter is determined to be subject to (and not exempt from) Code Section 409A, the amount of any such expenses eligible for reimbursement, or the provision of any in-kind benefit, in one calendar year will not affect the expenses eligible for reimbursement or in kind benefits to be provided in any other calendar year, in no event will any expenses be reimbursed after the last day of the calendar year following the calendar year in which you incurred such expenses, and in no event will any right to reimbursement or the provision of any in-kind benefit be subject to liquidation or exchange for another benefit.

280G

If any payment or benefit you will or may receive from the Company or from another source would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code ("**Code Section 280G**"), and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then any such payment pursuant to this Agreement (each a "**Payment**") shall be equal to the Reduced Amount. The "**Reduced Amount**" shall be the largest portion, up to and including the total, of the Payments after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), that results in your receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payments may be subject to the Excise Tax. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "**Pro Rata Reduction Method**"). Notwithstanding any provision above to the contrary, if the reduction method or the Pro Rata Reduction Method would result in any portion of the Payments being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the reduction method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for you as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A of the Code shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A of the Code.

Exhibit 10.34

[***] CERTAIN INFORMATION IN THIS DOCUMENT HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Manufacturing and Supply Agreement

MANUFACTURING AND SUPPLY AGREEMENT

THIS MANUFACTURING AND SUPPLY AGREEMENT (the "Agreement") is made as of the date of last signature (the "**Effective Date**")

BY AND BETWEEN:

CHEMOCENTRYX, INC.
850 Maude Avenue, Mountain View, CA 94043
a corporation existing under the laws of the State of Delaware

("**CCX**")

- and -

VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA LTD.
Rechenstrasse 37, 9014 St. Gallen Switzerland

("**VF**")

WHEREAS CCX is a pharmaceutical company that is commercialising the Product (as defined in the License Agreement) and has licensed VF to conduct studies and commercialize the Product in certain countries pursuant to that certain Collaboration and License Agreement between CCX and VF's affiliate, Vifor (International) Ltd., dated May 9, 2016 (as amended from time to time, the "**License Agreement**"). The License Agreement was assigned by Vifor (International) Ltd. to VF on December 30, 2016.

WHEREAS, pursuant to the License Agreement, the Parties agreed to enter into this Agreement to ensure supply of Bulk Drug Product (as defined in this Agreement) for commercialization of the Product in accordance with the License Agreement.

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each Party), and intending to be legally bound the Parties agree as follows:

ARTICLE 1

STRUCTURE OF AGREEMENT AND INTERPRETATION

1.1 Definitions.

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

"**Active Pharmaceutical Ingredients**" or "**API**" has the meaning ascribed to it in the License Agreement.

"**Affiliate**" has the meaning ascribed to it in the License Agreement.

"**Annual Forecast**" has the meaning specified in Section 5.1(b).

"**Annual Product Review Report**" means the annual product review report prepared by CCX or an Affiliate of CCX as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e) and respective EU laws, directives and regulations;

"**Applicable Laws**" has the meaning ascribed to it in the License Agreement.

"**Batch**" means a defined quantity of Bulk Drug Product, Manufactured in one process or series of processes, so that it is expected to be homogeneous, in the quantity set out in the Specifications.

"**Breach Notice**" has the meaning specified in Section 8.2(a).

"**Bulk Drug Product**" has the meaning ascribed to it in the License Agreement.

"**Business Day**" has the meaning ascribed to it in the License Agreement.

"**cGMPs**" means, as applicable, current good manufacturing practices as described in:

(a) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations;

(b) EudraLex - Volume 4 Good Manufacturing Practices Guidelines published by the European Commission relating to Directive 2017/1572 (art. 2); and

(c) Division 2 of Part C of the *Food and Drug Regulations* (Canada);

"**Components**" means, collectively, all packaging components, starting materials, excipients, ingredients, and other materials required to manufacture the Bulk Drug Products in accordance with the Specifications, other than the Active Pharmaceutical Ingredients.

"**Confidential Information**" has the meaning ascribed to it in the License Agreement.

"**Continuous Improvements**" has the meaning specified in Section 2.2.

"**Contract Manufacturing Organization**" or "**CMO**" means CCX's Third Party manufacturer of the API, Component or Drug Product.

"**Costs of Goods**" has the meaning ascribed to it in the License Agreement.

"**Deficiency Notice**" has the meaning specified in Section 6.1(a).

"**Delivery Date**" means the date scheduled for shipment of Bulk Drug Product under a Firm Order as set forth in Section 5.1(d).

"**EMA**" means the European Medicines Agency.

"**FDA**" means the United States Food and Drug Administration.

"**Firm Orders**" has the meaning specified in Section 5.1(c).

"**Governmental Authority**" has the meaning ascribed to it in the License Agreement.

"**Initial Forecast"** has the meaning specified in Section 5.1(b).

"**Intellectual Property**" includes, without limitation, rights in Patents, Patent applications, formulae, Trademarks, Trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and Know-how.

"**Inventions**" means all inventions whether or not patentable, discovered, made, conceived, or conceived and reduced to practice, in the course of activities contemplated by this Agreement.

"**Know-how**" has the meaning ascribed to it in the License Agreement.

"**Late Delivery**" has the meaning specified in Section 5.4.

"**Long Term Forecast**" has the meaning specified in Section 5.1(a).

"**MAD**" has the meaning specified in Section 6.1(a).

"**Manufacture**" or "**Manufacturing**" means, all operations in the scheduling, production, packaging, labeling, warehousing, quality control testing (including as requested all in-process, release and stability testing), release and shipping of the Components, API and Bulk Drug Product performed by CCX qualified CMOs at their Manufacturing Sites in accordance with the Specifications and under the terms of this Agreement and the Quality Agreement for the Components, API and Bulk Drug Product hereunder.

"**Manufacturing Services**" means all Manufacturing to be carried out by or on behalf of CCX and/or its CMOs.

"**Manufacturing Site**" means the facility owned and operated by CCX's CMOs as agreed with VF where the Manufacturing Services will be performed by such CMOs.

"**MBR**" has the meaning specified in Section 6.1(a).

"Minimum Order Quantity" means the minimum Batch size of a Bulk Drug Product to be produced as set forth on Schedule C.

"Party" means CCX or VF, individually, or collectively as the "Parties".

"Patents" has the meaning ascribed to it in the License Agreement.

"**Product Claims**" has the meaning specified in Section 6.3(c).

"**Quality Agreement**" means the agreement between the Parties that sets out the quality assurance standards for the Manufacturing Services to be performed by CCX or its subcontractors for VF.

"**Rampdown Period**" has the meaning specified in Section 8.3(a) (iii).

"**Recall**" has the meaning specified in Section 6.2(a).

"**Regulatory Approval**" has the meaning ascribed to it in the License Agreement.

"**Regulatory Authority**" has the meaning ascribed to it in the License Agreement.

"**Representatives**" means a Party's directors, officers, employees, advisers, agents, consultants, subcontractors, service partners, professional advisors, or representatives.

"**Specifications**" means the specifications for Bulk Drug Product supplied under this Agreement along with the set of analytical tests, methods and acceptance criteria applicable (schedule A) thereto, as such specifications may be amended and revised from time to time upon mutual agreement of the Parties in accordance with the terms of this Agreement to obtain or maintain approval of the Finished Product from any Regulatory Authority, including, without any limitation:

(a) Manufacturing specifications, directions, instructions and packaging processes for the API, Components and Bulk Drug Product;

(b) Storage requirements for API, Components and Bulk Drug Product;

(c) All environmental, health and safety information for the API, Components and Bulk Drug Product, including material safety data sheets;

(d) The drug product composition packaging specifications and shipping requirements for the Bulk Drug Product; and

(e) The Specifications will include regulatory compliance obligations, as provided in this Agreement and in the Quality Agreement.

"**Supply Failure**" means any situation where CCX is unable to supply at least seventy-five (75%) of a Firm Order for a period of three (3) months from the applicable Delivery Date.

"**Territory**" has the meaning ascribed to it in the term "VIT Territory" in the License Agreement.

"**Third Party**" means any entity other than CCX or VF or any Affiliate of CCX or VF.

"**Third Party Rights**" means the Intellectual Property of any Third Party.

"**Trademarks**" has the meaning ascribed to it in the License Agreement.

"**Transfer Price**" means the transfer price for Bulk Drug Product as set forth in Section 7.3 of the License Agreement. For clarity, Transfer Price shall, without limitation, include or exclude the items as expressly identified in Schedule B.

"**Year**" means in the first year of this Agreement, the period from the Effective Date up to and including December 31 of the same calendar year, and thereafter will mean a calendar year.

1.2 Currency.

All monetary amounts expressed in this Agreement are in United States Dollars (USD).

1.3 Sections and Headings.

The division of this Agreement into Articles, Sections, Subsections, an Appendix, Schedules and Exhibits and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix, Schedule or Exhibit refers to the specified Section, Appendix, Schedule or Exhibit to this Agreement. In this Agreement, the terms "**this Agreement**", "**hereof**", "**herein**", "**hereunder**" and similar expressions refer to this Agreement as a whole and not to any particular part, Section, Appendix, Schedule or Exhibit of this Agreement.

1.4 Singular Terms.

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

1.5 Schedules and Exhibits.

The Schedules hereto and the following Exhibits are attached to, incorporated in, and form part of this Agreement:

Schedule A -API, Components and Bulk Drug Product Specifications

Schedule B -Transfer Price

Schedule C - Minimum Order Quantity

Schedule D - List of approved CMOs

Schedule E -Technical Dispute Resolutions

ARTICLE 2

CCX MANUFACTURING SERVICES

2.1 Manufacturing and Supply Services.

The Parties agree to enter into this Agreement to ensure supply of Bulk Drug Product for commercialization of the Product (as defined in the License Agreement). Manufacturing and Supply of Bulk Drug Product for other purposes such us clinical trials, MAP programs or any other use beyond commercialization shall be agreed by the Parties on case by case basis and will be formalized in a separate agreement.

(a) Sourcing, Manufacturing and Supply of Bulk Drug Product. CCX shall be responsible for sourcing Components and API, and for the Manufacture and supply to VF of the Bulk Drug Product in a professional manner in full compliance with industry standard and that level of care and skill ordinarily exercised by other professional manufacturers in similar circumstances and in accordance with the Specifications, applicable laws, the Quality Agreement and the terms and conditions of this Agreement, pursuant to individual purchase orders placed by VF. CCX shall use and ensure that its CMO uses the necessary and appropriate machinery and equipment and its personnel shall be adequately selected, trained and monitored for manufacturing and supplying the Bulk Drug Products. In case of any intended change to the equipment used for Manufacturing, the change control process set forth in the Quality Agreement shall be followed. CCX shall provide VF with reasonable opportunities to review and provide comment upon any proposes CMO agreement(s) which CCX shall reasonably execute.

(b) Subcontractors. CCX shall not be entitled to subcontract any Manufacturing Services hereunder to any subcontractor that is not an approved CMO without VF's prior written consent. The Quality Agreement sets forth further stipulations to be abided by regarding subcontracting for Manufacturing Services. In any case, CCX remains responsible and fully liable for any acts or omissions of its subcontractors (including any CMO) in accordance with the provisions of Section 7.1 of the License Agreement. For greater certainty, a list of the agreed CMOs on the Effective Date is attached hereto as Schedule D and shall be amended by the Parties from time to time, following discussions at the JMC.

More in particular, if the JMC desires to qualify an additional source for the API, Component or Bulk Product, the Parties shall comply with the provisions of Section 7.1 of the License Agreement and CCX will provide VF with advance notice of any such change and the Parties shall cooperate to address any Regulatory Authority notices or Regulatory Approvals that may be required. CCX will not use such additional source before it is approved by both Parties as set forth in the paragraph above. CCX will promptly advise VF if it or any of its CMOs encounter supply problems, including delays and/or delivery of non-conforming API or Components.

(c) Further Assistance. CCX shall provide and shall cause any CMO to provide all such assistance, documents and information as VF or any of its Affiliates may reasonably request in connection with obtaining and maintaining Regulatory Approvals regarding the Product with any relevant Regulatory Authorities of any country in the Territory.

(d) Authorizations and Permits. CCX warrants that it and its CMOs hold throughout the term of this Agreement at its own cost all necessary authorizations, licenses and permits for all activities performed under this Agreement by CCX and its CMOs, respectively, including without limitation with respect to Manufacture of all API, Components and Bulk Drug Products to be sold in the Territory, from the competent Regulatory Authorities, including but not limited to a valid cGMP certificate. CCX shall provide [***] and upon VF's request all customary confirmations and authorizations that are necessary or useful for the registration and commercialization of the Product by VF. Without prejudice to any of VF's other rights under this Agreement, CCX shall inform VF promptly in writing in the event any such authorization is not obtained timely or is withdrawn or otherwise under investigation.

(e) Quality Control and Quality Assurance. CCX will perform or have its agents perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to VF will be the responsibility of CCX's quality assurance group. CCX will perform its Batch review and release responsibilities in accordance with CCX's and or its CMO's standard operating procedures, cGMP and the Specifications. Each time CCX ships Bulk Drug Products to VF, it will give VF for each Batch of Bulk Drug Products a certificate of analysis and certificate of compliance (see Batch certificate requirements pursuant to European guideline EMA/INS/MRA/387218) including [***] Bulk Drug Product samples and a statement that the Batch has been manufactured and tested in accordance with Specifications and cGMPs. In the case of major deviations, critical deviations or out-of-Specification ("**OOS**") investigations, a copy of the respective reports will be supplied to VF. Copies (e.g. as pdf) of Batch documents are sent to VF upon request or in accordance with the Quality Agreement. VF will have the sole responsibility for the release of Products to the market in the Territory. The form and style of Batch documents, including, but not limited to, Batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of CCX or its CMO. VF, as applicable will be permitted to review and comment on the form and style of all Batch documents prior to initiation of Manufacturing Services and will have the right to use the Batch documents as required for any Regulatory filing ascribed to it in the License Agreement or otherwise to meet VF's obligations under Applicable Law. Specific Bulk Drug Product related information contained in the Batch documents is CCX's property.

(f) Stability Testing. CCX will conduct stability testing on the API and Bulk Drug Products in accordance with the protocols set out in the Specifications. CCX will not make any changes to these testing protocols without prior written approval from VF. If a confirmed stability test failure occurs, CCX will notify VF within [***] Business Days, after which CCX and VF will have [***] Business Days to review the documents. CCX will provide VF with an opportunity to review and comment on CCX's proposed response to its CMOs with respect to a confirmed stability test failure, which CCX shall reasonably consider. CCX and VF will jointly agree on the measures to be undertaken to investigate the cause of the failure, including which Party will bear the cost of the investigation. CCX will not be liable for these costs unless it has failed to perform the Manufacturing and/or the stability testing in accordance with the Specifications and cGMPs. CCX will give VF all stability test data and results promptly upon VF's request. Notwithstanding anything to the contrary, taking any regulatory actions into account, CCX shall [***] with respect to the proceedings and methods to be to be undertaken in such investigations, and shall communicate with its CMOs regarding such matters. CCX shall provide to VF a copy of any related correspondence from its CMOs within [***] Business Days after CCX's receipt thereof.

(g) Additional Services. If VF requests services other than those contemplated herein (such as qualification of a new packaging configuration or shipping studies, or validation of alternative Batch sizes), CCX will provide a good faith and commercially reasonable written quote of the fee for the additional services and VF will advise CCX whether it wishes to have the additional services performed by CCX. The scope of work and fees will be set forth in a separate agreement signed by the Parties. The terms and conditions of this Agreement will apply to these services.

(h) Safety Stock. To ensure continuity of supply CCX or its CMO's will manufacture and store a reasonable quantity of safety stock of the components and API at the Manufacturing Sites (the "**Safety Stock**").

(i) Quality Agreement. The Parties will negotiate in good faith to enter into a Quality Agreement within following three months as the Effective Date, which will govern the quality assurance obligations of the Parties with respect to the Manufacture and supply of the Bulk Drug Product. In the event of a discrepancy between the provisions of the Quality Agreement and the provisions of this Agreement, the provisions of the Quality Agreement shall control with respect to terms governing quality of the Bulk Drug Product and the provisions of this Agreement shall control with respect to all other terms.

2.2 Continuous Improvement.

CCX will use commercially reasonable efforts to ensure continuous improvements of the processing performance for the Bulk Drug Product at the Manufacturing Site in order to ensure efficient production, thereby generating potential savings that could be shared equally with VF through a reduction in the Transfer Price ("**Continuous Improvements**"). VF may assist CCX in its activities to generate and develop efficiency improvement and cost reduction ideas, new concepts and measures for implementation at the Manufacturing Site. This assistance may include audits, evaluation of joint engineering practices, new technologies and/or new manufacturing and supply chain management methods. CCX will use commercially reasonable efforts to make available sufficient resources to generate, develop and implement the Continuous Improvements. VF will reimburse CCX the reasonable costs incurred by CCX in carrying out the requested activities if the activities were pre-approved by VF in writing. The Joint Manufacturing Sub-committee ("**JMC**") as regulated in the License Agreement will regularly meet and discuss continuous improvement matters. The Parties agree that any of VF's sub-licensees may participate in the JMC. The Parties will conduct an annual JCM meeting where (i) CCX will inform VF about its annual continuous improvement and best practices goals and strategies in terms of potential savings and any potential reduction in the Transfer Price, and (ii) The Parties will agree on the allocation of costs required in implementing any Continuous Improvement efforts.

ARTICLE 3

VF'S OBLIGATIONS

3.1 Payment

VF will pay CCX for performing the Manufacturing Services according to Article 4.

ARTICLE 4

PAYMENTS

4.1 Pricing.

(a) Payment. The purchase price charged by CCX for costs associated with the Manufacture of the Bulk Drug Product ordered by VF under this Agreement shall be the Transfer Price. CCX shall determine the Transfer Price in accordance with Section 7.3 of the License Agreement, including GAAP or IFRS, as applicable. Upon delivery of the Bulk Drug Product in accordance with Section 5.4, CCX may invoice VF the Transfer Price for the type and quantity of the Bulk Drug Product delivered. The Transfer Price payable by VF for the Bulk Drug Product delivered in each Year will be calculated by capsule on the basis of the number of Batches of the Bulk Drug Product forecasted to be manufactured by CCX in such Year, as set forth in VF's Rolling Forecast submitted [***] pursuant to Section 5.1(b). On an annual basis, CCX shall determine such Transfer Price and deliver notice thereof to VF by [***]. Such Transfer Price shall take effect and be deemed the Transfer Price for the following Year (commencing January 1 and continuing until December 31 of such Year). VF shall pay the undisputed amount set forth in each original (i.e., not a copy) invoice delivered by CCX electronically to VF under this Section 4.1 within [***] days of receipt of such invoice. Any term or condition in an invoice or other document furnished by CCX that is inconsistent with the terms and conditions of this Agreement or in addition to the terms and conditions of this Agreement, shall not be binding on VF.

(b) Reconciliation. On an annual basis and as part of the Transfer Price notice delivered by CCX to VF pursuant to Section 4.1(a), CCX shall perform a reconciliation to determine the actual Transfer Price for the Bulk Drug Product delivered to VF by CCX from [***] (the "Actual Transfer Price"). Notwithstanding the foregoing, for calendar year 2021, the Actual Transfer Price shall be calculated based on the Bulk Drug Product delivered to VF by CCX from [***] based on the Rolling Forecast submitted by VF on or before [***], pursuant to Section 5.1(b). If the Transfer Price paid to CCX for the Bulk Drug Products delivered in such time period is less than the Actual Transfer Price for such Bulk Drug Products, the difference between such amounts will be factored in the Transfer Price for the following Year (commencing January 1 and continuing until December 31 of such Year). Likewise, if the Transfer Price payments made to CCX by VF for the Bulk Drug Products delivered in such time period exceeds the Actual Transfer Price for such Bulk Drug Products, the difference between such amounts will be factored in the Transfer Price for the following Year (commencing January 1 and continuing until December 31 of such Year).

For purposes of illustration only, a sample calculation of Transfer Price for the Year 2024 follows:

[***]

[***]

[***]

4.2 Manner of Payment.

All payments to be made under this Agreement shall be made in U.S. dollars by wire transfer of immediately available funds to such U.S. bank account as shall be designated by a Party. Late payments shall bear interest at the rate provided in Section 4.7.

4.3 Disputed Amounts.

In the event that a Party disputes any amounts payable under this Agreement, such dispute shall be resolved (a) in accordance with Article 6 with respect to non-conforming Product and (b) in accordance with Article 12 with respect to any other dispute. Pending resolution of such disputes, a Party shall pay any amounts (whether under an invoice or otherwise) that are not in dispute. Upon resolution of any such dispute in favor of a Party, the other Party shall pay all remaining amounts owing under this Agreement within [***] Business Days after such resolution.

4.4 Taxes.

(a) Cooperation and Coordination. The Parties acknowledge and agree that it is their mutual objective and intent to appropriately calculate and minimize, to the extent feasible and legal, taxes payable with respect to any payments under this Agreement and that they shall use commercially reasonable efforts to cooperate and coordinate with each other to achieve such objective. Without limiting the generality of the foregoing, the Parties shall use commercially reasonable efforts to cooperate and coordinate with each other in completing and filing documents required under the provisions of any Applicable Laws (including treaties) in connection with the making of any required tax payment or withholding payment, in connection with a claim of exemption from, or entitlement to, a reduced or zero rate of withholding or in connection with any claim to a refund of or credit for any such payment.

(b) Payment of Tax. All payments made by VF to CCX pursuant to this Agreement shall be made without reduction for any taxes, charges or remittance fees. If Applicable Laws require that taxes be deducted and withheld from a payment made pursuant to this Agreement, the remitting Party shall (a) deduct those taxes from the payment; (b) pay the taxes to the proper taxing authority; and (c) send evidence of the obligation together with proof of payment to the other Party promptly following that payment. VF shall be responsible for the payment of any taxes (including VAT, sales and use taxes and excluding income or franchise taxes), customs and excise duties incurred by VF with respect to the sale or importation of the Product by VF in the Territory.

(c) Tax Residence Certificate. A Party receiving a payment pursuant to this Agreement shall provide the remitting Party appropriate certification from relevant governmental authorities that such Party is a tax resident of that jurisdiction, if such receiving Party wishes to claim the benefits of an income tax treaty to which that jurisdiction is a Party. Upon the receipt thereof, any deduction and withholding of taxes shall be made at the appropriate treaty tax rate.

(d) Assessment. Either Party may, at its own expense, protest any assessment, proposed assessment, or other claim by any governmental authority for any taxes, interest or penalties or seek a refund of such amounts paid if permitted to do so by Applicable Laws. The Parties shall cooperate with each other in any protest or refund by providing records and such additional information as may reasonably be necessary for a Party to pursue such protest or refund.

4.5 Records.

CCX shall keep, and, subject to the terms of the applicable agreement between CCX and a CMO, shall cause each of its CMOs to keep, full, true, and accurate books of accounting containing all particulars that may be necessary for the purpose of calculating the payments payable to CCX in accordance with GAAP or IFRS, as applicable, under this Article 4, for a period of [***] years after the calendar year in which the Bulk Drug Product was delivered, in sufficient detail to permit VF to confirm the accuracy of any payments paid hereunder.

4.6 Financial-Audit Rights.

During the term of this Agreement and for a period of [***] years thereafter, at the request and expense of VF, subject to the terms of the applicable agreement between CCX and a CMO, CCX shall permit an independent, certified public accountant of nationally recognized standing appointed by VF, and reasonably acceptable to CCX, during normal business hours and upon not less than [***] Business Days prior notice and in compliance with the audit limitations of any CMO agreement, but in no case more than [***] per calendar year, to examine such records of CCX as may be necessary for the sole purpose of verifying the calculation and reporting of the payments payable under this Agreement for any period within the preceding [***] calendar years. Results of any such examination shall be made available to both VF and CCX. Such accountant shall disclose to VF only the amounts which the accountant believes to be due and payable hereunder to VF or due and payable to CCX, and any information reasonably necessary for VF to evaluate any discrepancy from the amount paid and the amount due, and shall disclose no other information revealed in such audit. Any and all records examined by such accountant shall be deemed CCX's Confidential Information, which may not be disclosed by such accountant to any Third Party. If, as a result of any inspection of the books and records of CCX, it is shown that payments made by VF under this Agreement were more than the amount that should have been made, then CCX shall promptly refund any amount required to eliminate any discrepancy revealed by said inspection, such refund to occur in any event within [***] days after notice thereof. If, as a result of any inspection of the books and records of CCX, it is shown that payments made by VF under this Agreement were less than the amount that should have been made, then VF shall promptly pay to CCX the difference between the amount actually paid and the amount that should have been paid within [***] days after the conclusion of such inspection. VF shall pay for such audits, except that in the event that CCX overcharged such payments by more than [***] during the period in question as per the audit, CCX shall pay the reasonable costs of the audit.

4.7 Interest.

Without limiting any other rights or remedies available to CCX, VF shall pay CCX interest on any payments that are not paid on the date such payments are due under this Agreement at a rate equal to the lesser of (a) the [***] or (b) the highest rate permitted under the Applicable Law.

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts.

(a) Long Term Forecast. Promptly after the execution of this Agreement, VF will give CCX a non-binding three-year forecast of VF's volume requirements for the Bulk Drug Product for each Year during the term of this Agreement (the "**Long Term Forecast**"). The Long Term Forecast will thereafter be updated each Year on [***]. If CCX is unable to accommodate any portion of the Long Term Forecast, it will notify VF within [***] days of receiving the Long term Forecast or any update and the Parties will agree on any revisions to the forecast.

(b) Rolling 18 Month Forecast. Promptly after the execution of this Agreement, VF will give CCX a written 18-month forecast of the volume of Bulk Drug Product that VF expects to order in the first 18 months of commercial manufacture of the Bulk Drug Product (the "**Initial Forecast**"). On a rolling monthly basis during the term of this Agreement, VF will issue an updated 18 month forecast on or before the first day of each month (the Initial Forecast and each updated 18 month forecast are a "**Rolling Forecast**"). Each Rolling Forecast after the Initial Forecast will start on the first day of the month immediately following the date on which the Annual Forecast is to be provided. This forecast will then be updated by

VF once every month on a rolling forward basis. These forecasts should be reasonably consistent with the Long Term Forecast. The Rolling Forecast for the first [***] months following the date of forecast shall be firm and binding on VF and CCX (the "**Binding Period**") and will be covered by Firm Orders. The quantities projected in the Rolling Forecast for the following [***] months are non-binding, good faith estimates; provided that the forecast for the seventh through ninth month (the "**Semi Flexible Period**") may only be modified within the range of [***] from month to month during the Semi Flexible Period.

The Rolling 18 Month Forecast will be binding on both parties, as follows:

(i) the Bulk Drug Product volumes ordered by Firm Orders during the first [***] months of the then-current Rolling Forecast may only be changed by written agreement between the Parties; and

(ii) the Semi Flexible Period of the then-current Rolling Forecast may only be modified within the range of [***] from month to month.

(c) Firm Orders.

(i) Concurrent with the delivery of the then-current Rolling Forecast, VF will issue a new firm written order in the form of a purchase order (specifying the Delivery Date or Delivery Dates that are at least [***] days after the date of the respective purchase order) ("**Firm Order**") for deliveries of the Bulk Drug Products to VF, ensuring that CCX always has at least [***] days lead-time to deliver Bulk Drug Product to VF. When accepted by CCX as specified below, such Firm Order for CCX to Manufacture and deliver the agreed quantity of the Bulk Drug Products. In case of first launch, at least [***] calendar days prior to the requested initial Shipping Date of Bulk Product or as soon as practicable after the Effective Date of this Agreement, VF shall place an initial purchase order. CCXI will confirm receipt of such request and will use commercially reasonable efforts to accept and fulfill such purchase order.

(ii) Firm Orders submitted to CCX will specify VF's purchase order number, quantities by Bulk Drug Product type, Delivery Date, and delivery location. The quantities of Bulk Drug Products ordered and Delivery Dates in those Firm Orders will be firm and binding on VF and CCX (unless rejected under Section 5.1(d)) and may not be reduced by VF or CCX except as expressly permitted in this Agreement. Expedited Firm Orders will be subject to additional fees as agreed in writing by the Parties.

(iii) If and when VF applies for a tender of Product to a Governmental Authority or if VF prepares for a launch of Product in a country, or if VF requires Product prior to a launch date due to e.g., regulatory requirements as part of a submission, VF shall notify CCXI in writing and provide to CCXI information relating to the anticipated volumes to be supplied under such tender or launch and the timing for deliveries thereunder. In such events, the Parties will discuss in good faith reasonable mechanisms for CCXI to provide supply of Product for such tender or launch The Parties agree that lead times for such orders related to a tender and/or a launch may have shorter lead times than regular orders.

(d) Acceptance of Firm Order. CCX will accept Firm Orders by sending a written confirmation to VF within [***] Business Days of its receipt of the Firm Order. The confirmation will include the Delivery Date for the Bulk Drug Product ordered. The Delivery Date may be amended by agreement of the Parties. If CCX fails to acknowledge receipt of or reject a Firm Order within the [***] Business Day period, the Firm Order will be considered to have been accepted by CCX. CCX may not reject a Firm Order other than on the basis of (i) a failure by VF to include the information required to be provided in the Firm Order under this Section; or (ii) a Firm Order that imposes requirements that conflict with this Agreement. CCX will include in any rejection a reasonable explanation of the basis for the rejection.

(e) API Safety Stock for Bulk Drug Product manufacturing. [***], CCX agrees to use commercially reasonable efforts to hold enough safety stock of API to be able to manufacture at least the amount of Bulk Drug Product for the projected upcoming [***] months. This means in detail that CCX will hold or will make CMO hold enough API to ensure that CMO is able to manufacture Bulk Drug Product in the amount forecasted with the current Rolling Forecast at all times.

5.2 Minimum Orders.

VF may order Manufacturing Services for whole Batches of Bulk Drug Products only in multiples of the Minimum Order Quantities as set out in Schedule C.

5.3 Delivery and Shipping.

(a) Delivery of Bulk Drug Products will be made [***] (Incoterms 2010) CCX's CMO's warehouse on the Delivery Date, provided that for any transatlantic shipments title, risk of loss or of damage to Bulk Drug Products should remain with CCX until the Bulk Drug Products are [***]. CCX will engage a third party courier to move the Bulk Drug Products from Patheon to the VFMCRP appointed transatlantic carrier. Shipment expenses to be expressly included in Transfer Price. CCX will not be entitled to deliver partial shipments of the Bulk Drug Products unless expressly authorized by VF in writing. With each shipment, CCX will provide the documents as set forth in the Quality Agreement and otherwise as required for shipment. CCX will provide up to [***] days' storage in accordance with the applicable Specifications for Bulk Drug Product after release and VF's receipt of information required for shipment to enable VF to arrange shipping from CCX's CMO's warehouse.

(b) Subject to Section 13.5, and except for shelf life deficiencies resulting from delays attributable to VF or from agreed deviation investigations, CCX will deliver each Bulk Drug Product together with its release certificates with a shelf life of at least [***] of the total shelf life of the Bulk Drug Product.

(c) If CCX anticipates to be unable to deliver the Bulk Drug Product to VF in accordance with a confirmed Firm Order for whatever reason, CCX will immediately inform VF thereof, and without prejudice to any of VF's rights under this Agreement, the Parties will agree on the necessary arrangements for minimizing the possible loss and damage which VF may suffer from the delay in delivery. Any deviation from a Delivery Date already set forth in a confirmed Firm Order is subject to VF's prior approval. If VF provides this approval, VF will have no claims against CCX as a result of the rescheduled Delivery Date. If CCX does not deliver the Bulk Drug Products ordered by means of a confirmed Firm Order (for any reason other than as a result of force majeure event), CCX will promptly notify VF about the reasons for delay.

(d) Vifor shall accept delivery of Bulk Drug Product provided that the relevant quantity is within [***] of the quantity confirmed in the Firm Order. In case of shortfall, CCX will carry over the shortfall and supply this latter together with the next Firm Order. In case of a supply exceeding [***] of the quantity confirmed in the Firm Order, the Parties will discuss in good faith how to manage the over-delivery.

5.4 Liquidated Damages For Late Delivery.

If CCX is unable to deliver the Bulk Drug Product to VF in accordance with the terms of a Firm Order due to an act or omission by CCX or any of its agents, subcontractors or suppliers (a "Late Delivery"), CCX will, solely to the extent liquidated damages are actually received by CCX from its CMO for Bulk Drug Product, pay to VF its share of such liquidated damages received from such CMO. As of the Effective Date, CCX's CMO for Bulk Drug Product is Patheon Pharmaceuticals Inc., and the liquidated damages are as follows:

(a) If Bulk Drug Product delivery occurs [***] days after the applicable Delivery Date, CCX pays [***];

(b) If Bulk Drug Product delivery occurs [***] days after the applicable Delivery Date, CCX reimburses to VF [***]% of the cost to VF of the applicable Firm Order;

(c) If Bulk Drug Product delivery occurs [***] days after the applicable Delivery Date, CCX reimburses to VF [***]% of the cost to VF of the applicable Firm Order;

(d) If Bulk Drug Product delivery occurs [***] days after the applicable Delivery Date, CCX reimburses to VF [***]% of the cost to VF of the applicable Firm Order;

(e) If Bulk Drug Product delivery occurs [***] days after the applicable Delivery Date, CCX reimburses to VF [***]% of the cost to VF of the applicable Firm Order; or

(f) If Bulk Drug Product delivery occurs [***] or more days after the applicable Delivery Date, CCX reimburses to VF [***]% of the cost to VF of the applicable Firm Order;

A Late Delivery will not include any delay in shipment of Bulk Drug Product while CCX is exercising a right of excused performance in accordance with the requirements of Section 13.5.

5.5 Supply Failure; Technology Transfer

(a) Supply Failure. If a Supply Failure occurs, the Parties agree to, in accordance with Section 7.1 (Manufacturing Committee) of the License Agreement, [***]. If a second Supply Failure occurs within any [***] year period during the term of this Agreement, (i) such second Supply Failure (and only such supply failure) [***], and (ii) VF shall have the right to have CCX undertake technology transfer of the Manufacturing Services for the Product to a Third Party [***]. Such technology transfer costs will be at CCX's expense and will be executed in a timely manner and in accordance with industry standards. The rights and obligations under this Section 5.5 (a) shall be subject to the terms and conditions of any applicable CMO agreement(s).

(b) Backup CMOs. Upon written request by VF, the Parties shall mutually agree upon and select backup CMO(s) in accordance with the terms of Section 7.1 (Manufacturing Committee) of the License Agreement. Upon mutual selection of any backup CMO, CCX shall engage such backup CMO(s) and perform technology transfer to qualify such backup CMO(s) as soon as reasonably practicable. The Parties shall share equally in the costs of such technology transfer to backup CMOs. For clarity, except as set forth above, [***].

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1 Product Claims

(a) Product Claims. VF has the right to reject any portion of or all (to the extent reasonable) of any shipment of Bulk Drug Product that was not Manufactured in accordance with the Specifications, the Marketing Authorisation Dossier ("**MAD**"), Manufacturing Batch record ("**MBR**"), cGMPs, or Applicable Laws, without invalidating any remainder of the shipment that was not rejected. VF will inspect the Bulk Drug Product manufactured by CCX upon receipt and will give CCX written notice (a "**Deficiency Notice**") of all claims for Bulk Drug Product that was not manufactured in accordance with the Specifications, MAD or MBR, cGMPs, or Applicable Laws, within [***] days after VF's receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Bulk Drug Product, within [***] days after discovery by VF, but not after the expiration date of the Product). Other than with respect to defects not reasonably susceptible to discovery, if VF fails to give CCX the Deficiency Notice within the applicable [***] day period, then the delivery will be considered to have been accepted by VF on the [***]th day after delivery or discovery, as applicable. CCX will have no liability for any deficiency for which it has not received notice within the applicable [***]-day period.

(b) Determination of Deficiency. Upon receipt of a Deficiency Notice, CCX will have [***] days to advise VF by notice in writing that it disagrees with the contents of the Deficiency Notice. If VF and CCX fail to agree within [***] days after CCX's notice to VF as to whether any Bulk Drug Product identified in the Deficiency Notice was not Manufactured in accordance with the Specifications, MAD or MBR, cGMPs, or Applicable Laws, the Parties will engage a mutually-acceptable independent Third Party to perform testing and investigation to resolve the deficiency and liability issues. The Parties agree to accept the independent Third Party's conclusive determination and identify if any aspect of the Third Party testing and investigation proves inconclusive, executives from both Parties will meet and use good faith efforts to resolve any remaining deficiency and liability issues. If the JMC is unable to resolve the dispute within [***] days, the dispute will be handled as a technical dispute under Exhibit A.

(c) Shortages and Price Disputes. Claims for shortages in the amount of Bulk Drug Product shipped by CCX or a Transfer Price dispute will be dealt with by reasonable agreement of the Parties.

6.2 Product Recalls and Returns.

(a) Records and Notice. CCX, its CMO's and VF will each maintain records necessary to permit a Recall of any Product delivered to VF or customers of VF. Each Party will promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Product or which might result in the Recall or seizure of the Product. Upon receiving this notice or upon this discovery, each Party will confirm which Product batches in its possession or control, as applicable, are likely to be non-conforming and stop making any further shipments of any Product batch in its possession or control that is likely to be non-conforming until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by VF. "**Recall**" will mean any action (i) by VF to recover title to or possession of quantities of the Product sold or shipped to Third Parties (including, without limitation, the voluntary withdrawal of Product from the market); or (ii) by any Regulatory Authorities to detain or destroy any of the Product. Recall will also include any action by either Party to refrain from selling or shipping quantities of the Product to Third Parties which would be subject to a Recall if sold or shipped.

(b) Recalls. If (i) any Regulatory Authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) VF determines that any Product should be Recalled or that a "Dear Doctor" letter is required relating the restrictions on the use of any Product, CCX will co-operate as reasonably required by VF, having regard to all applicable laws and regulations.

(c) Product Returns. VF will have the responsibility for handling customer returns of the Product. CCX will give VF any assistance that VF may reasonably require to handle the returns.

(d) Recall Expenses. All expenses related to a Product Recall shall be borne by the Party responsible for the defect(s) or issue(s) that resulted in such Recall. To the extent both Parties bear responsibility for such Recall, then each Party shall pay its pro-rata portion of such Product Recall expenses. In the event of a dispute regarding allocation of responsibility between the Parties under this Section 6.2(d), the Parties shall submit such dispute for resolution in a manner consistent with Section 6.1(b) (Determination of Deficiency).

6.3 CCX's Responsibility for Defective and Recalled Products.

(a) Defective Product. If VF rejects Bulk Drug Product under Section 6.1 and the deficiency is determined to have arisen from CCX's failure to provide the Manufacturing Services in accordance with the Specifications, cGMPs or Applicable Laws, CCX will [***] for the defective Bulk Drug Product. If VF previously paid for the defective Bulk Drug Product, CCX will promptly, [***], either: (i) replace the Bulk Drug Product with conforming Bulk Drug Product within the following [***] months, as of rejection by VF, without VF being liable for payment therefor under Section 3.1. or (ii) [***].

(b) Recalled Product. If a Recall or return results from, or arises out of, a failure by CCX to perform the Manufacturing Services in accordance with the agreed Specifications, cGMPs, or Applicable Laws, CCX will be responsible for the [***].

(c) Except as set forth in Sections 6.3 (a) and (b) above and Sections 6.4 and 6.5 below, CCX will not be liable to VF nor have any responsibility to VF for any deficiencies in, or other liabilities associated with, any Bulk Drug Product manufactured by it (collectively, "Product Claims") to the extent the Product Claim (i) [***], (ii) [***], (iii) [***], or (iv) [***].

(d) Notwithstanding anything to the contrary in this Agreement, CCX will only be required to [***] to the extent [***] in accordance with the terms of this Agreement.

6.4 Disposition of Defective or Recalled Products.

VF will not dispose of any damaged, defective, returned, or recalled Bulk Drug Products or Products for which it intends to assert a claim against CCX without CCX's prior written authorization to do so. Alternatively, CCX may instruct VF within [***] days after determination of the Bulk Drug Products or Products being defective to return the Bulk Drug Products or Products to CCX. CCX will [***]. In all other circumstances, [***].

6.5 Healthcare Provider or Patient Questions and Complaints.

VF will have the sole responsibility for responding to questions and complaints from its customers. Any such questions or complaints received by CCX from VF's customers, healthcare providers or patients will be promptly referred to VF. Relevant complaints received at VF from VF's customers will be transmitted to CCX for its assessment / investigation. CCX will investigate the received complaints and send an investigation report within [***] days to VF (for further information of VF's customers). CCX will co-operate as reasonably required to allow VF to determine the cause of and resolve any questions and complaints. This assistance will include follow-up investigations, including e.g. testing. In addition, CCX will give VF all agreed upon information that will enable VF to respond properly to questions or complaints about Product as set forth in the Quality Agreement. Unless it is determined that the cause of the complaint resulted from a failure by CCX to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws, all reasonable and demonstrated costs incurred under this Section 6.5 will be borne by VF.

6.6 Sole Remedy.

Except for the indemnity set forth in Section10.3 and subject to any applicable limitations set forth in Sections 10.1 and 10.2, the remedies described in this Article 6 will be VF's sole remedy in contract, tort, equity or otherwise for any failure by CCX to provide the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws. This Section 6.6 does not affect the availability of any other remedy that VF may have for CCX's breach of any of its other obligations under this Agreement.

6.7 Deviations / Change Control.

The detailed process for deviations and change control between CCX and VF is defined in the Quality Agreement. Major or critical deviations must be [***] prior to batch release at CCX.

ARTICLE 7

CO-OPERATION

7.1 Governmental Authorities.

Each Party may, subject any applicable terms in the Quality Agreement, communicate with any Governmental Authority, including but not limited to Governmental Authority responsible for granting Regulatory Approval for the Bulk Drug Products, regarding the Bulk Drug Products if, in the opinion of that Party's counsel, the communication is necessary to comply with the terms of this Agreement and Section 5 of the License Agreement or the requirements of any law, governmental order or regulation. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, a Party will permit the other Party to receive copies of all communications from the Governmental Authority pertaining to Manufacturing of the Product.

7.2 Records and Accounting by CCX.

Except as otherwise provided in the Quality Agreement, CCX will keep records of the manufacture, testing, and shipping of the API, Components and Bulk Drug Products, and reference and retention of samples of the API, Components and Bulk Drug Products as are necessary to comply with manufacturing regulatory requirements applicable to CCX, as well as to assist with resolving API, Components and Bulk Drug Product complaints and other similar investigations. Unless otherwise agreed to in the Quality Agreement, copies of the records and samples will be retained for [***] year following the date of API, Components or Bulk Drug Product expiry, or longer if required by law or regulation, following which time VF will be contacted concerning the delivery or destruction of the documents and/or samples of API, Components and Bulk Drug Products. CCX reserves the right to destroy or return to VF, at VF's sole expense, any document or samples for which the retention period has expired if VF fails to arrange for destruction or return within [***] days of receipt of notice from CCX. CCX is responsible for retention of samples of the API, Components and Bulk Drug Products necessary to comply with the legal/regulatory requirements applicable to VF.

7.3 Audit.

VF may inspect CCX's or its CMO's (subject to the terms and conditions of CCX's CMO agreements) processes, facilities and premises, including reports and records relating to this Agreement during normal business hours and with reasonable advance notice, but a CCX representative shall have the right to be present during the inspection. CCX shall procure the inspection by VF of its CMO's (subject to the terms and conditions of CCX's CMO agreements).

7.4 cGMP-type Audit.

Subject to the terms and conditions of CCX's CMO agreements, CCX will arrange to give VF, together with CCX, reasonable access at agreed times to the areas of the Manufacturing Site in which the API, Components, Bulk Drug Product and Products are manufactured, stored, handled, or shipped to permit VF to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, and Applicable Laws. But, with the exception of "for-cause" audits, VF will be limited to [***] cGMP-type audit every [***] per each CMO [***], [***]. The right of access set forth in Sections 7.3 and 7.4 will not include a right to access or audit CCX's or its CMO's financial records. This Agreement does not limit or modify VF's audit rights under the License Agreement. To the extent any CMO audits hereunder require additional costs payable to such CMO under the applicable CMO agreement, [***].

7.5 Inspections.

(a) PAI Inspections. CCX will support and will ensure CCX's CMO`s will support all Product Approval Inspections ("**PAIs**") of the FDA or any equivalent regulatory inspection for other jurisdictions (where applicable) and provide a copy of the resulting reports to VF [***].

(b) Notification of Regulatory Inspections. CCX will notify VF within [***] Business Day of receipt of notice of any planned inspection or audit by any Governmental Authority specifically involving the API, Components and Bulk Drug Products and/or the Manufacturing Sites and will notify VF promptly regarding any inspection or audit that is unannounced. CCX will permit VF and VF's licensees to be present at the Manufacturing Site for these audits and inspections but VF will not be permitted to actively participate in the audit/inspection or onsite responses thereto. CCX will promptly provide to VF copies of any Governmental Authority correspondence relating to Manufacturing hereunder, and more in particular FDA Forms 483, the response to the Form 483 and other notices of inspectional observations, warning letters, untitled letters, GMP compliance inspection notifications/results, GMP certificates and other similar actions and correspondence including from any other Regulatory Authority which could reasonably affect the regulatory status of the API, Components and Bulk Drug Products. CCX will provide VF with copies of all proposed responses to the regulatory actions and correspondence with reasonable time for VF to review prior to submission. CCX will duly consider any VF comments prior to submitting the responses to any governmental agency.

7.6 Reports.

CCX will supply on an annual basis a copy of the Annual Product Review Report (complying with the US APR and EU PQR requirements) which includes all Product data and its control, including release test results, complaint test results, and all deviations or investigations (in manufacturing, testing, and storage), that VF reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that VF is required to file with any Regulatory Authority in the Territory. Due date for the report is [***] months after the review period. Any additional data or report requested by VF beyond the scope of cGMPs and customary national requirements, including Continuous Process Verification data, will be subject to an additional fee at costs to be agreed upon between CCX and VF.

7.7 Regulatory Filings.

The Parties' responsibilities for carrying out regulatory activities under or in connection with this Agreement shall be as specified in Section 5 of the License Agreement.

ARTICLE 8

TERM AND TERMINATION

8.1 Term.

This Agreement will become effective as of the Effective Date and will continue until the expiration or termination of the License Agreement, unless terminated earlier by one of the Parties in accordance herewith. Any expiration or termination of this Agreement will have no effect on the Parties' obligations under the License Agreement.

8.2 Termination.

(a) Either Party at its sole option may terminate this Agreement upon written notice where the other Party has failed to remedy a material breach of any of its representations, warranties, or other obligations under this Agreement within 45 days following receipt of a written notice (the "Remediation Period") of the breach from the aggrieved Party that expressly states that it is a notice under this Section 8.2(a) (a "Breach Notice").

(b) Either Party may, at its sole option, immediately terminate this Agreement upon written notice, but without prior advance notice, to the other Party if: (i) the other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other Party; or (iii) this Agreement is assigned by such other Party for the benefit of creditors.

(c) VF may terminate this Agreement upon [***] days' prior written notice if the Product (i) the EMA or PDMA does not approve an application for Regulatory Approval for the Product, or issue a letter indicating that such an application is approvable within [***] years after VF (or its sublicensee) submits such application; (ii) VF (or its sublicensee) withdraws its application for Regulatory Approval for the Product in the E.U. or Japan; (c) VF (or its sublicensee) withdrawns the Product for sale in the E.U. or Japan. But if this occurs, VF must still fulfill all of its obligations under Section 8.3 below.

(d) Commencing five (5) years after the first Regulatory Approval of the Product, VF may terminate the Agreement without liability (except for its obligations under Section 8.3) upon six months' prior written notice for any reason.

(e) This Agreement may be terminated by mutual agreement of the Parties.

(g) This Agreement may be terminated by either Party in the event that a force majeure event as further described in Article 13.5 lasts [***] months as of its occurrence.

8.3 Obligations on Termination.

(a) If this Agreement is terminated for any reason, then:

(i) If the Agreement is terminated (i) by VF, for CCX's material breach pursuant to Section 8.2(a), (ii) by VF, for CCX insolvency or bankruptcy pursuant to Section

8.2(b), or (c) by either Party for force majeure pursuant to Section 8.2(g), to the extent requested by VF, the Parties will work together to ensure smooth transition of the Manufacturing Services from CCX to VF or a Third Party determined by VF, and CCX will provide VF or a VF designated manufacturer reasonable services, information and instruction on a reasonable time and materials basis regarding the technology, processes and techniques necessary to enable VF or VF's designated manufacturer to manufacture the Bulk Drug Product;

(ii) [***], VF will take delivery of and pay for all undelivered Bulk Drug Products that are manufactured and/or packaged in accordance with this Agreement under a Firm Order if the manufacture of the Bulk Drug Product started before termination or expiration of this Agreement, at the Transfer Price in effect at the time the Firm Order was placed;

(iii) To the extent requested by VF, for [***] months after completion, expiration or termination of this Agreement (the "**Rampdown Period**"), CCX will continue to provide VF with the applicable Bulk Drug Product in accordance with the terms of this Agreement;

(iv) [***], VF will purchase, [***] within [***] days after the end of the Rampdown Period, the inventory applicable to the Bulk Drug Products which was purchased, maintained or produced by CCX in contemplation of filling Firm Orders or in accordance with Section 5; and

(v) [***], VF will satisfy the [***] under CCX's orders with suppliers of Components, that CCX was not able to mitigate using commercially reasonable efforts (e.g., using Inventory for other purposes or cancelling orders for Components) within [***] month after the end of the Rampdown Period, if the orders were made and not cancelable by CCX in reliance on Firm Orders or in accordance with Section 5.2.

(b) Any termination or expiration of this Agreement will not affect any outstanding obligations or payments due prior to the completion, termination or expiration, nor will it prejudice any other remedies that the Parties may have under this Agreement. Completion, termination or expiration of this Agreement for any reason will not affect the obligations and responsibilities of the Parties under Articles 4 (with respect to any payments outstanding), 6.6, 8.3, 10, 11, 13.1 and 13.3, all of which survive any completion, termination or expiration.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority.

Each Party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

9.2 CCX Warranties.

CCX covenants, represents, and warrants that:

(a) It or its CMOs have been granted and will maintain all licenses necessary to perform its obligations hereunder;

(b) It or its CMOs will perform the Manufacturing Services using an adequate number of skilled, trained and qualified individuals; with due care, skill, judgment and diligence, in a competent, workmanlike manner and in accordance with the Specifications, cGMPs, and Applicable Laws and that level of care and skill ordinarily exercised by other professional manufacturers in similar circumstances;

(c) The Bulk Drug Products will be manufactured in accordance with cGMP and the Quality Agreement and will meet the Specifications for the duration of the Product shelf life, except to the extent the failure to meet the Specifications is not due to CCX's fault;

(d) Any CCX Intellectual Property used by CCX to perform the Manufacturing Services (i) is CCX's or its Affiliate's unencumbered property, (ii) may be lawfully used by CCX, and (iii) does not infringe and will not infringe any Third Party Rights;

(e) It will not in the performance of its obligations under this Agreement use the services of any person it knows is debarred or suspended under 21 U.S.C. §335(a) or (b);

(f) It does not currently have, and it will not hire, as an officer or an employee any person whom it knows has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the United States *Federal* Food, Drug, and Cosmetic Act;

(g) At the time of delivery to VF, the Bulk Drug Product will have been Manufactured, handled and stored using an adequate number of skilled, trained and qualified individuals, with due care, skill, judgment and diligence, in a competent, workmanlike manner and in accordance with Applicable Laws, cGMP, and in compliance with the Specifications (including in compliance with the packing and labeling indications contained therein) and the Quality Agreement and will not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws;

(h) All documents to be provided to VF in relation with the Manufacturing and the API, Components and Bulk Drug Product are accurate;

(i) It will convey good and clear title to the Bulk Drug Product supplied hereunder; and

(j) At the time of delivery to VF, the Bulk Drug Product will be free from interest, lien, encumbrance and any other kind of security.

9.3 **Permits**.

(a) VF will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

(b) CCX will maintain at all relevant times all governmental permits, licenses, approval, and authorities required to enable it or its CMO to lawfully and properly perform the Manufacturing Services in accordance with this Agreement, the Quality Agreement and cGMP.

9.4 **Limited Warranties**.

CCX MAKES NO WARRANTY OR CONDITION OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT.

CCX MAKES NO WARRANTY OR CONDITION OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OR CONDITION OF MERCHANTABILITY FOR THE BULK DRUG PRODUCTS.

ARTICLE 10

INDEMNITIES

10.1 Consequential and Other Damages.

Except for a breach of Article 11, Section 13.8 or for a Party's willful misconduct, under no circumstances whatsoever will either Party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for any indirect loss of profits, of production, of anticipated savings, of business, of goodwill, or costs of any other consequential damages. For greater certainty, claims under Articles 10.3 and 10.4 will not limited by this provision.

10.2 Limitation of Liability.

(a) Defective Product. CCX's maximum aggregate liability to VF for any obligation to (i) refund, offset or replace any defective Product under Section 6.3(a) or (ii) replace any recalled Products under Section 6.3(b), will not exceed [***] for the defective or recalled Product as applicable. This Section 10.2(a) will not be subject to Section 10.2(b). For clarity, any CCX liability for VF's out of pocket expenses of a Recall or Product return under Section 6.3(b) will be subject to Section 10.2(b) and not this Section 10.2(a).

(b) Maximum Liability. [***], CCX's maximum liability to VF under this Agreement for any reason whatsoever, including, without limitation, any liability arising under Section 6.3(b) relating to the expenses of a Recall or Product return or Section 2.2 of this Agreement or resulting from any and all breaches of its representations, warranties, or any other obligations under this Agreement will not exceed the greater of (i) [***], (ii) [***], and (iii) [***].

10.3 Indemnification by CCX.

CCX hereby agrees to defend, indemnify and hold harmless VF, VF's Affiliates and any sublicensees and their respective directors, officers, employees and agents (each, a "**VF Indemnitee**") from and against any and all liabilities, expenses and losses, including reasonable legal expenses and attorneys' fees ("**Losses**"), to which any VF Indemnitee may become subject as a result of any alleged claim, claim, demand, action or other proceeding by any Third Party to the extent such Losses arise out of: (a) the use, handling, storage, sale or other disposition of any Bulk Drug Product by CCX or its Affiliates, (b) the negligence or willful misconduct of any CCX Indemnitee, or (c) the breach by CCX of any warranty, representation, covenant or agreement made by CCX in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of the negligence or willful misconduct of any VF Indemnitee or the material breach by VF of any warranty, representation, covenant or agreement made by VF in this Agreement or the Quality Agreement.

10.4 Indemnification by VF.

VF hereby agrees to defend, indemnify and hold harmless CCX, its Affiliates and their respective directors, officers, employees and agents (each, a "**CCX Indemnitee**") from and against any and all Losses to which any CCX Indemnitee may become subject as a result of any alleged claim, claim, demand, action or other proceeding by any Third Party to the extent such Losses arise out of: (a) the, use, handling, storage, sale or other disposition of any Product by VF or its Affiliates or sublicensees, (b) the negligence or willful misconduct of any VF Indemnitee, or (c) the breach by VF of any warranty, representation, covenant or

agreement made by VF in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of the negligence or willful misconduct of any CCX Indemnitee or CCX's CMO or the material breach by CCX or CCX's CMO of any warranty, representation, covenant or agreement made by **CCX** in this Agreement or the Quality Agreement.

10.5 Procedure.

A Party that intends to claim indemnification under this Article 10 (the "**Indemnitee**") shall promptly notify the indemnifying Party (the "**Indemnitor**") in writing of any Third Party claim, demand, action or other proceeding (each, a "**Claim**") in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense or settlement thereof. The Indemnitee may participate at its expense in the Indemnitor's defense of and settlement negotiations for any Claim with counsel of the Indemnitee's own selection. The indemnity arrangement in this Article 12 shall not apply to amounts paid in settlement of any action with respect to a Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 10 if and to the extent the Indemnitor is actually prejudiced thereby. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification.

ARTICLE 11

CONFIDENTIALITY

The provision of Section 13 of the License Agreement "Confidentiality" shall apply in all respects to Confidential Information shared under this Agreement.

ARTICLE 12

DISPUTE RESOLUTION

The provisions of Section 15 of the License Agreement "Dispute Resolution" shall apply to all disputes that arise under this Agreement.

ARTICLE 13

MISCELLANEOUS

13.1 Insurance.

Each Party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that Party under this Agreement through the term of this Agreement and for a period of [***] years thereafter. This insurance will have policy limits of not less than (i) $[***] for each occurrence for personal injury or property damage liability (inclusive of any umbrella liability insurance policy); and (ii) $[***] in the aggregate per annum for product and completed operations liability. If requested each Party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. Each Party will further provide for a minimum of [***] days' written notice to the other Party of a cancellation of the insurance except for non-payment of premium. If a Party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the Party will forthwith notify the other Party in writing and the Parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.2 Independent Contractors.

The Parties are independent contractors and this Agreement will not be construed to create between CCX and VF any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners, or any similar relationship, the existence of which is expressly denied by the Parties.

13.3 No Waiver.

Neither Party's failure to require the other Party to comply with any provision of this Agreement will be deemed a waiver of the provision or any other provision of this Agreement.

13.4 Assignment

The provisions of Section 16.5 of the License Agreement shall apply to any proposed assignment of rights or duties under this Agreement.

13.5 Force Majeure.

Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement (other than failure to make payment when due) by reason of any reasonably unforeseeable event beyond such Party's reasonable control including but not limited to Acts of God, fire, flood, explosion, earthquake, pandemic flu, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction or other casualty, any lack or failure of transportation facilities resulting from any of the foregoing conditions or events, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. Notice of a Party's failure or delay in performance due to force majeure must be given to the other Party within [***] days after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any Party be required to prevent or settle any labor disturbance or dispute.

13.6 Notices.

Any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other Party by personal delivery or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses or electronic mail addresses set forth below:

If to CCX:

ChemoCentryx, Inc.
850 Maude Avenue
Mountain View, CA 94043
Attention: [***]
Email address: [***]

With a copy to:

ChemoCentryx, Inc.
850 Maude Avenue
Mountain View, CA 94043
Attention: [***]
Email address: [***]

If to VF

Vifor Fresenius Medical Care Renal Pharma Ltd.
Rechenstrasse 37, 9014 St. Gallen
Attention: [***]

With a copy to:

Vifor Pharma Management AG
Flughofstrasse 61
8152 – Glattbrugg
Attention: [***]
Facsimile: [***]

or to any other addresses or electronic mail addresses given to the other Party in accordance with the terms of this Section 13.6. Notices or written communications made or given by personal delivery, or electronic mail will be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt, whichever is sooner.

13.7 Severability.

If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

13.8 Intellectual Property.

Ownership of any and all Inventions conceived or reduced to practice solely by a Party or such Party's employees, consultants, or contractors (including CMOs) or jointly by the Parties or the Parties' employees, consultants or contractors (including CMOs) in the course of activities performed under or contemplated by this Agreement, any and all Intellectual Property therein, and any and all Patent applications and Patents resulting therefrom shall be subject to the provisions of Article 10 of the License Agreement.

13.9 Entire Agreement.

This Agreement, together with the License Agreement and the Quality Agreement, constitutes the full, complete, final and integrated agreement between the Parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof. Any modification, amendment, or supplement to this Agreement must be in writing and signed by authorized representatives of both Parties. In case of conflict, the prevailing order of documents will be this Agreement and the Quality Agreement.

13.10 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by VF or CCX will have any effect on the rights, duties, or obligations of the Parties under or otherwise modify this Agreement, regardless of any failure of VF or CCX to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement and is signed by both Parties.

13.11 No Third Party Benefit or Right.

For greater certainty, nothing in this Agreement will confer or be construed as conferring on any third Party any benefit or the right to enforce any express or implied term of this Agreement.

13.12 Execution in Counterparts.

This Agreement may be executed in two or more counterparts, by original, facsimile or "pdf" signature, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

13.13 Compliance.

The terms of Section 11.2(b) and (c) of the License Agreement shall apply to CCX, its CMOs and VF with respect to all activities under this Agreement.

13.14 Governing Law.

This Agreement and will be governed by and construed in accordance with the laws of the State of New York without reference to any rules of conflicts of laws.

[Signature page to follow]

IN WITNESS WHEREOF, the duly authorized representatives of the Parties have executed this Agreement as of the Effective Date.

CHEMOCENTRYX, INC.

By: /s/ Thomas Schall
Name: Thomas Schall
Title: President, CEO
Date: 2020-10-29

VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA LTD.

By: /s/ Roman Bauer
Name: Roman Bauer
Title: Head of Global Supply Chain
Date: 29-Okt-20

By: /s/ Juan Antonio De Lassaletta Fernandez
Name: Juan Antonio De Lassaletta Fernandez
Title: Head Legal & Compliance
Date: 29-Oct-20

SCHEDULE A

BULK DRUG PRODUCT SPECIFICATIONS

[***]

SCHEDULE B

TRANSFER PRICE

The following cost items shall be included in the "Cost of Goods" (as such term is defined in the License Agreement) for the Products

[***]

The following cost items shall not be included in the Cost of Goods for the Products:

[***]

SCHEDULE C

MINIMUM ORDER QUANTITY

[***]

SCHEDULE D

LIST OF APPROVED CMOs (including their affiliates)

[***]

Patheon Pharmaceuticals Inc. (2110 East Galbraith Road, Cincinnati, Ohio 45237 USA)

Hovione LLC (40 Lake Drive East Windsor, NJ 08520 USA)

[***]

[***]

[***]

SCHEDULE E

TECHNICAL DISPUTE RESOLUTION

Technical Disputes which cannot be resolved by negotiation as provided in Article 12 will be resolved in the following manner:

1. **Appointment of Expert**. Within [***] Business Days after a Party requests under Article 12 that an expert be appointed to resolve a Technical Dispute, the Parties will jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the Parties are unable to so agree within the [***] Business Day period, or if there is a disclosure of a conflict by an expert under Paragraph 2 hereof which results in the Parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of the American Arbitration Association.

2. **Conflicts of Interest**. Any person appointed as an expert will be entitled to act and continue to act as an expert even if at the time of his appointment or at any time before he gives his determination, he has or may have some interest or duty which conflicts or may conflict with his appointment if before accepting the appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses the interest or duty and the Parties will, after the disclosure, have confirmed his appointment.

3. **Not Arbitrator**. No expert will be deemed to be an arbitrator and the provisions of the American Arbitration Act or of any other applicable statute (foreign or domestic) and the law relating to arbitration will not apply to the expert or the expert's determination or the procedure by which the expert reaches his determination under this Schedule E.

4. **Procedure. Where an expert is appointed**:

(a) Timing. The expert will be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the Parties and that he issues the authorizations to the Parties and any relevant Third Party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within [***] Business Days (or another date as the Parties and the expert may agree) after receipt of all information requested by him under Paragraph 4(b) hereof.

(b) Disclosure of Evidence. The Parties undertake one to the other to give to any expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they will disclose promptly and in any event within [***] Business Days of a written request from the relevant expert to do so.

(c) Advisors. Each Party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their respective cases so that at all times the Parties will co-operate and seek to narrow and limit the issues to be determined.

(d) Appointment of New Expert. If within the time specified in Paragraph 4(a) above the expert will not have rendered a decision in accordance with his appointment, a new expert may (at the request of either Party) be appointed and the appointment of the existing expert will thereupon cease for the purposes of determining the matter at issue between the Parties except if the existing expert renders his decision with full reasons prior to the appointment of the new expert, then this decision will have effect and the proposed appointment of the new expert will be withdrawn.

(e) Final and Binding. The determination of the expert will, except for fraud or manifest error, be final and binding upon the Parties.

(f) Costs. Each Party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the Parties.

For greater certainty, [***] and further that nothing in this Agreement (including this Exhibit A) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

The following is a list of subsidiaries of the Registrant as of December 31, 2020.

Company	Jurisdiction of Incorporation
ChemoCentryx Limited	United Kingdom
ChemoCentryx Ireland Limited	Ireland

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements (Form S-3 Nos. 333-210731, 333-231257 and 333-239072) of ChemoCentryx, Inc. and the Registration Statement (Form S-8 No. 333-179507) pertaining to the ChemoCentryx, Inc. 2012 Equity Incentive Award Plan, the ChemoCentryx, Inc. Amended and Restated 2002 Equity Incentive Plan, the ChemoCentryx, Inc. Amended and Restated 1997 Stock Option/Stock Issuance Plan, and the ChemoCentryx, Inc. 2012 Employee Stock Purchase Plan of our reports dated March 1, 2021, with respect to the consolidated financial statements of ChemoCentryx, Inc. and the effectiveness of internal control over financial reporting of ChemoCentryx, Inc. included in this Annual Report (Form 10-K) of ChemoCentryx, Inc. for the year ended December 31, 2020.

/s/ ERNST & YOUNG LLP

Redwood City, California
March 1, 2021

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Thomas J. Schall, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of ChemoCentryx, Inc. for the fiscal year ended December 31, 2020;

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(s) 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(s) 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.

/s/ Thomas J. Schall, Ph.D.
Thomas J. Schall, Ph.D.
Chief Executive Officer

Date: March 1, 2021

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Susan M. Kanaya, certify that:

1. I have reviewed this Annual Report on Form 10-K of ChemoCentryx, Inc. for the fiscal year ended December 31, 2020;

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(s) 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(s) 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.

/s/ Susan M. Kanaya
Susan M. Kanaya
Chief Financial and Administrative Officer

Date: March 1, 2021

Exhibit 32.1

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Annual Report on Form 10-K of ChemoCentryx, Inc. (the "Company") for the period ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas J. Schall, Ph.D., as Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2021

/s/ Thomas J. Schall, Ph.D.
Thomas J. Schall, Ph.D.
Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Annual Report on Form 10-K of ChemoCentryx, Inc. (the "Company") for the period ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Susan M. Kanaya, as Chief Financial and Administrative Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2021

/s/ Susan M. Kanaya
Susan M. Kanaya
Chief Financial and Administrative Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.