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, 2021

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 001-37345

CHINOOK THERAPEUTICS, INC.

	(Ex	act name of Registrant as specifi	ed in its Charter)		
	Delaware (State or other jurisdiction of incorporation or organization)	400 Fairview Avenue North, Seattle, WA 98109	94-3348934 (I.R.S. Employer Identification No.) O Fairview Avenue North, Suite 900 Seattle, WA 98109		
	(Addı	ress of principal executive offices	including zip code)		
	Registrant	's telephone number, including a	rea code: (206) 485-7241		
Securities registered	pursuant to Section 12(b) of the Act:				
	Title of each class	Trading Symbol(s)	Name of e	each exchange on which registered	
Comm	on Stock, par value \$0.0001 per share	KDNY		e Nasdaq Stock Market LLC Nasdaq Global Select Market)	
Securities registered	pursuant to Section 12(g) of the Act: Non	e			
Indicate by check m	ark if the Registrant is a well-known seaso	ned issuer, as defined in Rule 405 of the	Securities Act. YES □ NO ⊠		
Indicate by check m	ark if the Registrant is not required to file	reports pursuant to Section 13 or 15(d) of	the Act. YES \square NO \boxtimes		
	ark whether the Registrant: (1) has filed all ich shorter period that the Registrant was re				
	ark whether the Registrant has submitted e the preceding 12 months (or for such short				32.405 of
	ark whether the Registrant is a large accele arge accelerated filer", "accelerated filer", '				npany. See
Large accelerated fi	ler 🗆			Accelerated filer	
Non-accelerated file	r 🗵			Smaller reporting company	\boxtimes
				Emerging growth company	
	th company, indicate by check mark if the s provided pursuant to Section 13(a) of the		ded transition period for compl	lying with any new or revised financia	al
	ark whether the registrant has filed a repor) of the Sarbanes-Oxley Act (15 U.S.C. 72				porting
	ark whether the Registrant is a shell compa			-	
	et value of the Registrant's common stock ch date, was \$460,117,610.	held by non-affiliates as of June 30, 2021	, based on the closing price of	the shares of common stock on the Na	ısdaq
	es of Registrant's Common Stock outstand	ing as of March 10, 2022 was 54,951,079			
	-	DOCUMENTS INCORPORATED BY	REFERENCE		
Registrant's fiscal	gistrant's definitive proxy statement for in year ended December 31, 2021, are inco- cally incorporated by reference in this A	rporated by reference in Part III, Items	10 through 14 of this Annual	Report on Form 10-K. Except with	
Auditor Firm Id:	238 Auditor Name:	PricewaterhouseCoopers LLP	Auditor Location:	Seattle, Washington, United States	

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Corporate Information

Chinook Therapeutics, Inc. (the "Company", "Chinook", "we", "our", or "us) is a clinical-stage biopharmaceutical company. On October 5, 2020, Aduro Biotech, Inc. ("Aduro") completed its merger with Chinook Therapeutics U.S., Inc. ("Private Chinook"), pursuant to the terms of a merger agreement dated as of June 1, 2020, and amended on August 17, 2020, by which a wholly owned subsidiary of Aduro merged with and into Private Chinook, with Private Chinook continuing as a wholly owned subsidiary of Aduro (the "Merger"). Immediately following the Merger, Aduro changed its name to "Chinook Therapeutics, Inc." and the business conducted by Private Chinook became the primary business conducted by the Company.

Forward Looking Statements

This Annual Report on Form 10-K contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements, other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases you can identify these statements by forward-looking words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect" or the negative or plural of these words or similar expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- our ability to develop and commercialize our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to fund our working capital needs for at least the next twelve months;
- our ability to use and expand our technologies to build a pipeline of product candidates;
- the potential of our technologies and our ability to execute on our corporate strategy;
- the strength and breadth of our patent portfolio;
- the potential for receipt of additional milestone payments;
- our ability to obtain and adequately protect intellectual property rights for our product candidates;
- our continued reliance on third parties for manufacturing our product candidates, conducting our clinical trials and certain research activities;
- our ability to in-license, acquire or invest in complementary businesses, technologies, products or assets to further expand or complement our portfolio of product candidates;
- expected timing of our clinical trials;
- the timing and availability of results of our clinical trials and those of our collaborators; and
- our ability to extend our operating capital.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors" and elsewhere in this Annual Report on Form 10-K. You should not rely upon forward-looking statements as predictions of future events. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, after the date of this report, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise.

We obtained industry, market and competitive position data in this report from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information or estimates.

PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing precision medicines for kidney diseases. Our pipeline is focused on rare, severe chronic kidney diseases with well-defined clinical pathways. Our lead clinical program is atrasentan, an endothelin A receptor antagonist. In March 2021 we initiated the phase 3 ALIGN trial of atrasentan for IgA nephropathy, or IgAN, and in April 2021 we initiated the phase 2 AFFINITY basket trial for proteinuric glomerular diseases. Our second product candidate, BION-1301, is an anti-APRIL monoclonal antibody also in development for patients with IgAN. We presented results from the ongoing phase 1/2 trial at the American Society of Nephrology, or ASN, Kidney Week in November 2021. We plan to maintain commercial rights for atrasentan and BION-1301 in North America and possibly Europe. In November 2021, we also established SanReno Therapeutics, or SanReno, a joint venture to develop, manufacture and commercialize kidney disease therapies in mainland China, Hong Kong, Macau, Taiwan and Singapore, or collectively, the Territory. East-Asian populations have a higher incidence and prevalence of IgAN than in the United States and Europe. We believe that a strong local presence in East-Asia may allow us to accelerate the clinical development and maximize the commercial potential of atrasentan and BION-1301 in the region. We are also advancing our third program, CHK-336 towards an expected start of a phase 1 clinical trial in healthy volunteers in the first half of 2022. We are developing CHK-336 for the treatment of primary hyperoxaluria, or PH, as well as secondary hyperoxaluria and idiopathic kidney stone formation. In addition, we are conducting research programs in several other rare, severe chronic kidney diseases. We seek to build our pipeline by leveraging insights from kidney single cell RNA sequencing, humanderived organoids and new translational models, to discover and develop therapeutic candidates with mechanisms of action targeted against key kidney disease pathways. To support these efforts, we have entered into a strategic collaboration with Evotec SE, or Evotec, to jointly identify, characterize and validate novel mechanisms and discover precision medicines for lupus nephritis, IgAN, polycystic kidney disease, or PKD, and other primary glomerular diseases. The collaboration with Evotec will also involve further characterization of pathways and patient stratification strategies for programs currently in our clinical and preclinical pipeline.

Chronic kidney disease is a large and growing problem globally, with few approved therapies and a large unmet medical need. Nearly one-in-ten people globally suffer from chronic kidney disease. In the United States alone, it is estimated that over \$138 billion is spent annually on managing and treating kidney diseases, much of which is dedicated to dialysis, transplant and supportive care after a patient's kidneys have already failed. Despite the large unmet medical need, there are few drugs approved to prevent the progression of kidney disease. Drug development in nephrology has historically been hindered by categorization of disease based on clinical presentation or kidney pathology, rather than underlying molecular mechanism or genetics. This has resulted in the development of drugs with non-specific mechanisms to address broad indications that contain heterogeneous patient populations with a variety of distinct disease drivers. Complicating matters, large, lengthy and expensive clinical outcome-based clinical trials have been required to establish proof of concept and regulatory approval for new drugs.

We believe now is an opportune time for precision medicine to be applied in kidney disease, since many of the historical barriers can be overcome. The field is rapidly changing as an increased understanding of underlying disease biology has led to new and validated drug targets, novel translational platforms, and patient stratification tools. Importantly, regulators have recently accepted biomarkers such as proteinuria and eGFR as registration endpoints in certain well-characterized disease populations, potentially reducing the time and cost previously associated with clinical trials in nephrology.

Our approach to precision medicines leverages recent advances in identifying targeted kidney therapies linked to mechanistic biomarkers by the application of systems biology approaches in nephrology. The application of systems biology to nephrology has advanced over the past decade through the study of multiple patient groups across a wide variety of kidney diseases and their associated multilevel data sets, including genome, transcriptome, proteome, metabolome, pathology and prospective long-term clinical characteristics and outcomes. A key objective of these investigations is to define kidney diseases in molecular terms to drive the development of targeted treatments. We believe we are well-positioned to exploit the insights provided into the key molecular drivers and classifiers of kidney diseases by the application of these systems biology tools to nephrology. Our strategy is to use these mechanistic insights to select compelling drug targets and deliver novel and differentiated product candidates for rare and severe kidney diseases with high unmet medical need.

Our experienced research and development team has partnered with academic founders and key opinion leaders to identify targets and utilize novel translational technologies to develop precision medicines for kidney diseases. One of the key challenges in defining molecular mechanisms of kidney disease has been the cellular heterogeneity of the kidney, with nearly 30 distinct cell types arranged in the complex three-dimensional structure of the nephron. This cellular diversity and structure have made it difficult to understand the specific mechanisms associated with loss in kidney function. The recent development of genome-wide single-cell RNA sequencing of cell populations harvested from the kidney presents a new opportunity to dissect molecular mechanisms of kidney function and disease. We utilize single-cell RNA sequencing techniques developed by one of our academic founders to gain high resolution molecular insights into kidney disease mechanisms.

The cellular heterogeneity of the kidney has historically presented barriers to developing translationally relevant in-vitro cellular models of human kidney diseases. Recently, pluripotent stem cell, or PSC, derived kidney organoids along with patient derived three-

dimensional cellular systems have emerged as advanced preclinical models to study kidney disease. Additionally, under our collaboration with Evotec, we are utilizing Evotec's proprietary comprehensive molecular datasets from thousands of patients across chronic kidney diseases of multiple underlying etiologies to identify, characterize and validate novel mechanisms and discover precision medicines for PKD, lupus nephritis, IgAN and other primary glomerular diseases. The collaboration will also involve further characterization of pathways and patient stratification strategies for programs currently in our clinical and preclinical pipeline.

We believe our research and discovery approach provides significant insights into human disease mechanisms and allows us to select and validate key targets that are central drivers of human kidney diseases.

Atrasentan

Our lead product candidate is atrasentan, a potent and selective endothelin A receptor antagonist that we are developing for the treatment of proteinuric glomerular diseases. In March 2021 we initiated a phase 3 trial of atrasentan called ALIGN for IgAN, and in April 2021 we initiated a phase 2 basket trial called AFFINITY for proteinuric glomerular diseases.

IgAN, the leading cause of primary glomerulonephritis, is a serious progressive autoimmune disease of the kidney with only one steroidal treatment approved. Up to 45 percent of IgAN patients progress to end-stage kidney disease, or ESKD. We estimate that IgAN affects approximately 140,000 – 150,000 people in the United States, approximately 200,000 people in Europe and several million people in Asia. Galactose-deficient immunoglobulin A1, or Gd-IgA1, is recognized as a critical autoantigen to which IgAN patients develop circulating autoantibodies, resulting in the formation and deposition of immune complexes in the glomeruli of the kidney. This process initiates an inflammatory cascade that damages the glomeruli, resulting in protein and blood leaking into the urine, called proteinuria or hematuria, respectively. Ultimately the filtration function of the kidney is impaired, reducing the ability to remove waste products from the blood. As the disease progresses, these waste products accumulate and can result in potentially life-threatening complications that often lead to the need for dialysis or kidney transplant. Sustained proteinuria is the most widely studied and the strongest predictor for the rate of progression to ESKD in IgAN.

Activation of the endothelin A receptor, or ET_A receptor, has been implicated as a key driver of proteinuria, renal cell injury, including podocyte dysfunction and mesangial cell activation, along with promoting kidney inflammation and fibrosis, all resulting in the progression of IgAN. Atrasentan, by blocking ET_A, has the potential to provide benefit in multiple chronic kidney diseases by reducing proteinuria and having direct anti-inflammatory and anti-fibrotic effects to preserve kidney function. We in-licensed atrasentan in December 2019 from AbbVie, which previously developed atrasentan for diabetic kidney disease through multiple clinical trials, including the phase 3 SONAR trial, which evaluated atrasentan in over 5,000 patients. We presented new preclinical data elucidating the mechanism of action of atrasentan in IgAN at multiple nephrology congresses in 2021, including the ISN World Congress of Nephrology, or WCN, International Podocyte Conference and ASN Kidney Week. In preclinical studies, atrasentan rapidly reduced albuminuria and downregulated intra-renal transcriptional proliferative, inflammatory and fibrotic signaling in the gddY mouse IgAN model. The data also showed that atrasentan attenuated human renal mesangial cell activation induced by endothelin-1 or IgAN patient immune-derived immune complexes in a translational model system.

In 2015, AbbVie made a strategic decision to exit kidney disease drug development and ultimately discontinued the SONAR trial in 2017 when less than half of the planned events had occurred due to a lower than predicted annual occurrence of the primary renal outcome. Clinical investigators closed the trial per protocol during which time further events accrued, and in April 2019 the data was reported at the WCN and simultaneously published in *The Lancet*. At that time, after only 184 out of a planned 425 events had been observed, the trial showed a statistically significant p-value of 0.029 on its primary endpoint of a composite of hard kidney outcomes, consisting of time to first occurrence of progression to end-stage kidney disease or doubling of serum creatinine. In the SONAR trial, atrasentan also demonstrated statistically significant reductions in proteinuria as well as improvements in the estimated glomerular filtration rate, or eGFR, both of which are measures of kidney function. Trial results showed atrasentan having well-characterized and manageable safety results in this high-risk diabetic kidney disease patient population. Fluid retention-related adverse events were more frequent in the atrasentan group than in the placebo group; however, these adverse events are a known class effect of endothelin receptor antagonists, and they were anticipated and generally well-managed in this high-risk diabetic population.

Based on the encouraging data from SONAR and strong mechanistic rationale, in March 2021 we initiated the phase 3 ALIGN trial of atrasentan in patients with IgAN at high risk of kidney function decline. We chose IgAN as the lead indication for evaluation of atrasentan due to the role of endothelin activation and proteinuria in disease progression, potential improved tolerability of atrasentan in this patient population, high unmet need and the possibility of submitting a new drug application, or NDA, seeking accelerated approval based on surrogate endpoints, including proteinuria. In April 2021 we initiated the phase 2 AFFINITY trial in other proteinuric glomerular diseases, including cohorts of patients with lower proteinuria IgAN, focal segmental glomerosclerosis, or FSGS, and Alport syndrome, as well as diabetic kidney disease combined with sodium glucose co-transporter 2, or SGLT2. inhibitors, such as canagliflozin or dapagliflozin, which have recently been shown to provide clinical benefit in patients with diabetic kidney disease. If our trials proceed as planned, we plan to present data from the IgAN patient cohort of the AFFINITY trial in an oral

presentation at the ERA Congress in May 2022, and one or more additional cohorts of the AFFINITY trial during the second half of 2022, as well as data for the primary proteinuria endpoint in the ALIGN trial in 2023 to support accelerated approval.

BION-1301

We are also developing BION-1301, an investigational humanized IgG4 monoclonal antibody that blocks APRIL, a soluble factor that is believed to be implicated in IgAN and other indications, from binding to its receptors.

Patients with IgAN have significantly higher levels of APRIL than healthy individuals, and higher APRIL levels in these patients correlate with poor prognosis in the form of increased Gd-IgA1, increased proteinuria and decreased eGFR. Published literature has demonstrated that APRIL critically drives IgA class switching, the survival of IgA-producing plasma cells and the secretion of Gd-IgA1 (Hit 1 in the multi-hit pathogenesis of IgAN). Our preclinical experiments demonstrate that blocking APRIL inhibits the survival of and immunoglobulin production by human plasma cells. We have also demonstrated that IgA-producing plasma cells are more sensitive to immunomodulation by BION-1301, with a lesser effect observed on IgG, providing the potential to deplete IgA with BION-1301, while tempering effects on IgG and minimizing the potential for immunosuppression associated with IgG depletion. Blocking APRIL with BION-1301 is a distinct approach to IgAN by reducing circulating levels of Gd-IgA1 which is considered to be the pathogenic variant of IgA in IgAN. We believe BION-1301 represents a novel potential disease-modifying treatment for IgAN.

Preclinical studies have demonstrated that BION-1301 binds to a specifically defined epitope on APRIL, resulting in complete blockade of APRIL-induced receptor activation. In a preclinical study of BION-1301 in non-human primates, we observed a significant reduction of blood IgA levels and a favorable safety profile. Additional preclinical studies demonstrated that APRIL transgenic mice produce rising levels of IgA as well as IgA deposits in the kidney. Administration of mouse anti-human APRIL was shown to reduce levels of IgA in both the serum and the kidney. In patients with IgAN, BION-1301 has been shown to neutralize APRIL and deplete Gd-IgA1, resulting in clinically meaningful reductions in proteinuria.

A phase 1/2 clinical trial of BION-1301 is currently ongoing. Parts 1 and 2 of this trial evaluating the safety and tolerability of BION-1301 in healthy volunteers have been completed. In healthy volunteers, BION-1301 was well-tolerated, demonstrated dose-dependent increases in target engagement as measured by free APRIL levels, dose-dependently and durably reduced IgA, IgM and IgG levels (to a lesser extent) and had a half-life of approximately 33 days, suggesting the potential for an extended dosing interval. Additional data in healthy volunteers from this trial were presented at the 2021 WCN, or WCN'21, demonstrating BION-1301 produced dose-dependent reductions in serum Gd-IgA1 levels that were greater in magnitude than previously reported for total IgA concentrations.

In addition, we completed a phase 1 intravenous, or IV to subcutaneous, or SC, bioavailability study in healthy volunteers. Results from the bioavailability study were presented at WCN'21. In this study, BION-1301 was well-tolerated when administered by both IV and SC routes in healthy volunteers, the pharmacokinetic profile of BION-1301 was consistent with previous clinical studies, the absorption rate of BION-1301 was typical of a monoclonal antibody and the magnitude of pharmacodynamic responses were largely retained with SC dosing compared to IV dosing.

We are currently enrolling patients with IgAN in Cohort 2 of Part 3 of the phase 1/2 trial in which patients with IgAN are dosed with 600 mg of BION-1301 SC every two weeks for up to 52 weeks. We presented data from Cohort 1 of Part 3 of this trial, in which patients were dosed with 450 mg of BION-1301 IV every two weeks, at ASN Kidney Week 2021 in early November. The data presented at the conference demonstrate that BION-1301 was generally well-tolerated to date in patients with IgAN, with no serious adverse events or treatment discontinuations due to adverse events. The pharmacokinetics of BION-1301 observed in patients with IgAN were consistent with those previously reported in healthy volunteers and sufficient to drive rapid and sustained reductions in free APRIL levels, as well as durable reductions in Gd-IgA1, IgA, IgM, and to a lesser extent, IgG levels. BION-1301 demonstrated a greater than fifty percent (50%) geometric mean reduction in 24-hour urine protein creatinine ratio, or UPCR, in patients with IgAN after three (n=6) to six months (n=4) of treatment, a clinically meaningful result in this patient population.

Recent amendments to the design of Part 3 also include the option for a third cohort of patients to receive a SC dose of BION-1301 at a dose and schedule that would be determined based on data generated from Cohort 2. We believe moving forward with Cohort 3 may help us better understand the SC dose-response relationship prior to moving into a pivotal trial in IgAN, which we anticipate initiating in 2023.

CHK-336

Our third clinical development candidate is CHK-336, a liver-targeted oral small molecule lactate dehydrogenase, or LDHA, inhibitor, which we are developing for the treatment of PH, secondary hyperoxaluria and idiopathic kidney stone formation. Hyperoxalurias, including PH, are diseases caused by excess oxalate, a potentially toxic metabolite typically filtered by the kidneys

and excreted as a waste product in urine. Symptoms of PH include recurrent kidney stones, which when left untreated, can result in kidney failure requiring dialysis or dual kidney/liver transplantation. In patients with hyperoxalurias, excess oxalate combines with calcium to form calcium oxalate crystals that deposit in the kidney, resulting in the formation of painful kidney stones and driving progressive kidney damage over time. PH1, PH2 and PH3 are a group of ultra-rare diseases caused by genetic mutations that result in excess oxalate, and in their most severe forms, can lead to end-stage kidney disease at a young age. We also believe CHK-336 may have potential in the treatment of patients with secondary hyperoxaluria and idiopathic stone formation. We have submitted an investigational new drug application, or IND, and are advancing CHK-336 towards an expected start of a phase 1 clinical trial in healthy volunteers in the first half of 2022 for the treatment of PH. We have also received rare pediatric disease designation from the FDA for CHK-336 for the treatment of PH.

Research and Discovery Programs

Beyond CHK-336, we have active research and discovery efforts focused on other rare, severe kidney diseases. Our precision medicine research approach focuses on developing product candidates targeting the most promising molecular pathways identified as key disease drivers in collaboration with key scientific advisors. Our scientific advisors provide valuable guidance on target selection, prioritization and validation strategies, as well as access to technology platforms that support target validation efforts through biological insights into human disease mechanisms and translational cellular and animal model systems.

In March 2021, we announced a strategic collaboration with Evotec focused on the joint identification, characterization and validation of novel mechanisms as well as the discovery of precision medicines for lupus nephritis, IgAN, PKD and other primary glomerular diseases. The collaboration leverages access to the National Unified Renal Translational Research Enterprise, or NURTuRE, patient biobank for chronic kidney diseases and nephrotic syndrome as well as Evotec's proprietary PanOmics platform, which combines enhanced throughput proteomics, high throughput transcriptomics and cell imaging with PanHunter, Evotec's unique data analysis platform. Through our collaboration with Evotec, we intend to characterize molecular drivers, identify and validate novel targets and drive patient stratification strategies in kidney disease.

Our Pipeline

We have assembled a portfolio of precision medicines product candidates designed to address rare, severe chronic kidney diseases with potentially well-defined and efficient clinical pathways. We intend to further enhance our portfolio by identifying novel kidney disease targets for research and development and in-licensing promising product candidates for kidney diseases. Our development programs consist of the following:



Our Strategy

Our goal is to be a leader in the discovery, development and commercialization of precision medicines to treat kidney diseases. Our strategy includes the following key components:

Continue to advance the phase 3 ALIGN trial of atrasentan for IgAN towards an expected topline proteinuria data readout in 2023, and begin presenting data from the phase 2 AFFINITY basket trial for proteinuric glomerular diseases during 2022. In March 2021, we initiated the phase 3 ALIGN trial of our lead product candidate, atrasentan, for IgAN. We received feedback from the U.S. Food and Drug Administration, or the FDA, and the European Medicines Agency, or the EMA, on the design of our phase 3 trial, which utilizes reduction in proteinuria after six months of treatment as the primary endpoint to support an application for accelerated approval under Subpart H in the United States, and reduction in eGFR decline following 2.5 years of treatment followed by a wash-

out period as the potential confirmatory endpoint for full approval, if accelerated approval is granted. In April 2021 we initiated the phase 2 AFFINITY basket trial in proteinuric glomerular diseases. We plan to present data from the IgAN patient cohort of the AFFINITY trial in an oral presentation at the ERA Congress in May 2022, and one or more additional cohorts of the AFFINITY trial during the second half of 2022, followed by topline proteinuria data from ALIGN expected in 2023. We believe the hemodynamic, anti-fibrotic and anti-inflammatory properties of atrasentan, as well as its impact to reduce mesangial cell activation, could provide significant clinical benefit on top of standard-of-care RASis for patients with IgAN.

Determine the optimal dose and schedule for BION-1301 to advance into a pivotal trial for IgAN in 2023. We plan to complete Part 3 of the ongoing phase 1/2 clinical trial in which patients with IgAN receive subcutaneous BION-1301 during 2022. Data from Part 3 of this trial is intended to confirm the SC dose-response relationship of BION-1301 and inform the design of a pivotal trial in IgAN, which we anticipate initiating in 2023. We believe the mechanism of action of BION-1301 could potentially be disease-modifying for patients with IgAN.

Advance CHK-336 into a phase 1 trial in healthy volunteers during 2022 to position the program for a proof-of-concept trial in hyperoxaluria patients in 2023. We are advancing CHK-336 towards an expected start of a phase 1 clinical trial in healthy volunteers in the first half of 2022 for the treatment of PH. We believe CHK-336 could represent an important new treatment option for patients with diseases caused by excess oxalate production.

Identify and validate novel targets and utilize translational platforms to develop a pipeline of product candidates for rare, severe chronic kidney diseases. Our chemistry and biology teams have partnered with our academic founders and key opinion leaders, to identify, validate and develop precision medicines to add to our preclinical pipeline. Our lead program from these internal research efforts is CHK-336 for hyperoxalurias, and we also have multiple active research programs underway in other rare, severe chronic kidney diseases. Our collaboration with Evotec will supplement our internal efforts to define the molecular drivers of kidney diseases, identify novel targets for drug development in selected patient sub-populations and continue to build the foundation for our precision medicine approach.

Enhance our product portfolio by identifying novel disease targets and in-licensing promising product candidates for kidney diseases. We are actively evaluating and pursuing novel targets, intellectual property and product candidates for acquisition and in-licensing to supplement our internal research efforts and continue to build our pipeline of precision medicines for kidney disease. Through our team's focus and expertise in kidney disease, as well as our connections within the nephrology community, we are positioning the company as a partner of choice for promising renal programs. We believe continued advances in the biological understanding of kidney diseases will provide opportunities to further expand our portfolio with preclinical and/or clinical product candidates.

Maintain broad commercial rights to our product candidates. We plan to maintain commercial rights for atrasentan and BION-1301 in North America and possibly Europe. In November 2021, we also established SanReno Therapeutics, a joint venture in China to develop, manufacture and commercialize kidney disease therapies in mainland China, Hong Kong, Macau, Taiwan and Singapore. There is a large unmet medical need due to the higher incidence and prevalence of IgAN among east-Asian populations, and we believe it is important to have a strong local presence that may allow us to accelerate the clinical development and maximize the commercial potential of atrasentan and BION-1301 in the region. As we continue to advance our programs, we may pursue additional strategic collaborations to share risk and supplement our resources at the appropriate time, especially in regions outside of North America.

Continue to strengthen and expand our intellectual property portfolio. We have an intellectual property portfolio that includes issued and pending claims for atrasentan and BION-1301, as well as pending claims relating to CHK-336, in the United States and other countries. We will also look to inlicense any third-party patents relating to our pipeline programs as needed. Our proprietary position is reinforced by additional technical know-how and trade secrets. We continually assess and refine our intellectual property strategy and will file additional patent applications as appropriate.

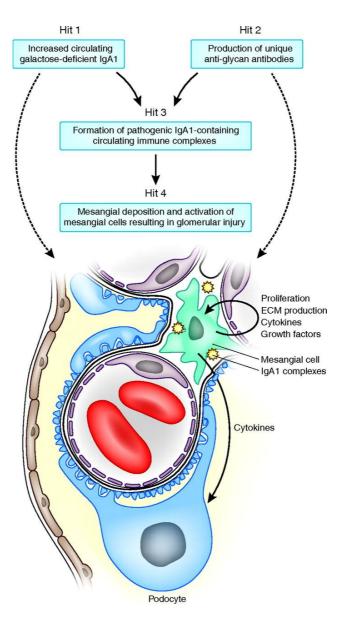
Chronic Kidney Disease Background

Chronic kidney disease, or CKD, is a large and growing problem globally. In 2017, the global prevalence of CKD was 9.4 percent (697.3 million cases) and CKD has risen from the 29th leading cause of global disability-adjusted life-years, or DALYs, in 1990 for all ages to the 18th in 2019. Overall, nearly one in ten people around the world have CKD. In the United States alone, the health care system spends over \$120 billion annually on kidney disease, much of which is dedicated to dialysis and transplant after a patient's kidneys have already failed. There have been few new drugs developed and approved for chronic kidney diseases over the past several decades. Current management of CKD largely consists of supportive care, focused mainly on controlling high blood pressure with medications. Therefore, there is a large unmet medical need for therapies that can delay or prevent progression of kidney disease, preserve kidney function and improve quality of life for people living with kidney disease. We are focused initially on developing atrasentan and BION-1301 in IgAN and other proteinuric glomerular diseases.

Immunoglobulin A Nephropathy (IgAN)

IgAN is the most common primary glomerular disease in the developed world and a leading cause of CKD and ESKD, requiring dialysis or kidney transplantation. Although the disease may follow a benign clinical course in many patients, it is estimated that up to 45 percent of IgAN patients will develop ESKD, requiring dialysis or kidney transplant, over a period of 20 to 25 years. IgAN is most commonly diagnosed in the second or third decade of life and more commonly affects males in North America and Europe, while having equal gender prevalence in Asia. There is considerable regional and ethnic variation in the epidemiology of IgAN, with a higher incidence in Caucasians and Asians and a lower incidence in individuals of African descent. Limited data from population-based studies in the United States indicate that the annual incidence of biopsy-proven disease is approximately one per 1,400 adults.

Recent research has suggested that an abnormal mucosal immune response stimulating the production of Gd-IgA1 (Hit 1), which is recognized as an autoantigen by circulating autoantibodies (Hit 2), may be the initiating event causing IgAN. As demonstrated in the figure below, immune recognition results in the formation of pathogenic immune complexes (Hit 3) that deposit in the kidney and activate mesangial cells (Hit 4), which are key cells in the kidney that provide structural support to the glomerulus. Activated mesangial cells proliferate and produce excess amounts of extracellular matrix components, such as cytokines and



Excessive tubular reabsorption of filtered proteins is thought to stimulate a pro-inflammatory response in tubular epithelial cells that results in the secretion of cytokines, chemokines, growth factors and vasoactive molecules into the tubulointerstitial space. This results in interstitial inflammation and fibrosis, which drives kidney function decline.

The clinical presentation of IgAN is heterogenous and can range from intermittent hematuria and low-level proteinuria with a benign clinical course over time and a low risk of progression to ESKD, to a more aggressive form with high levels of proteinuria and rapid loss of kidney function. Given the variable disease course, a major advance in the care of IgAN patients is the recognition of prognostic factors that can identify patients at greater risk of progression to ESKD. These prognostic markers include the presence of hypertension, evidence of reduced eGFR, and the presence of sustained proteinuria of more than one gram per day. These factors, in addition to biopsy histologic characteristics, prior medication use and race/ethnicity, have given rise to a risk prediction tool that can stratify newly diagnosed patients into risk groups. Of these various factors, the strongest risk factor for rapid progression, identified through multivariate analyses, is sustained proteinuria. The importance of this factor was demonstrated in multiple studies showing

that proteinuria over one gram per day was associated with more rapid kidney function loss in a dose-dependent fashion, and that interventions that reduce proteinuria to below one gram per day led to decreased risk of kidney failure. Therefore, clinical management of IgAN is focused on reduction of proteinuria in order to slow progression of kidney function loss.

Importantly, in patients whose proteinuria at diagnosis was greater than three grams per day, treatments that resulted in proteinuria reduction to less than one gram per day generally led to slowing of kidney function loss to a rate that was comparable to those with less than one gram per day proteinuria values at diagnosis. It is estimated that for every one-gram per day increase in proteinuria over a baseline of one gram per day there is a 10 to 25-fold higher risk of kidney failure.

The primary focus of patient management is to control glomerular pressure through the administration of hypertension medications, such as angiotensin converting enzyme inhibitors, or ACE inhibitors, and angiotensin II receptor blockers, or ARBs, as well as lifestyle management such as dietary salt restriction, smoking cessation, weight control and exercise. Patients who fail conservative management and continue to have levels of proteinuria greater than one gram per day have limited established safe and effective treatment options. Current treatment guidelines suggest that a sixmonth course of glucocorticoids can be administered to these patients, although the potential for toxicity needs to be carefully considered. In December 2021, the FDA approved a corticosteroid treatment called Tarpeyo (budesonide) for patients with IgAN at risk of rapid progression, which is generally a UPCR ≥ 1.5 g/g. Tarpeyo was approved under accelerated approval based on a reduction in proteinuria, and it has not been established whether Tarpeyo slows kidney function decline in patients with IgAN. Historically, the evidence in support of the use of corticosteroids is of low quality, and any benefit in renal protection may potentially be offset by important systemic acute and chronic toxicities. The evidence to support use of corticosteroids as well as other immunosuppressants such as rituximab, cyclophosphamide and mycophenolate mofetil remains unclear and practice patterns vary widely. Therefore, there is an important unmet medical need to develop therapies for patients with IgAN who remain at risk for progressive renal function loss despite optimal conservative management.

Other Proteinuric Glomerular Diseases

Many glomerular diseases, such as FSGS, Alport syndrome, membranous nephropathy and sickle cell nephropathy, include proteinuria as an important feature in disease progression. These glomerular diseases currently have very limited treatment options that often involve immunosuppressive therapy. For example, FSGS is an important cause of ESKD. There are currently no FDA-approved pharmacologic treatments for FSGS, and off-label treatments are limited to ACE inhibitors and ARBs, steroids and other immunosuppressant agents, which are effective in only a subset of patients. The global incidence of FSGS has been estimated at eight per million people and we estimate that there are approximately 40,000 FSGS patients in the United States and a similar number in Europe. Additionally, Alport syndrome is a rare, genetic form of CKD caused by mutations in the genes encoding type IV collagen, which is a major structural component of the glomeruli in the kidney. Patients with Alport syndrome experience a progressive worsening of the kidney's capacity to filter waste products out of the blood, which can lead to ESKD and the need for chronic dialysis treatment or a kidney transplant. Alport syndrome affects both children and adults. In patients with the most severe forms of the disease, approximately 50 percent progress to dialysis by age 25, 90 percent by age 40, and nearly 100 percent by age 60. According to the Alport Syndrome Foundation, the disease affects approximately 30,000 to 60,000 people in the United States. There are currently no approved therapies to treat Alport syndrome, and current management focuses on blood pressure control.

Our Product Candidates

Atrasentan

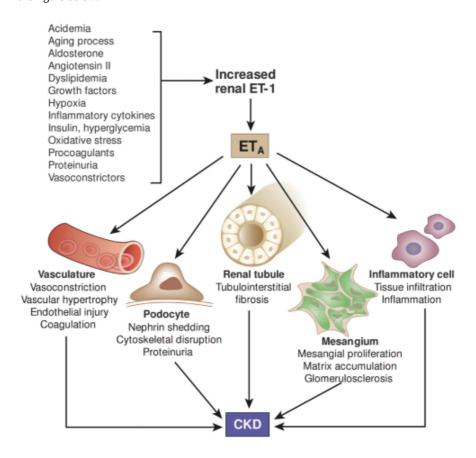
Our lead product candidate is atrasentan, a potent and selective endothelin A receptor antagonist that we are developing for the treatment of proteinuric glomerular diseases. Atrasentan is designed to reduce proteinuria and slow the progression of IgAN. In March 2021, we initiated a phase 3 trial of atrasentan called ALIGN for the treatment of IgAN, and in April 2021, we initiated a phase 2 basket trial called AFFINITY for the treatment of other proteinuric glomerular diseases.

Endothelin System in Chronic Kidney Disease

The endothelin, or ET, system consists of three peptides, ET-1, ET-2 and ET-3, which typically act locally. ET-1 is considered of most biological relevance to kidney physiology and disease. Two ET receptors, ET_A and ET_B, mediate the effects of the ET peptides. ET_A receptor activation typically results in blood vessel constriction, cellular proliferation and extracellular matrix deposition, whereas ET_B activation generally opposes these effects producing blood vessel dilation, antiproliferative and antifibrotic responses.

In kidney physiology, the ET system modulates regional kidney blood flow, mesangial cell and podocyte function and tubular acid/base handling. The ET system also regulates sodium and water excretion, so blockade of ET receptors can be accompanied by fluid retention, which is a known clinical observation with this class of agents.

The kidney ET system is activated in virtually all causes of experimental and human CKD in which it has been investigated, irrespective of the initiating cause. Activation of the ET_A receptor by ET-1 has been implicated as a key driver of proteinuria, renal cell injury, including podocyte dysfunction and mesangial cell activation, along with promoting kidney inflammation and fibrosis, all resulting in the progression of CKD. The key effects of ET_A activation in CKD are shown in the figure below.



ET-1 is the most potent and long-lasting vasoconstrictor that has been identified. This effect of ET-1 contributes to systemic and local increases in blood pressure in the kidney that support the progression of CKD. While this effect can help maintain glomerular filtration rate, or GFR, in the short term, ultimately, it is maladaptive and a central driver of kidney damage and CKD progression.

 ET_A activation also appears to have additional direct negative effects in CKD, independent of its effects on blood pressure. These additional effects include increased permeability of the glomerular filtration barrier to proteins leading to proteinuria, mesangial cell activation and kidney inflammation and fibrosis. Pharmacological studies indicate that these pathogenic effects are primarily mediated by the ET_A receptor. Combined, these observations have encouraged the investigation of ET_A inhibition as a potential therapeutic strategy in CKD.

ET pathway activation has been documented in patients with IgAN. High kidney levels of ET-1 are often seen in patients with IgAN with high levels of proteinuria, and predict rapid progression of IgAN. Selective inhibition of ET_A was studied in a clinical trial of proteinuric CKD patients without diabetes, with the selective ET_A inhibitor sitaxsentan. In this study, sitaxsentan was shown to reduce proteinuria by approximately 30 percent in this proteinuric CKD population including individuals with IgAN. In addition, ET_A blockade with sitaxsentan reduced arterial stiffness and appeared to be well tolerated with no clinically significant adverse effects reported. However, sitaxsentan was subsequently removed from the market due to liver toxicity believed to be specifically associated with the chemical structure of sitaxsentan and unrelated to ET_A inhibition.

Mechanism of Action of Atrasentan

Atrasentan is designed to be a potent, selective blocker of the ET_A receptor, and to reduce proteinuria, kidney inflammation and fibrosis, and delay the progression of kidney function loss. In preclinical studies, atrasentan has shown substantially more potency as an ET_A receptor antagonist than ET_B , with an ET_A inhibition constant [Ki] = 0.034 nanomolar, or nM, more than 1,800-fold selective

over ET_B ([Ki] = 63.3 nM). We believe atrasentan has the required selectivity profile for therapeutic benefit in CKD, while minimizing the potential for fluid retention.

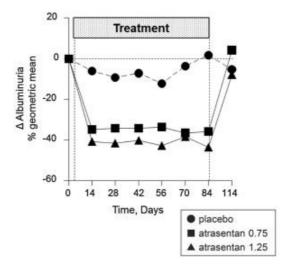
Previous Clinical Development of Atrasentan

We in-licensed atrasentan from Abbvie in late 2019. Before AbbVie made the strategic decision to terminate development of atrasentan, it had been investigated in multiple phase 1, 2 and 3 clinical trials involving approximately 622 healthy volunteers, and more than 5,000 patients with diabetic nephropathy. Atrasentan is designed to be orally bioavailable, readily absorbed with linear dose proportionality and administered once daily. Dedicated pharmacokinetic studies in special populations have demonstrated that no dose adjustment was needed based on race, degree of renal impairment, or mild or moderate hepatic impairment. Population pharmacokinetic studies have shown that the only factor significantly affecting atrasentan exposure was body weight. In prior trials, the recommended dose for evaluating atrasentan in patients with diabetic nephropathy was determined to be 0.75 mg daily, which resulted in the greatest proteinuria reduction with least fluid retention.

Atrasentan demonstrated a statistically significant and clinically meaningful reduction in proteinuria, as assessed by urine albumin to creatinine ratio, or UACR, in multiple phase 2 and phase 3 trials in diabetic nephropathy patients. In these trials, the change in UACR was generally observed within the first two weeks after treatment initiation and remained stable thereafter for the duration of chronic administration. Across phase 2 and phase 3 trials, the placebo-adjusted mean reduction in proteinuria was approximately 30 to 35 percent, although considerable intra-subject and inter-subject variability has been observed.

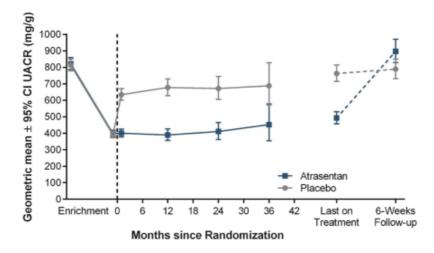
From 2013 to 2017, AbbVie conducted the global phase 3 SONAR trial, which was a randomized, double-blind, parallel, placebo-controlled, multicenter study designed to assess the effects of atrasentan on renal outcomes in patients with type 2 diabetes and CKD while they continued to be treated with the current standard of care. Despite early termination of the trial by AbbVie in 2017 for strategic reasons and due to a lower than anticipated accrual of primary endpoint events, patients who remained on trial and reached the primary endpoint of at least a 30 percent reduction in UACR following an initial six-week open label enrichment period with daily atrasentan experienced a clinically important and statistically significant improvement on the primary composite renal endpoint of time to doubling of serum creatinine or progression to ESKD (p-value=0.029). A similarly favorable trend was also observed in a smaller cohort of patients with a less than 30 percent UACR reduction in response to atrasentan following the six-week enrichment period (p-value=0.15).

The following figure shows mean UACR change from baseline to recovery for the placebo, 0.75 milligrams per day, or mg/d, atrasentan, and 1.25 mg/d atrasentan groups in AbbVie's phase 2b RADAR trial. The RADAR trial was a randomized, double-blind, placebo-controlled trial completed in 2012 that tested in 161 patients the effects of atrasentan on albuminuria reduction in patients with type 2 diabetes and nephropathy who were treated with the maximum tolerated labeled dose of a Renin Angiotensin System, or RAS, inhibitor.



The following figure shows the mean UACR levels in SONAR among the patients that experienced at least a 30 percent reduction in UACR following the initial six-week open label enrichment period. Among these 2,648 patients, UACR decreased from

baseline by an average of 51.8 percent during the enrichment period. During the double-blind period, UACR increased in the placebo group as compared to the atrasentan group (a difference of 33.6 percent, p-value<0.0001).



We believe the observed reduction in UACR across multiple clinical trials, as well as the favorable results observed on long-term renal outcomes, provide strong rationale for clinical evaluation of atrasentan in IgAN, a disease in which clinical management is centered around proteinuria reduction.

The most common and consistent safety findings across clinical studies of atrasentan in the diabetic nephropathy patient population were fluid retention and associated manifestations and dilutional anemia. In the phase 3 SONAR trial, fluid retention events were reported in approximately 26 percent of atrasentan-treated patients within the first six weeks. During the double-blind period, events of fluid retention were higher in the atrasentan groups (36.6 percent) than placebo groups (32.3 percent); however, across the population, atrasentan was associated with less than a one-kilogram increase in body weight and a six percent increase in brain natriuretic peptide levels, which is a peptide that is associated with fluid retention. In the phase 3 SONAR trial for patients with diabetic kidney disease, atrasentan was associated with a numerically higher, but not statistically significantly increased risk of heart failure hospitalizations due to fluid retention. Over time, anemia events were reported in approximately 18 percent of atrasentan patients compared with ten percent of placebo treated patients, with mean change in hemoglobin between groups of approximately one g/dL; these findings are consistent with mechanism-based hemodilution. Notably, there were no significant differences in adverse events leading to discontinuation during the double-blind treatment period between atrasentan and the placebo group.

As a class, endothelin receptor antagonists have a well-characterized embryo-fetal toxicity profile, resulting in Risk Evaluation and Mitigation Strategies, or REMS, programs and mandatory birth control for women of child-bearing age. We expect the FDA to require similar restrictions on the use of atrasentan, if approved. The endothelin system is also known to play a role in spermatogenesis, and although atrasentan was linked to reduced sperm concentrations in a small study (n=17) evaluating the effect of atrasentan on sperm concentration, sperm concentrations subsequently recovered in the four affected patients to within the normal range following drug discontinuation. The impact of long-term atrasentan treatment on spermatogenesis and male fertility is not known.

We expect that the patient population in the phase 3 ALIGN trial of atrasentan will be younger and have fewer cardiovascular co-morbidities than in the SONAR study. While patients in each clinical trial have a unique set of baseline characteristics, the mean ages of patients in two previous clinical trials in IgAN conducted by competitors were both 39 years old, while the mean age of patients in the SONAR trial was 65 years old. Additionally, patients with diabetic kidney disease are at greater risk of myocardial infarction, congestive heart failure and stroke than the non-diabetic population.

The diuretic effects achieved with SGLT2 inhibitors may offset the fluid retention effects of atrasentan, while the effects on albuminuria and kidney protection of both drug classes may be complementary due to distinct mechanisms of action. A third-party post-hoc analysis of the SONAR trial showed that in patients with type 2 diabetes and chronic kidney disease, six-weeks of treatment with atrasentan combined with an SGLT2 inhibitor versus atrasentan alone decreased body weight, a surrogate for fluid retention, and

further decreased albuminuria. We believe this data supports future exploration of the long-term efficacy and safety of atrasentan in combination with SGLT2 inhibitors in IgAN.

Rationale for Atrasentan Development in IgAN

Chronic proteinuric kidney diseases, including IgAN and other proteinuric glomerular diseases, are characterized by progressive renal function loss, accompanied by excessive levels of urinary protein excretion, and have been proposed to progress by a final common pathway, irrespective of initiating cause. Glomerular hypertension, a maladaptive response to reduced kidney function, along with increased glomerular permeability results in the increased filtration of plasma proteins, which causes proteinuria. The consequent excess exposure of protein to glomerular and tubular epithelial cells has been shown preclinically to play a key pathogenic role in the progression of CKD. Kidney cells exposed to an excessive protein load release pro-fibrotic factors that can act locally to drive glomerulosclerosis. In vitro and in vivo studies have been used to develop a model of the final common pathway whereby excessive tubular reabsorption of filtered proteins stimulates a pro-inflammatory response that results in the secretion of cytokines, chemokines, growth factors and vasoactive molecules into the tubulointerstitial space. This results in interstitial inflammation and fibrosis, which drive renal function decline.

Clinical evidence consistent with proteinuria as a causal factor in CKD pathogenesis includes the observation that proteinuria is an independent predictor of disease progression. In IgAN, there appears to be a dose-dependent effect of proteinuria on the risk of renal progression, beginning at a urinary protein excretion rate of greater than one gram per day, with increasing levels of proteinuria associated with increased risk of ESKD. Sustained proteinuria has demonstrated to be the most important predictor of the rate of kidney progression in IgAN and sustained improvements in proteinuria to less than one gram per day are associated with an excellent long-term prognosis. The finding that the rate of eGFR decline correlates negatively with proteinuria reduction and positively with residual proteinuria provides further evidence for the pathogenetic role of proteinuria in CKD progression.

In preclinical studies, atrasentan has protected the kidney in nondiabetic CKD and has also been shown to reduce proteinuria and reduce the risk of progression to ESKD clinically in type 2 diabetics with CKD. In addition, a different ET_A antagonist significantly reduced proteinuria, diminished glomerular hypercellularity and prevented the loss of kidney function in a mouse model of IgAN. Further, in a randomized, double-blind, placebo and active controlled study in proteinuric CKD subjects already achieving optimal RAS inhibition, over half of which had biopsy-proven IgAN, selective ET_A antagonist sitaxsentan significantly reduced proteinuria and substantially reduced measured GFR and effective filtration fraction, consistent with a reduction in intraglomerular hypertension.

We are investigating atrasentan in IgAN based on the scientific rationale for targeting endothelin signaling, the strong association between high levels of protein excretion in IgAN and kidney function loss, the extent of clinical data demonstrating protein-lowering effects of atrasentan and other endothelin antagonists, the potential for a better tolerated dosing regimen in the IgAN patient population, and the clear unmet medical need for specific therapies to slow disease progression to ESKD.

Proteinuria as a Surrogate Marker for IgAN

CKD trials have typically relied on clinical outcomes for the primary endpoint, such as time to first occurrence of doubling of serum creatinine or ESKD (dialysis or transplantation). This generally requires very large trials of long duration, which have proved challenging in IgAN. The Kidney Health Initiative, or KHI, a partnership between the American Society of Nephrology and the FDA launched a project in 2016 to identify surrogate endpoints that could serve as reliable predictors of a treatment's effect on long-term kidney outcomes in IgAN and be used as a basis for accelerated approval. Surrogate endpoints are used in clinical trials as a substitute for a direct measure of how a patient feels, functions or survives and although they do not measure the clinical benefit of primary interest, they are expected to predict that clinical benefit. The KHI project focused on proteinuria reduction as the most widely recognized and studied risk factor for progression to ESKD in IgAN and found a consistent relationship between the level and duration of proteinuria and loss of kidney function from epidemiologic studies. In addition, trial-level analyses of 13 randomized IgAN clinical trials showed a strong association between treatment effects on percent reduction of proteinuria at approximately nine months (measurements ranged from seven to 12 months) and treatment effects on a composite of time to doubling of serum creatinine, ESKD, or death. The analyses also indicated that the reduction of proteinuria must be sustained to confer protection against progressive loss of GFR. The KHI project concluded that proteinuria reduction is a surrogate endpoint reasonably likely to predict a treatment's effect on progression to ESKD in IgAN. In the United States, surrogate endpoints reasonably likely to predict clinical benefit can be used as a basis for accelerated approval of therapies intended to treat serious or life-threatening conditions, such as IgAN. The predicted clinical benefit of products granted accelerated approval

A recently published meta-analysis of 12 randomized clinical trials in IgAN to compare treatment effects on change in proteinuria to change in eGFR slope, provides new evidence supporting that early reduction in proteinuria can be used as a surrogate endpoint for studies of CKD progression in IgAN.

Ongoing Phase 3 ALIGN Trial of Atrasentan for the Treatment of IgAN

The ALIGN study, a phase 3, randomized, double-blind, placebo-controlled study of atrasentan in patients with IgAN at risk of progressive loss of kidney function, is designed to evaluate change from baseline in proteinuria and eGFR in 320 patients with IgAN. We have designed the trial in collaboration with a steering committee composed of leading global experts in glomerular diseases and are evaluating atrasentan at 0.75 mg daily, the dose used in the SONAR trial. The primary endpoint of the trial is change from baseline in proteinuria in the first 270 patients at six months post randomization. The key secondary endpoint is change from baseline in eGFR after all 320 patients have completed approximately two and half years of treatment. This global study is expected to be conducted in approximately 15-20 countries on four continents at approximately 160-170 investigative sites. We initiated the trial in March 2021 and anticipate data for the primary proteinuria endpoint in 2023 to support potential accelerated approval.

We have held a Type B End of phase 2 meeting with the FDA to discuss the design of the ALIGN trial and, if the data from the trial are positive, we plan to seek approval of an NDA under the accelerated approval pathway in the United States. Additionally, we have also received feedback on the study design from the EMA and the Pharmaceuticals and Medical Devices Agency, or PMDA, in Japan. Based upon this feedback, we believe that upon completion, the ALIGN trial could serve as the basis of a successful marketing authorization application, or MAA, in European countries, Japan, China and other countries.

Ongoing Phase 2 AFFINITY Basket Trial for the Treatment of Other Proteinuric Glomerular Diseases

In April 2021 we initiated a phase 2 basket study of atrasentan called AFFINITY in several populations of proteinuric glomerular disease patients. Four initial cohorts will include IgAN patients with lower levels of proteinuria (UPCR >0.5g/g <1.0 g/g urine protein/creatinine), FSGS, Alport syndrome, and diabetic kidney disease combined with an SGLT2 inhibitor. Approximately 20 patients are planned to be treated with open-label atrasentan in each cohort. The primary endpoint for each cohort will be the change from baseline in proteinuria at 12 weeks. Additional cohorts may be added to the basket study. We plan to present data from the IgAN patient cohort of the AFFINITY trial in an oral presentation at the ERA Congress in May 2022, and one or more additional cohorts of the AFFINITY trial during the second half of 2022, and believe the study will provide signal-seeking data to inform our life cycle management strategy for atrasentan.

BION-1301

Our second product candidate, BION-1301, is an investigational humanized IgG4 monoclonal antibody that blocks APRIL binding to its receptors and is being developed as a novel disease-modifying therapy for IgAN. BION-1301 is currently in an ongoing phase 1/2 clinical trial for patients with IgAN.

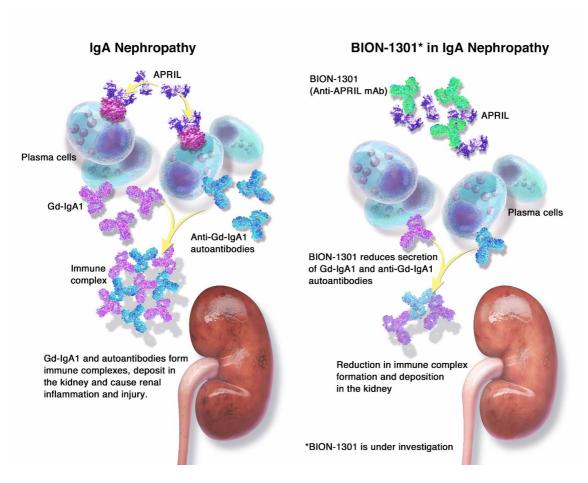
We believe the key attributes of our BION-1301 product candidate include:

- *Early Evidence of Potency.* BION-1301, a humanized antibody that blocks APRIL from binding to both its receptors, has been shown in mice and monkeys in preclinical studies to reduce serum IgA levels and to reduce IgA as well as Gd-IgA1 levels in healthy volunteers, demonstrating compelling rationale for its use in patients with IgAN.
- *Novel Mechanism.* Blocking APRIL is a distinct approach to reduce circulating levels of IgA and Gd-IgA1, with disease-modifying potential in IgAN.
- Versatility. APRIL is implicated in the pathogenesis of multiple indications including IgAN and other diseases that involve plasma cells.
- Ease of Manufacture. BION-1301 is a biologic that can be manufactured through well-established processes.
- Broad Applicability. BION-1301 is a monoclonal antibody, an established therapeutic class to treat cancer as well as autoimmune diseases.

Patients with IgAN have significantly higher levels of APRIL than healthy individuals, and higher APRIL levels in these patients correlate with poor prognosis in the form of increased Gd-IgA1, increased proteinuria and decreased eGFR. We know from published literature that APRIL critically drives IgA class switching, the survival of IgA-producing plasma cells and the secretion of Gd-IgA1 (Hit 1 in the multi-hit pathogenesis of IgAN). Our preclinical experiments demonstrate that blocking APRIL inhibits the survival of and immunoglobulin production by human plasma cells. We have also demonstrated that IgA-producing plasma cells are more sensitive to immunomodulation by BION-1301, with a lesser effect observed on IgG, providing the potential to deplete IgA with BION-1301, while tempering effects on IgG and minimizing the potential for immunosuppression associated with IgG depletion.

Blocking APRIL with BION-1301 is a distinct approach to IgAN by reducing circulating levels of Gd-IgA1 which is considered to be the pathogenic variant of IgA in IgAN. We believe BION-1301 represents a novel potential disease-modifying treatment for IgAN.

Preclinical studies have demonstrated that BION-1301 binds to a specifically defined epitope on APRIL, resulting in complete blockade of APRIL-induced receptor activation. In a preclinical study of BION-1301 in non-human primates, we observed a significant reduction of blood IgA levels and a favorable safety profile. Additional preclinical studies demonstrated that APRIL transgenic mice produce rising levels of IgA as well as IgA deposits in the kidney. Administration of mouse anti-human APRIL was shown to reduce levels of IgA in both the serum and the kidney. In patients with IgAN, BION-1301 has been shown to neutralize APRIL and deplete Gd-IgA1, resulting in clinically meaningful reductions in proteinuria. The illustration below shows the potential reduction of immune complex formation in the kidneys by BION-1301 and its effect in IgAN.



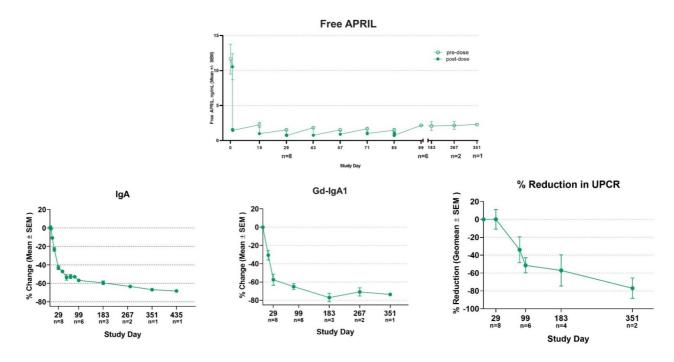
In May 2019, we initiated a phase 1/2 clinical trial evaluating BION-1301 in healthy volunteers and patients with IgAN. The phase 1/2 multi-center trial evaluated the safety and tolerability of BION-1301 in 63 healthy volunteers in double-blinded, placebo-controlled single-ascending dose, or SAD, and multiple-ascending dose, or MAD, settings. Healthy volunteers in the SAD portion of the study (Part 1) received placebo or a single IV dose of BION-1301 ranging from 10 mg to 1350 mg on day 1. Healthy volunteers in the MAD portion of the study (Part 2) received placebo or IV doses of BION-1301 ranging from 50 mg to 450 mg on days 1, 15 and 29 (three doses total).

We presented data from Parts 1 and 2 of the study in healthy volunteers at the 57th ERA-EDTA Virtual Congress in June 2020 and ASN Kidney Week 2020 Reimagined. BION-1301 was well-tolerated, with no significant adverse events, treatment discontinuations or events meeting stopping criteria, across a wide range of doses. Non-neutralizing ADAs occurred in less than 10 percent of subjects with no correlation to dose. The PK profile of BION-1301 was well-behaved, generally dose proportional, and had a half-life of approximately 33 days, suggesting the potential for an extended dosing interval. BION-1301 demonstrated a dose-dependent increase in target engagement as measured by free APRIL levels in serum; over 90 percent target engagement was achieved

with a single 450 mg dose. BION-1301 dose-dependently and durably reduced IgA and IgM levels, and to a lesser extent, IgG levels. Approximately 50 to 60 percent reduction in IgA levels was achieved with 150 mg to 450 mg of BION-1301. At all doses tested, IgG levels remained in the normal lab range, thereby providing a PD window to potentially exploit reductions in IgA, while tempering reductions in IgG. Additional data in healthy volunteers from this trial were presented at WCN'21. BION-1301 produced dose-dependent reductions in serum Gd-IgA1 levels that were greater in magnitude than previously reported for total IgA concentrations.

In addition, we have completed a phase 1 IV to SC bioavailability study in healthy volunteers. Results from this study were presented at WCN'21. In this study, BION-1301 was well-tolerated when administered by both IV and SC routes in healthy volunteers, the pharmacokinetic profile of BION-1301 was consistent with previous clinical studies, the absorption rate of BION-1301 was typical of a monoclonal antibody and the magnitude of pharmacodynamic responses were largely retained with SC dosing compared to IV dosing.

We are currently enrolling patients with IgAN in Cohort 2 of Part 3 of a phase 1/2 trial in which patients with IgAN are dosed with 600 mg of BION-1301 SC every two weeks for up to 52 weeks. We presented data from Cohort 1 of Part 3 of this trial, in which patients were dosed with 450 mg of BION-1301 IV every two weeks, at ASN Kidney Week 2021 in early November. The data presented at the conference demonstrated that BION-1301 was generally well-tolerated to date in patients with IgAN, with no serious adverse events or treatment discontinuations due to adverse events. The pharmacokinetics of BION-1301 observed in patients with IgAN are consistent with those previously reported in healthy volunteers and, as demonstrated in the figures below, are sufficient to drive rapid and sustained reductions in free APRIL levels, as well as durable reductions in Gd-IgA1, IgA, IgM, and to a lesser extent, IgG levels. BION-1301 demonstrated a greater than fifty percent (50%) geometric mean reduction in 24-hour urine protein creatinine ratio (UPCR) in patients with IgAN after three (n=6) to six months (n=4) of treatment, a clinically meaningful result in this patient population. We plan to present additional data from Cohort 1 of Part 3 of this trial in a mini-oral presentation at the ERA Congress in May 2022, and additional data from Cohort 2 of Part 3 of this trial in the second half of 2022.



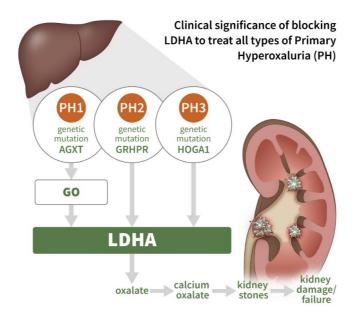
Recent amendments to the design of Part 3 also include the option for a third cohort of patients to receive a SC dose of BION-1301 at a dose and schedule that would be determined based on data generated from Cohort 2. Moving forward with Cohort 3 may help us better understand the SC dose-response relationship prior to moving into a pivotal trial in IgAN, which we anticipate initiating in 2023.

CHK-336

Our third product candidate is CHK-336, a liver-targeted oral small molecule LDHA inhibitor, which we are developing for the treatment of PH, secondary hyperoxaluria, and idiopathic kidney stone formation. Hyperoxalurias, including PH, are diseases caused by excess oxalate, a potentially toxic metabolite typically filtered by the kidneys and excreted as a waste product in urine. Symptoms

of PH include recurrent kidney stones, which when left untreated, can result in kidney failure requiring dialysis or dual kidney/liver transplantation. In patients with hyperoxalurias, excess oxalate combines with calcium to form calcium oxalate crystals that deposit in the kidney, resulting in the formation of painful kidney stones and driving progressive kidney damage over time. PH1, PH2 and PH3 are a group of ultra-rare diseases caused by genetic mutations that result in excess oxalate, and in their most severe forms, can lead to end-stage kidney disease at a young age. We also believe CHK-336 may have potential in the treatment of patients with secondary hyperoxaluria and idiopathic stone formation. We are advancing CHK-336 towards an expected start of a phase 1 clinical trial in healthy volunteers in the first half of 2022 for the treatment of PH.

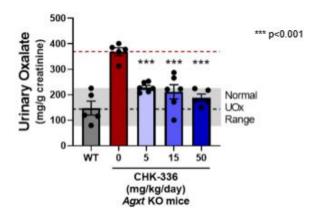
As seen in the illustration below, LDHA catalyzes the terminal step in the production of oxalate from glyoxylate in the liver, therefore LDHA inhibition has the potential to treat all forms of PH – PH1, PH2 and PH3 – as well as other disorders arising from excess oxalate. This is a point of differentiation for CHK-336 since inhibition using small molecules or silencing using small-interfering RNAs (siRNAs) of glycolate oxidase (GO), the enzyme involved in the production of glyoxylate from glycolate, is limited to the treatment of PH1 only. An oral, liver-targeted LDHA small molecule inhibitor has the potential for robust efficacy by rapidly distributing to the site of oxalate production, while minimizing systemic exposures and potential for off-target activity, to facilitate a favorable tolerability profile required in this chronic disease.



With the goal of developing a best-in-class treatment applicable to all types of PH, our research team designed, synthesized and characterized hundreds of LDHA inhibitors to engineer the required properties of potent and selective LDHA inhibition with a liver-targeted tissue-distribution profile. We designed CHK-336 to demonstrate a promising preclinical pharmacokinetic and safety profile.

In preclinical studies, CHK-336 has demonstrated tight LDHA binding and a slow enzyme off-rate, potentially extending the duration of action and enabling the potential of a once-daily oral dose in humans. In order to maximize efficacy and reduce the potential for any systemic toxicities as is observed with complete loss-of-function of LDHA, our team engineered into CHK-336 a liver-targeted tissue distribution profile by incorporating moieties that result in liver-selective OATP transporter uptake and simultaneously reducing non-specific passive permeability.

To evaluate efficacy, we generated a novel mouse model of PH1 using CRISPR-Cas9 gene editing to delete the AGXT gene responsible for PH1 in humans, which created mice with significantly elevated urinary oxalate excretion compared to normal wild-type (WT) control mice. CHK-336 was dosed orally at three different dose levels, once-daily for seven days and urinary oxalate excretion was compared to a control group of PH mice treated with vehicle. As demonstrated in the figure below, CHK-336 demonstrated significant dose-dependent reductions in urinary oxalate levels, with the majority of CHK-336 treated mice reaching the normal range seen in WT mice.



We have submitted an IND and are advancing CHK-336 towards an expected start of a phase 1 clinical trial in healthy volunteers in the first half of 2022 for the treatment of PH. We believe clinical proof of concept for CHK-336 can be achieved efficiently in small studies using urinary oxalate as a validated surrogate biomarker and primary endpoint with the potential for full approval of this program in PH. We have also received rare pediatric disease designation from the FDA for CHK-336 for the treatment of PH.

Preclinical Product Candidates

In addition to our lead product candidates, we are also conducting discovery and research efforts to develop a pipeline of product candidates in other rare, severe chronic kidney diseases.

We have initiated drug discovery programs against promising biological targets across kidney disease indications with high unmet medical need selected in alignment with our guiding precision medicine principles:

- Focus on key pathways driving kidney disease, especially where definitive genetic evidence of a causal, pathogenic role exists;
- Design novel, differentiated molecules;
- Utilize new and efficient translational approaches to speed research and development; and
- Execute clinical trials in defined patient populations with rapid, robust endpoints.

To supplement our internal research efforts, we have entered into a strategic collaboration with Evotec focused on the discovery and development of novel precision medicine therapies for patients with chronic kidney diseases. Based on Evotec's proprietary comprehensive molecular datasets from thousands of patients across chronic kidney diseases of multiple underlying etiologies, we and Evotec will jointly identify, characterize and validate novel mechanisms and discover precision medicines for lupus nephritis, IgAN, PKD, and other primary glomerular diseases. The collaboration will also involve further characterization of pathways and patient stratification strategies for programs currently in Chinook's clinical and preclinical pipeline.

Gaining access to the NURTuRE cohort study and other proprietary patient biobanks, along with Evotec's multi-omics integration platform, enables us to characterize the molecular drivers of kidney diseases, identify and validate novel targets and drive patient stratification strategies in kidney disease. With a focus on comprehensive molecular disease classification, combined with prospective clinical outcomes, we believe we have the opportunity to potentially deliver targeted therapies to the right patient populations.

License Agreements

AbbVie

In December 2019, we entered into an agreement with AbbVie, through its affiliate AbbVie Ireland Unlimited Company for an exclusive, sublicensable, worldwide license to atrasentan, along with claims in several issued patents and associated know-how, to manufacture, have manufactured, use and sell defined licensed products for use within the field of all human and non-human diagnostic, prophylactic, and therapeutic uses. Under the terms of this license, we paid an initial licensing fee and issued AbbVie 1,999,415 shares of common stock. The license agreement requires us to pay potential milestone payments totaling up to \$135 million upon the achievement of certain developmental, regulatory and commercial milestones, as well as royalties ranging from the high single digits to the high teens based on annual thresholds for net sales of licensed products by us, our affiliates and our sublicensees.

Under the AbbVie license, we have a continuing obligation to use commercially reasonable efforts to develop, obtain regulatory approvals and commercialize licensed products. The license agreement is effective on a per-country basis until the later of: (i) the last expiration of a claim in a licensed patent that covers the licensed product in such country, (ii) the expiration of any period of regulatory exclusivity for a licensed product that bars the entry of generic competitors in such country, or (iii) a specified period after the first commercial sale of the licensed product. Each party has the right to terminate the license for the other party's material breach or in the event of the other party's bankruptcy or insolvency, subject to specified notice and cure periods. Additionally, AbbVie can terminate the license if we challenge claims in licensed patents or fail to meet our diligence obligations with respect to licensed products. Upon any termination of the license, we may grant AbbVie an exclusive, sublicenseable license to any improvements that we make to the licensed technology, including those that we license from third parties, subject to a mutually agreed royalty.

Manufacturing

We currently contract with third parties to manufacture our products and anticipate using third parties for our clinical and commercial manufacturing. We do not own or operate facilities for product manufacturing, packaging, storage and distribution, or testing. We have internal personnel and utilize consultants with extensive technical, manufacturing, analytical and quality experience to oversee contract manufacturing and testing activities. We will continue to expand and strengthen our network of third-party providers but may also consider investing in internal manufacturing capabilities in the future if there is a technical need, or a strategic or financial benefit.

Manufacturing is subject to extensive regulations that impose procedural and documentation requirements. At a minimum these regulations govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance. Our systems, procedures and contractors are required to be in compliance with these regulations and are assessed through regular monitoring and formal audits.

Atrasentan. Under our license agreement with AbbVie, we received a substantial amount of drug product and drug substance to support clinical trials of atrasentan. We plan to resupply our clinical trials and prepare for future commercial launch with additional manufacturing campaigns conducted by AbbVie. In addition, we believe that the synthesis from regulatory starting material to drug substance can be manufactured at scale, resulting in a commercially competitive cost of goods.

BION-1301. We rely on third-party contract manufacturing organizations, or CMOs, to manufacture product for clinical use based on engineered cell lines that express and secrete the antibody product candidate. We have contracted with a CMO to develop, produce and release drug substance and drug product for use in the ongoing phase 1/2 clinical trial. We expect to continue to rely on CMOs for further manufacturing of BION-1301, including the development and manufacturing of alternative formulations.

CHK-336. In 2021, we continued manufacturing activities for CHK-336 initiated in 2020 to support IND-enabling studies.

Sales and Marketing

We do not currently have sales and marketing infrastructure to support commercial launch of our products. We intend to build such capabilities in North America prior to launch of atrasentan. Outside of North America, we may rely on licensing, co-sale and co-promotion agreements with strategic partners for the commercialization of our products, including the recently formed joint venture, SanReno Therapeutics, in East Asia. If we build a commercial infrastructure to support marketing in North America, such commercial infrastructure could be expected to include a targeted sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to any confirmation that atrasentan will be approved.

Coverage & Reimbursement

The regulations that govern pricing and reimbursement for new drugs 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 approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, a drug company can obtain regulatory approval for a product in a country, but then be subject to price regulations that delay commercial launch of that product.

A drug company's ability to successfully commercialize any products will also depend on the extent to which coverage and adequate reimbursement for these products will be available from government authorities, private health insurers and other organizations. Even if one or more products are successfully brought to the market, these products may not be considered cost effective, and the amount reimbursed for such products may be insufficient to allow them to be sold on a competitive basis. Third-party payors who reimburse patients or healthcare providers, such as government plans, are requiring that drug companies provide them with predetermined discounts from list prices and are seeking to reduce the prices charged or the amounts reimbursed for biopharmaceutical products.

Significant delays can occur in obtaining reimbursement for newly-approved drugs or therapeutic biologics, and coverage may be more limited than the purposes for which the drug or therapeutic biologic is approved by the FDA or similar foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be reimbursed in all cases or at a rate that covers a drug company's costs, including research, development, manufacture, sale and distribution.

Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover a drug company's costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drugs or therapeutic biologics that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs or therapeutic biologics may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs or therapeutic biologics from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for coverage and reimbursement exists in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement can differ significantly from payor to payor.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapid evolution of technologies, fierce competition and vigorous defense of intellectual property. Any product candidates that we successfully develop and commercialize will have to compete with existing and future new therapies. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions.

If our lead product candidate atrasentan is approved for the treatment of IgAN, it may compete with other products used to treat this disease. To our knowledge, there is only one FDA-approved drug for IgAN, the corticosteroid treatment Tarpeyo (budesonide), but there are a variety of additional treatments utilized, including renin angiotensin inhibitors, steroids, chemotherapy drugs and immunomodulatory approaches. In addition, there are a number of competitors in clinical development for the treatment of IgAN at a similar stage of development or more advanced than us, including AstraZeneca PLC, Calliditas Therapeutics AB, Novartis AG, Omeros Corporation, Reata Pharmaceuticals, Inc., Travere Therapeutics, Inc., Vera Therapeutics and Otsuka Pharmaceutical Co., Ltd.

Many of our potential competitors, alone or with strategic partners, may have substantially greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Accordingly, our competitors may be more successful than us in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining approval for treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive. Mergers and acquisitions in the biotechnology and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or less expensive than any product candidates that we may develop. In geographies that are critical to our commercial success, competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to

enter the market, if ever. The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience and availability of reimbursement. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic drugs.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including obtaining, maintaining and defending patent rights, whether developed internally or licensed from third parties. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, platforms and product candidates that are important to the development and implementation of our business. Our patent portfolio, including in-licensed patents and patent applications, is intended to cover, but is not limited to, our technology platforms, product candidates and components thereof, their methods of use and processes for their manufacture, and any other inventions that are commercially important to our business. We also rely on trade secret protection of our confidential information and know-how relating to our proprietary technology, platforms and product candidates, continuing innovation, and in-licensing opportunities to develop, strengthen, and maintain our position in our platform and product candidates. Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to maintain our licenses to use intellectual property owned or controlled by third parties; to defend and enforce our proprietary rights, including our patents; to defend against challenges and assertions by third parties of their purported intellectual property rights; and to operate without infringement of valid and enforceable patents and other proprietary rights of third parties.

With respect to atrasentan, we have exclusively licensed issued U.S. and foreign patents and pending U.S. and foreign patent applications that cover formulations and methods of use related directly to atrasentan from AbbVie. These exclusively licensed patents included eight issued U.S. patents and three pending foreign patent applications. These patents, and any patents that issue from the pending applications, that we have licensed from AbbVie are anticipated to expire between 2028 and 2034, absent any patent term adjustments or extensions.

Separately, we have filed U.S. patent applications with claims that are intended to cover additional methods of treatment and combinations of atrasentan with other therapies in kidney disease. Any patents that may issue from these currently pending patent applications, which include PCT international applications, U.S. patent applications, and foreign patent applications, are expected to expire in 2040-2041, absent any patent term adjustments or extensions.

With respect to BION-1301, we have four issued U.S. patents, eleven issued foreign patents, one pending U.S. patent and 12 pending foreign patents, that cover the composition of matter of BION-1301, as well as methods of use. These patents, and any patents that issue from the pending applications are anticipated to expire between 2030 and 2041, absent any patent term adjustments or extensions.

With respect to CHK-336, we have in-licensed issued U.S. and foreign patents and have filed U.S. and foreign patent applications with claims that cover the composition of matter of CHK-336 and other related compounds, as well as methods of use. As of December 31, 2021, any patents that may issue from these currently pending patent applications, which include PCT international applications, U.S. patent applications, and foreign patent applications, are expected to expire in 2041, absent any patent term adjustments or extensions.

The term of individual patents depends upon the laws of the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. However, the term of United States patents may be extended for delays incurred due to compliance with the FDA requirements or by delays encountered during prosecution that are caused by the United States Patent and Trademark Office, or the USPTO. For example, for drugs that are regulated by the FDA under the Hatch-Waxman Act, it is permitted to extend the term of a patent that covers such drug for up to five years beyond the normal expiration date of the patent. For more information on patent term extensions, see "— *Government regulation—The Hatch-Waxman Act—Patent term extension.*" In the future, if and when our biopharmaceutical product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates. We intend to seek patent term extensions to any of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the USPTO and FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. Our currently issued patents will likely expire on dates ranging from 2028 to 2036, unless we receive patent term extension. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2036 to 2041, unless we receive patent term extension or patent term adjustment, or both. However, 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, specific claims issues, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. The patent situation outside of the United States is even more uncertain. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in the United States and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, importing or otherwise commercializing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending and enforcing patent claims that cover our technology, inventions, and improvements. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our platform and product candidates and the methods used to manufacture them. Moreover, our issued patents and those that may issue in the future may not guarantee us the right to practice our technology in relation to the commercialization of our platform's product candidates. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology. Our issued patents and those that may issue in the future may be challenged, narrowed, circumvented or invalidated, which could limit our ability to stop competitors from marketing related platforms or product candidates or limit the length of the term of patent protection that we may have for our product candidates. In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or third parties may seek to develop our clinical candidates in countries where we do not have patent protection. This risk may also affect our ability to partner rights in those countries. For these reasons, we may have competition for our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before any product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. For this and other risks related to our proprietary technology, inventions, improvements, platforms and product candidates, please see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

We have filed for trademark protection of the "Chinook Therapeutics" mark with the USPTO and foreign trademark registries. We intend to register and maintain the trademark "Chinook Therapeutics" in the USPTO and in numerous other jurisdictions, including, but not limited to, the European Union (EU), China, India, Switzerland, the United Kingdom, or UK, and Canada.

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our confidential and proprietary information as trade secrets, including through contractual means with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements under the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In many cases our confidentiality and other agreements with consultants, outside scientific collaborators, sponsored researchers and other advisors require them to assign or grant us licenses to inventions they invent as a result of the work or services they render under such agreements or grant us an option to negotiate a license to use such inventions. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breache

We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. To the extent that our employees, contractors, consultants, collaborators and advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in relation to the resulting know-how or inventions. For more information, please see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries

and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA, the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including Good Laboratory Practices, or GLP. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with Good Clinical Practices, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, and ethics committee for approval. The IRB will also monitor the clinical trial until completed. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in phase 2 evaluations, phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases the FDA requires two adequate and well-controlled phase 3 clinical trials to demonstrate the efficacy of the drug. A single phase 3 trial may be sufficient in rare instances, including (1) where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) when in conjunction with other confirmatory evidence.

The manufacturer of an investigational drug in a phase 2 or 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls.

The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding \$3,100,000 for Fiscal Year 2022 for an application containing clinical data. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved NDA are also subject to annual program fees, currently exceeding \$360,000 for each prescription product. The FDA adjusts the user fees on an annual basis, and the fees typically increase annually.

The FDA reviews each submitted NDA before it determines whether to file it and may request additional information. The FDA must make a decision on whether to file an NDA within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is filed, the FDA begins an in-depth review of the NDA. The FDA has agreed to certain performance goals in the review of NDAs. Most applications for standard review drug products are reviewed within ten to twelve months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines may offer significant improvement in safety or effectiveness compared to marketed products or where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA does not always meet its goal dates for standard and priority NDAs, and the review process can be extended by FDA requests for additional information or clarification.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an outside advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with Good Manufacturing Practices, or cGMP, requirements. The FDA will not approve the product 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. The FDA also typically inspects clinical trial sites to ensure compliance with GCP requirements and the integrity of the data supporting safety and efficacy.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter, or CRL, generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application, such as additional clinical data, additional pivotal clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant may resubmit the NDA addressing all of the deficiencies identified in the letter, withdraw the application, engage in formal dispute resolution or request an opportunity for a hearing. The FDA has committed to reviewing resubmissions in two or six months depending on the type of information included. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If, or when, the deficiencies identified in the CRL have been addressed to FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a REMS to help ensure that the benefits of the drug outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of an NDA supplement or, in some case, a new NDA, before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their

clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Expedited Development and Review Programs

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition.

Fast Track Designation

Fast track designation may be granted for a product that is intended to treat a serious or life-threatening disease or condition for which preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. The sponsor of an investigational drug product may request that the FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the submission of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's NDA before the application is complete. This rolling review is available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. At the time of NDA filing, the FDA will determine whether to grant priority review designation. Additionally, fast track designation may be withdrawn if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Accelerated Approval

Accelerated approval may be granted for a product that is intended to treat a serious or life-threatening condition and that generally provides a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval 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. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. The accelerated approval pathway is contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies to verify and describe the product's clinical benefit. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making the product for this type of disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The first NDA applicant to receive FDA approval for a particular active moiety to treat a rare disease for which it has such designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Other benefits of orphan drug designation include tax credits for certain research and an exemption from the NDA user fee.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted, with certain exceptions.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or nonpatent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Rare Pediatric Disease Vouchers

The Rare Pediatric Disease Voucher Program is intended to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Although there are existing incentive programs to encourage the development and study of drugs for rare diseases, pediatric populations, and unmet medical needs, this program provides an additional incentive for the development of drugs for rare pediatric diseases, which may be used alone or in combination with other incentive programs. A rare pediatric disease is defined as a disease that is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and is a rare disease or condition as defined in the FD&C Act, which includes diseases and conditions that affect fewer than 200,000 persons in the U.S. and diseases and conditions that affect a larger number of persons and for which there is no reasonable expectation that the costs of developing and making available the drug in the U.S. can be recovered from sales of the drug in the U.S.

The sponsor of a human drug application for a rare pediatric disease drug product may be eligible for a voucher that can be used (or sold) to obtain a priority review for a subsequent human drug application submitted under section 505(b)(1) of the FD&C Act or section 351 of the Public Health Service Act after the date of approval of the rare pediatric disease drug product. The rare pediatric disease priority review voucher program was most recently reauthorized by Congress in the Consolidated Appropriations Act of 2021, extending the rare pediatric disease program through September 30, 2024, with the potential for priority review vouchers to be granted through September 30, 2026.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, 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. Drugs may be marketed only for the approved indications and in a manner consistent with the approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the Agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The Hatch-Waxman Amendments

Orange Book Listing

Under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch Waxman Amendments, NDA applicants are required to identify to the FDA each patent whose claims cover the applicant's drug or approved method of using the drug. Upon approval of a drug, the applicant must update its listing of patents to the NDA in timely fashion and

each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredient(s), strength, route of administration, and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. An approved ANDA product is considered to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved under the ANDA pathway are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug pursuant to each state's laws on drug substitution.

The ANDA applicant is required to certify to the FDA concerning any patents identified for the reference listed drug in the Orange Book. Specifically, the applicant must certify to each patent in one of the following ways: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. For patents listed that claim an approved method of use, under certain circumstances the ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents through a Paragraph IV certification, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA-holder and patentee(s) once the ANDA has been accepted for filing by the FDA (referred to as the "notice letter"). The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice letter. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months from the date the notice letter is received, expiration of the patent, the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired. In some instances, an ANDA applicant may receive approval prior to expiration of certain non-patent exclusivity if the applicant seeks, and the FDA permits, the omission of such exclusivity-protected information from the ANDA prescribing information.

Exclusivity

Upon NDA approval of a new chemical entity, or NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot receive any ANDA seeking approval of a generic version of that drug unless the application contains a Paragraph IV certification, in which case the application may be submitted one year prior to expiration of the NCE exclusivity. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA for a generic version of the drug may be filed before the expiration of the exclusivity period.

Certain changes to an approved drug, such as the approval of a new indication, the approval of a new strength, and the approval of a new condition of use, are associated with a three-year period of exclusivity from the date of approval during which the FDA cannot approve an ANDA for a generic drug that includes the change. In some instances, an ANDA applicant may receive approval prior to expiration of the three-year exclusivity if the applicant seeks, and the FDA permits, the omission of such exclusivity-protected information from the ANDA package insert.

Patent Term Extension

The Hatch Waxman Amendments permit a patent term extension as compensation for patent term lost during the FDA regulatory review process. Patent term extension, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. After NDA approval, owners of relevant drug patents may apply for the extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval) up to a maximum of five years. The time can be reduced for any time the FDA determines that the applicant did not pursue approval with due diligence.

The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. However, the USPTO may not grant an extension because of, for example, failing to exercise due diligence during the testing phase or

regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested.

The total patent term after the extension may not exceed 14 years, and only one patent per product can be extended. The application for the extension must be submitted prior to the expiration of the patent, and for patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain general business and marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes, false claims statutes and other healthcare laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully offering, soliciting or receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of the Anti-Kickback Statute or specific intent to violate it in order to commit a violation.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicare and Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, 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 federal civil False Claims Act. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises of any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services. 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 commit a violation.

Further, pursuant to the ACA, the Centers for Medicare & Medicaid Services, or CMS, has issued a final rule that requires manufacturers of prescription drugs to collect and report information on certain payments or transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, certain types of advance practice nurses and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The reported data is made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties.

In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the posting of information relating to clinical studies and their outcomes. Some states require the reporting of certain drug pricing information,

including information pertaining to and justifying price increases. In addition, certain states require pharmaceutical companies to implement compliance programs and/or marketing codes. Certain states and local jurisdictions also require the registration of pharmaceutical sales and medical representatives. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

Efforts to ensure that business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. If a drug company's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other federal or state government healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment, and reputational harm. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

U.S. Healthcare Reform

Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. On September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The Department of Health and Human Services, or HHS, plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. Many similar proposals, including the plans to give Medicare Part D authority to negotiate drug prices, require drug manufacturers to pay rebates on drugs whose prices increase greater than the rate of inflation, and cap out-of-pocket costs, have already been included in policy statements and legislation currently being considered by Congress. It is unclear to what extent these and other statutory, regulatory, and administrative initiatives will be enacted and implemented.

Data Privacy & Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes privacy, security and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates that perform certain services involving creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities.

Even when HIPAA does not apply, according to the Federal Trade Commission, or FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 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.

In addition, certain state and non-U.S. laws, notably the California Consumer Privacy Act, or CCPA, the EU's General Data Protection Regulation, or GDPR, and Canada's Personal Information Protection and Electronic Documents Act, or PIPEDA, 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, the CCPA, which went into effect January 1, 2020, provides for among other things, new data privacy obligations for covered companies and 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. Colorado and Virginia have also recently enacted comparable consumer privacy regimes set to take effect in 2023, and as of January 2022, fourteen states have pending legislation under review relating to consumer privacy. In Europe, the GDPR went into effect in May 2018 and introduced strict requirements for processing the personal data of individuals within the European Economic Area, or EEA. In addition, the GDPR increases the scrutiny of transfers of personal

data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws, and imposes substantial fines for breaches and violations. In Canada, PIPEDA and similar provincial laws impose obligations on companies with respect to processing personal information, including health-related information. PIPEDA requires companies to obtain an individual's consent when collecting, using or disclosing that individual's personal information. Individuals have the right to access and challenge the accuracy of their personal information held by an organization, and personal information may only be used for the purposes for which it was collected. If an organization intends to use personal information for another purpose, it must again obtain that individual's consent. Failure to comply with PIPEDA could result in significant fines and penalties.

Domestic laws in all 50 states have various thresholds requiring businesses to provide notice to customers whose personally identifiable information was been disclosed as a result of unauthorized access or data breach, in addition to requirements under foreign and federal laws. The laws and respective regulations are not consistent and frequently amended.

Employees and Human Capital Resources

As of December 31, 2021, we had 138 employees, of which 40 held a Ph.D. or M.D. We have not experienced any work stoppages. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Corporate Information

On October 5, 2020, Chinook Therapeutics U.S., Inc. completed its business combination with Aduro Biotech, Inc., a publicly held company. In connection with the Merger, Aduro Biotech, Inc. changed its name to Chinook Therapeutics, Inc. For additional information regarding this business combination, refer to Note 3, "Reverse Merger and Contingent Value Rights" within Part II, Item 8, "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K. Aduro Biotech, Inc. was incorporated in Delaware in June 2011. Chinook Therapeutics U.S., Inc. (prior to its business combination with Aduro Biotech, Inc.) was incorporated in Delaware in November 2018.

Our principal executive offices are located at 400 Fairview Avenue North, Suite 900, Seattle, WA 98109 and our telephone number is (206) 485-7241. Our website address is www.chinooktx.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K. The following filings are available through the SEC, which maintains an Internet site at www.sec.gov, and through our website as soon as reasonably practicable after we file them with the SEC: Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, as well as any amendments to such reports and all other filings pursuant to Section 13(a) or 15 (d) of the Securities Act.

Chinook Therapeutics, the Chinook logo and other trade names, trademarks or service marks of Chinook appearing in this Annual Report on Form 10-K are the property of Chinook. Trade names, trademarks and service marks of other companies appearing in this report are the property of their respective holders.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and all of the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes and the section "Management's Discussion and Analysis of Financial Condition and Results of Operations," before investing in our common stock. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business. If any of the following risks materialize, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Summary of Risk Factors

Our business is subject to a number of risks and uncertainties, including those immediately following this summary. Some of these risks are:

- We have a history of operating losses, and may not achieve or sustain profitability. We anticipate that we will continue to incur losses for the foreseeable future. If we fail to obtain additional funding to conduct our planned research and development efforts, we could be forced to delay, reduce or eliminate our product development programs or commercial development efforts.
- The continued presence of COVID-19, or the outbreak of a similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including the execution of our planned clinical trials.
- We expect to need to raise additional funding before we can become profitable from any potential future sales of atrasentan or our other product candidates.
- We have identified material weaknesses in our internal control over financial reporting. Failure to achieve and maintain effective internal control over financial reporting could harm our business and negatively impact the value of our common stock.
- If we are unable to develop, obtain regulatory approval for and commercialize atrasentan or any other future product candidates, or if we experience significant delays in doing so, our business will be materially harmed.
- Success in preclinical studies and earlier clinical trials for our product candidates may not be indicative of the results that may be obtained in later clinical trials, including our phase 3 clinical trial for atrasentan, which may delay or prevent obtaining regulatory approval.
- Atrasentan and our other product candidates may cause undesirable and/or unforeseen side effects or be perceived by the public as unsafe, which could delay or prevent their advancement into clinical trials or regulatory approval, limit the commercial potential or result in significant negative consequences.
- Certain of the diseases we seek to treat have low prevalence and it may be difficult to identify patients with these diseases, which may lead to delays in enrollment for our trials or slower commercial revenue if atrasentan or our other product candidates are approved.
- The commercial success of our product candidates, including atrasentan, will depend upon their degree of market acceptance by providers, patients, patient advocacy groups, third-party payors and the general medical community.
- We face significant competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours.
- · The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production.
- We may attempt to secure FDA approval of atrasentan and our other product candidates through the accelerated approval pathway. If we are unable to obtain accelerated approval, we may be required to conduct additional clinical trials beyond those that we currently contemplate.
- Actual or perceived failure to comply with privacy and data protection laws or to adequately secure the personal information we hold could result in significant legal liability or reputational harm, and, in turn, create a material adverse effect on our potential future revenue and research & testing efforts.
- Our success depends in part on our ability to obtain, maintain and protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Risks Related to Our Financial Position

We have a history of operating losses, and may not achieve or sustain profitability. We anticipate that we will continue to incur losses for the foreseeable future. If we fail to obtain additional funding to conduct our planned research and development efforts, we could be forced to delay, reduce or eliminate our product development programs or commercial development efforts.

We are a clinical-stage biotechnology company with a limited operating history. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. Our operations to date have been limited primarily to organizing and staffing the Company, business planning, raising capital, acquiring and developing product and technology rights, manufacturing, and conducting research and development activities for our product candidates. We have never generated any revenue from product sales. We have not obtained regulatory approvals for any of our product candidates and have funded our operations to date through proceeds from sales of preferred stock and common stock.

We have incurred net losses in each year since our inception. We incurred a net loss of \$102.9 million for the year ended December 31, 2021. As of December 31, 2021, we had an accumulated deficit of \$231.8 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future as we intend to continue to conduct research and development, clinical testing, regulatory compliance activities, manufacturing activities, and, if any of our product candidates are approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in us incurring significant losses for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We expect to need to raise additional funding before we become profitable from any potential future sales of atrasentan or our other product candidates. This additional financing may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We will require substantial future capital in order to complete planned and future preclinical and clinical development for atrasentan and other product candidates and potentially commercialize these product candidates. Based upon our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities held as of December 31, 2021 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months. We expect our spending levels to increase in connection with our preclinical studies and clinical trials of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant expenses related to commercial launch, product sales, medical affairs, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations before any commercial revenue may occur.

Additional capital might not be available when we need it and our actual cash requirements might be greater than anticipated. If we require additional capital at a time when investment in our industry or in the marketplace in general is limited, we may not be able to raise funding on favorable terms, if at all. If we are not able to obtain financing when needed or on terms favorable to us, we may need to delay, reduce or eliminate certain research and development programs or other operations, sell some or all of our assets or merge with another entity.

Our operations have consumed significant amounts of cash since inception. Our future capital requirements will depend on many factors, including:

- the costs associated with the scope, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs associated with the manufacturing of our product candidates;
- the costs related to the extent to which we enter into partnerships or other arrangements with third parties to further develop our product candidates;
- the costs and fees associated with the discovery, acquisition or in-license of product candidates or technologies;
- our ability to establish collaborations on favorable terms, if at all;
- the costs of future commercialization activities, if any, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
 and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives, which may not be available to us on acceptable terms, or at all.

We have identified material weaknesses in our internal control over financial reporting. Failure to achieve and maintain effective internal control over financial reporting could harm our business and negatively impact the value of our common stock.

We have identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In preparing our consolidated financial statements as of and for the years ended December 31, 2021 and 2020, our management identified the following material weaknesses in its internal control over financial reporting: (i) we did not design or maintain an effective control environment commensurate with its financial reporting requirements due to lack of sufficient accounting professionals with the appropriate level of skill, experience and training commensurate with its financial reporting requirements. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of its financial reporting objectives, as demonstrated by, among other things, insufficient segregation of duties in its finance and accounting functions. This contributed to additional material weaknesses as: (ii) we did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting reporting and disclosures, including controls over the preparation and review of account reconciliations, journal entries and period end financial reporting; and (iii) we did not design and maintain controls over the operating effectiveness of information technology general controls for information systems that are relevant to the preparation of its financial statements. Specifically, we did not design and maintain effective controls over program change management; user access, including segregation of duties; or computer operations.

These material weaknesses could result in adjustments to our consolidated financial statements. Additionally, these material weaknesses could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our future annual or interim financial statements that would not be prevented or detected, and accordingly, we determined that these control deficiencies constitute material weaknesses.

In 2021, we hired additional accounting personnel with appropriate experience, certification, education and training as a component of our plans to remediate the material weaknesses. To the extent that we are not able to retain such individuals, the material weaknesses identified may not be remediated and management may be required to record additional adjustments to our financial statements in the future.

Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes-Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, could have a material adverse effect on our business and share price.

Our management is required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

In preparing our consolidated financial statements as of and for the years ended December 31, 2021 and 2020, we identified material weaknesses in our internal control over financial reporting. We cannot assure you that the material weaknesses identified will be remediated on the timelines currently anticipated by us, or at all, and/or that there will not be additional material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report on our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its reporting on internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biotechnology company and our operations to date have been limited to organizing and staffing the Company, business planning, raising capital, acquiring our technology, identifying potential product candidates, undertaking research

and preclinical studies of our product candidates, manufacturing, and establishing licensing arrangements. We have limited experience in conducting clinical trials and have not yet demonstrated the ability to successfully complete clinical trials of our product candidates, obtain marketing approvals, manufacture a commercial scale product or conduct sales and marketing activities necessary for commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Risks Related to Our Product Development and Regulatory Approval

If we are unable to develop, obtain regulatory approval for and commercialize atrasentan or any other future product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

We plan to invest a substantial amount of our efforts and financial resources in our current lead product candidates, atrasentan, an endothelin receptor antagonist, and BION-1301, an anti-APRIL monoclonal antibody. We initiated the ALIGN phase 3 clinical trial of atrasentan, for the treatment of IgAN in March 2021, and in April 2021 we initiated the phase 2 AFFINITY clinical trial for certain proteinuric glomerular diseases. In addition, we are conducting a phase 1/2 clinical trial of BION-1301 for the treatment of IgAN and we presented updated data from this trial at ASN in November 2021. We have submitted an IND and are advancing CHK-336 towards an expected start of a phase 1 clinical trial in healthy volunteers in the first half of 2022 for the treatment of PH. We are developing CHK-336 for the treatment of primary hyperoxaluria, as well as secondary hyperoxaluria and idiopathic kidney stone formation, and have received rare pediatric disease designation from the FDA for CHK-336 for the treatment of PH. In addition, we are conducting research programs in several other rare, severe chronic kidney diseases. Our ability to generate product revenue will depend heavily on the successful development and eventual commercialization of atrasentan and our other product candidates, which may never occur. We currently generate no revenue from sales of any product, and we may never be able to develop or commercialize a marketable product.

Each of our programs and product candidates will require further clinical and/or preclinical development, regulatory approval in multiple jurisdictions, obtaining preclinical, clinical and commercial manufacturing supply, capacity and expertise, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. Attrasentan and our other product candidates must be authorized for marketing by the FDA, the Health Products and Food Branch of Health Canada, or HPFB, the EMA, and certain other foreign regulatory agencies before we may commercialize any of our product candidates.

The success of atrasentan and our other product candidates depends on multiple factors, including:

- successful completion of preclinical studies, including those compliant with GLP, or GLP toxicology studies, biodistribution studies and minimum effective dose studies in animals, and successful enrollment and completion of clinical trials compliant with current GCPs;
- effective INDs and Clinical Trial Authorizations, or CTAs, that allow commencement of our planned clinical trials or future clinical trials for our product candidates in relevant territories;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development of our product candidates, both in the United States and internationally;
- maintenance of arrangements with third-party contract manufacturing organizations, or CMOs, for key materials used in our manufacturing processes and to establish backup sources for clinical and large-scale commercial supply;
- positive results from our clinical programs that are supportive of safety and efficacy and provide an acceptable risk-benefit profile for our product candidates in the intended patient populations;
- receipt of regulatory approvals from applicable regulatory authorities, including those necessary for pricing and reimbursement of our product candidates;
- establishment and maintenance of patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercial launch of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, patient advocacy groups, third-party payors and the general medical community;
- our effective competition against other therapies available in the market;
- establishment and maintenance of adequate reimbursement from third-party payors for our product candidates;
- our ability to acquire or in-license additional product candidates;
- prosecution, maintenance, enforcement and defense of intellectual property rights and claims;

- maintenance of a continued acceptable safety profile of our product candidates following approval, including meeting any post-marketing commitments or requirements imposed by or agreed to with applicable regulatory authorities;
- political factors surrounding the approval process, such as government shutdowns, political instability or global pandemics such as the outbreak of the novel strain of coronavirus, COVID-19; or
- disruptions in enrollment of our clinical trials due to the COVID-19 pandemic.

If we do not succeed in one or more of these factors in a timely manner or at all, then we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Success in preclinical studies and earlier clinical trials for our product candidates may not be indicative of the results that may be obtained in later clinical trials, including our phase 3 clinical trial for atrasentan, which may delay or prevent obtaining regulatory approval.

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies and early clinical trials may not be predictive of results in later-stage clinical trials, and successful results from early or small clinical trials may not be replicated or show as favorable an outcome in later-stage or larger clinical trials, even if successful. We will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are safe and effective for their intended uses before we can seek regulatory approvals for their commercial sale. The conduct of phase 3 trials and the submission of an NDA or BLA is a complicated process. We have limited experience in conducting clinical trials and preparing, submitting and supporting regulatory filings, and have not previously submitted an NDA or BLA. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials and other requirements in a way that leads to NDA or BLA submission and approval of any product candidate we are developing.

We in-licensed atrasentan from AbbVie. Atrasentan was previously investigated in a phase 3 clinical trial evaluating the effects of atrasentan on progression of kidney disease in patients with diabetic kidney disease, referred to as the SONAR trial. While patients receiving atrasentan in the SONAR trial had a lower rate of primary composite renal events than patients receiving placebo, the trial accrued measurable primary endpoints at a slower rate than expected, and AbbVie decided to close the study early for corporate strategic reasons. We believe the results of the SONAR trial support further evaluation of atrasentan in IgAN. Although the SONAR trial was not terminated due to safety concerns, further safety issues could be discovered in our phase 3 and phase 2 trials. Based on the data from the SONAR trial, we believe that atrasentan, combined with current standard of care, may have benefits compared to treatment with current standard of care. However, we cannot assure that any potential advantages that we believe atrasentan may have for treatment of patients with proteinuric glomerular diseases will be substantiated by our planned clinical trials or included in the product's labeling should we obtain approval. Without head-to-head data, we will not be able to make comparative claims with respect to any other treatments. In addition, the patient populations under investigation with atrasentan have many co-morbidities that may cause severe illness or death, which may be attributed to atrasentan in a manner that negatively affects its safety profile. If the results of our clinical trials for atrasentan are inconclusive with respect to efficacy, if we do not meet our clinical endpoints with statistical significance, or if there are unanticipated safety concerns or adverse events that emerge during clinical trials, we may have to conduct further preclinical studies and/or clinical trials before obtaining marketing approval, or we may be prevented from or delayed in obtaining marketing approval.

Though atrasentan has been evaluated by AbbVie in late-stage clinical trials, our other product candidates, such as BION-1301 and CHK-336, have only been evaluated in early-stage clinical trials or have yet to enter clinical trials, and we may experience unexpected or negative results in the future as our other product candidates are evaluated in clinical trials. Any positive results we have observed in preclinical animal models may not be predictive of our future clinical trials in humans, as animal models carry inherent limitations relevant to all preclinical studies. Our product candidates may also fail to show the desired safety and efficacy in later stages of clinical development even if they successfully advance through initial clinical trials. Even if our clinical trials demonstrate acceptable safety and efficacy of atrasentan or our other product candidates and such product candidates receive regulatory approval, the labeling we obtain through negotiations with the FDA or foreign regulatory authorities may not include data on secondary endpoints and may not provide us with a competitive advantage over other products approved for the same or similar indications.

Many companies in the biotechnology industry have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and there is a high failure rate for product candidates proceeding through clinical trials. In addition, different methodologies, assumptions and applications we utilize to assess particular safety or efficacy parameters may yield different statistical results. Even if we believe the data collected from clinical trials of our product candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities. Preclinical and clinical data can be interpreted in different ways. Accordingly, the FDA or foreign regulatory authorities could interpret these data in different ways from us or our

partners, which could delay, limit or prevent regulatory approval. If our study data do not consistently or sufficiently demonstrate the safety or efficacy of any of our product candidates, including atrasentan, to the satisfaction of the FDA or foreign regulatory authorities, then the regulatory approvals for such product candidates could be significantly delayed as we work to meet approval requirements, or, if we are not able to meet these requirements, such approvals could be withheld or withdrawn.

Even if we complete the necessary preclinical studies and clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate and the approval may be for a narrower indication than we seek.

Prior to commercialization, atrasentan and our other product candidates must be approved by the FDA pursuant to an NDA or BLA in the United States and pursuant to similar marketing applications by the HPFB, EMA and similar regulatory authorities outside the United States. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market atrasentan or any of our other product candidates from regulatory authorities in any jurisdiction. We have no experience in submitting and supporting the applications necessary to gain marketing approvals, and, in the event regulatory authorities indicate that we may submit such applications, we may be unable to do so as quickly and efficiently as desired. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept or file any application or may decide if our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpre

Approval of atrasentan and our other product candidates may be delayed or refused for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate, to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidates are safe and effective for any of their proposed indications;
- the populations studied in clinical trials may not be sufficiently broad or representative to assure efficacy and safety in the populations for which we seek approval;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval:
- we may be unable to demonstrate our product candidates' clinical and other benefits outweigh their safety risks;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the facilities of third-party manufacturers with which we contract or procure certain service or raw materials, may not be adequate to support approval of our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Even if our product candidates meet their pre-specified safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner and may not consider the clinical trial results sufficient to grant, or we may not be able to obtain, regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings, contraindications or REMS. These regulatory authorities may also grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and adversely affect our business, financial condition, results of operations and prospects.

The COVID-19 pandemic, or similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including the execution of our clinical trials.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. The measures taken in response to the COVID-19 pandemic have 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. The extent to which COVID-19 impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and the actions to contain the virus or treat its impact.

For instance, our phase 3 and phase 2 clinical trials of atrasentan and our phase 1/2 clinical trial of BION-1301 have been and may continue to be affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis for our clinical trials has been and may continue to be delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. Additionally, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. If the global effort to control the spread of COVID-19 and treat COVID-19 patients continues on the current trajectory for an extended period of time, we risk a delay in activating sites and enrolling subjects as previously projected. Any such delays in our phase 3 ALIGN clinical trial for atrasentan and the clinical trials for our other product candidates could impact the use and sufficiency of our existing cash reserves, and we may be required to raise additional capital earlier than we had previously planned. We may be unable to raise additional capital if and when needed, which may result in further delays or suspension of our development plans.

Further, infections and deaths related to COVID-19 are disrupting certain healthcare and healthcare regulatory systems globally. Such disruptions could divert healthcare resources away from, or materially delay review by, the FDA and comparable foreign regulatory agencies. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially adversely affect the development and study of our product candidates.

We currently utilize third parties to, among other things, manufacture raw materials and our product candidates, components, parts, and consumables, and to perform quality testing. If either we or any third-party in the supply chain for materials used in the production of our product candidates are adversely impacted by restrictions resulting from the COVID-19 pandemic, our supply chain may be disrupted, limiting our ability to manufacture product candidates for our clinical trials.

In response to the COVID-19 pandemic, we have at times limited access to our offices and have undertaken safety precautions to reduce the risk of transmission in our workforce. Due to mandated local travel restrictions, such as quarantine requirements, third parties conducting clinical or manufacturing activities may not be able to access laboratory or manufacturing space, and our core activities may be significantly limited or curtailed, possibly for an extended period of time.

The spread of COVID-19, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material adverse effect on our business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets and the trading prices of biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the global effort to control COVID-19 infections could materially and adversely affect our business.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on the Company's business, our planned clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on our business, financial condition and results of operations.

Atrasentan and our other product candidates may cause undesirable and/or unforeseen side effects or be perceived by the public as unsafe, which could delay or prevent their advancement into clinical trials or regulatory approval, limit the commercial potential or result in significant negative consequences.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our product candidates' use. For example, in the phase 3 SONAR trial, the most common adverse events of atrasentan included fluid retention and anemia. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. If any such adverse events occur, our clinical trials could be suspended or terminated and the FDA, the

HPFB, the European Commission, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Even if we can demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may adversely affect our business, financial condition, results of operations and prospects significantly. Other treatments for kidney diseases that utilize an ET_A receptor antagonist or similar mechanism of action could also generate data that could adversely affect the clinical, regulatory or commercial perception of atrasentan and our other product candidates.

Additionally, if any of our product candidates receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of the product outweigh its risks, which may include, for example, a Medication Guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners, or other elements to assure safe use of the product. For example, other approved ERAs have been required to include a REMS for women of child-bearing age regarding the risk of embryo-fetal toxicity. Furthermore, if we or others later identify undesirable side effects caused by our product candidates, several potentially significant negative consequences could result, including:

- · regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings in the labeling;
- · we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly.

Certain of the diseases we seek to treat have low prevalence, and it may be difficult to identify patients with these diseases, which may lead to delays in enrollment for our trials or slower commercial revenue growth if atrasentan or our other product candidates are approved.

While chronic kidney diseases represent a large market, primary glomerular kidney diseases, including IgAN, to which our lead product candidate is targeted, have relatively low incidence and prevalence. We estimate that IgAN affects approximately 140,000 – 150,000 patients in the United States, approximately 200,000 people in Europe and several million people in Asia. We are also developing CHK-336 for the treatment of primary hyperoxaluria, which is an ultra orphan disease with an even smaller number of patients. Small target patient populations could pose obstacles to the timely recruitment and enrollment of a sufficient number of eligible patients in our trials, or limit a product candidate's commercial potential. Patient enrollment may be affected by other factors including:

- the ability to identify and enroll patients that meet study eligibility criteria in a timely manner for clinical trials;
- the severity of the disease under investigation;
- design of the study protocol;
- the perceived risks, benefits and convenience of administration of the product candidate being studied;
- the patient referral practices of providers;
- the proximity and availability of clinical trial sites to prospective patients; and
- the availability of approved or investigational alternative treatment options.

Our inability to enroll a sufficient number of patients with these diseases for our clinical trials would result in significant delays and could cause us to not initiate or abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased time to potential approval and development costs for our product candidates, which would cause the value of the Company to decline and limit our ability to obtain additional financing.

Additionally, our projections of both the number of people who have IgAN and other proteinuric glomerular diseases, as well as the people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates derived from a commissioned market research study, which may not accurately identify the size of the market for our product candidates. The total addressable market opportunity for atrasentan and our other product candidates will ultimately depend upon, among other things, the final labeling for our product candidates, if our product candidates are approved for sale in our target

indications, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients globally may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Moreover, in light of the limited number of potential patients impacted by proteinuric glomerular diseases, our per-patient therapy pricing of atrasentan, if approved, may need to be high in order to recover our development and manufacturing costs, fund additional research and achieve profitability. We may also need to fund patient support programs upon the marketing of a product candidate, which would negatively affect our product revenue. We may be unable to maintain or obtain sufficient therapy sales volumes at a price high enough to justify our development efforts and our sales, marketing and manufacturing expenses.

We may not be successful in our efforts to expand our pipeline of product candidates and develop marketable products.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. Our business depends on our successful development and commercialization of the limited number of internal product candidates we are researching or have in preclinical development. Even if we are successful in continuing to build our pipeline, development of the potential product candidates that we identify will require substantial investment in additional clinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply capability, building a commercial organization, and significant marketing efforts before we generate any revenue from product sales. Furthermore, such product candidates may not be suitable for clinical development, including as a result of their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we cannot develop further product candidates, we may not be able to obtain product revenue in future periods, which would adversely affect our business, prospects, financial condition and results of operations.

Although our pipeline includes multiple programs, we are primarily focused on our lead product candidates, atrasentan, BION-1301 and CHK-336, and we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities and our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. Our understanding and evaluation of biological targets for the discovery and development of new product candidates may fail to identify challenges encountered in subsequent preclinical and clinical development. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if it fails to comply with regulatory requirements or if it experiences unanticipated problems with our product candidates, when and if any of them are approved.

Our product candidates and the activities associated with their development and potential commercialization, including their testing, manufacturing, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other U.S. and international regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, including current Good Manufacturing Practices, or cGMPs, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities and requirements regarding the distribution of samples to providers and recordkeeping. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of any approved product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure that they are marketed in a manner consistent with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. If we promote our product candidates in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. Violations of the FD&C Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws and similar laws in international jurisdictions.

In addition, later discovery of previously unknown adverse events or other problems with our product candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such product candidates, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- · warning or untitled letters;
- withdrawal of any approved product from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of product candidates;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our product candidates;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we have obtained, and we may not achieve or sustain profitability.

Non-compliance with Canadian and European requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with Canada's or Europe's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States.

To market and sell atrasentan and our other product candidates in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time and data required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Failure to obtain foreign regulatory approvals or non-compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

Risks Related to Commercialization and Manufacturing

The commercial success of our product candidates, including atrasentan, will depend upon their degree of market acceptance by providers, patients, patient advocacy groups, third-party payors and the general medical community.

Even with the requisite approvals from the FDA, the HPFB, the EMA and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, on the acceptance of providers, patients and third-party payors of drugs designed to act as a selective blocker of the ET_A receptor in particular for atrasentan, and our product candidates in general, as

medically necessary, cost-effective and safe. In addition, we may face challenges in seeking to establish and grow sales of atrasentan or our other product candidates. Any product that we commercialize may not gain acceptance by providers, patients, patient advocacy groups, third-party payors and the general medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of atrasentan and our other product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy, durability and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment relative to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA, the HPFB or the European Commission;
- the willingness of providers to prescribe new therapies;
- the willingness of the target patient population to try new therapies;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, the HPFB, EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the quality of our relationships with patient advocacy groups;
- publicity concerning our product candidates or competing products and treatments; and
- sufficient third-party payor coverage and adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.

The pricing, insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

Our target indications, including IgAN and other proteinuric glomerular diseases, are indications with relatively small patient populations. For product candidates that are designed to treat smaller patient populations to be commercially viable, the reimbursement for such product candidates must be higher, on a relative basis, to account for the lack of volume. Accordingly, we will need to implement a coverage and reimbursement strategy for any approved product candidate that accounts for the smaller potential market size. If we are unable to establish or sustain coverage and adequate reimbursement for our product candidates from third-party payors, the adoption of those product candidates and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved.

We expect that coverage and reimbursement by third-party payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of atrasentan and our other product candidates will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older, disabled or suffering from end-stage kidney disease. The Medicaid program, which varies from state-to-state, covers certain individuals and families who have limited financial means. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. One payor's determination to provide coverage for a drug product, however, does not assure that other payors will also provide coverage for the drug product. Further, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved.

In addition to government and private payors, professional organizations such as the American Medical Association, or the AMA, can influence decisions about coverage and reimbursement for new products by determining standards for care. In addition, many private payors contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our product candidates. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the EU, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of certain third-party payors, such as health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market. Recently there have been instances in which third-party payors have refused to reimburse treatments for patients for whom the treatment is indicated in the FDA-approved product labeling. Even if we are successful in obtaining FDA approvals to commercialize our product candidates, we cannot guarantee that we will be able to secure reimbursement for all patients for whom treatment with our product candidates is indicated.

If third parties on which we depend to conduct our preclinical studies or clinical trials, do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development program could be delayed with adverse effects on our business, financial condition, results of operations and prospects.

We rely on third party CROs, CMOs, consultants and others to design, conduct, supervise and monitor key activities relating to, discovery, manufacturing, preclinical studies and clinical trials of our product candidates, and we intend to do the same for future activities relating to existing and future programs. Because we rely on third parties and do not have the ability to conduct all required testing, discovery, manufacturing, preclinical studies or clinical trials independently, we have less control over the timing, quality and other aspects of discovery, manufacturing, preclinical studies and clinical trials than we would if we conducted them on our own. These investigators, CROs, CMOs and consultants are not our employees, and we have limited control over the amount of time and resources that they dedicate in our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties we contract with might not be diligent, careful or timely in conducting our discovery, manufacturing, preclinical studies or clinical trials, resulting in testing, discovery, manufacturing, preclinical studies or clinical trials being delayed or unsuccessful, in whole or in part.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for the trial, as well as in accordance with GLP, GCP and other applicable laws, regulations and standards. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. The FDA and other regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If the Company or any of these third parties fails to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials have complied with GCPs. In addition, our clinical trials must be conducted with product produced in accordance with cGMPs. Our failure to comply with these regulations may require us to repeat clinical trials,

which could delay or prevent the receipt of regulatory approvals. Any such event could have an adverse effect on our business, financial condition, results of operations and prospects.

We face significant competition in an environment of rapid technological change and it is possible that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may harm our business, financial condition and our ability to successfully market or commercialize atrasentan and our other product candidates.

The biotechnology and pharmaceutical industries are characterized by rapidly changing technologies, competition and a strong emphasis on intellectual property. We are aware of several companies focused on developing proteinuric glomerular disease treatments in various indications as well as several companies addressing other treatments for rare, severe chronic kidney diseases. We may also face competition from large and specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies and public and private research institutions that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing and commercialization.

Although several companies are focused on developing treatments on IgAN and other proteinuric glomerular diseases, there are currently limited treatment options for proteinuric glomerular diseases. To our knowledge, there is one approved drug for IgAN, as well as a variety of additional treatments utilized that include renin angiotensin inhibitors, steroids, chemotherapy drugs and immunomodulatory approaches. In addition, there are a number of competitors in clinical development for the treatment of IgAN at a similar stage of development or more advanced than us, including AstraZeneca PLC, Novartis AG, Omeros Corporation, Reata Pharmaceuticals, Inc., Travere Therapeutics, Inc., Vera Therapeutics, Inc., and Otsuka Pharmaceutical Co., Ltd.

Many of our potential competitors, alone or with their strategic partners, may have substantially greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market, if ever. Additionally, new or advanced technologies developed by our competitors may render our current or future product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

To become and remain profitable, we must develop and eventually commercialize product candidates with significant market potential, which will require us to be successful in a range of challenging activities. These activities include, among other things, completing preclinical studies and initiating and completing clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products that are approved and satisfying any post marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue operations. A decline in the value of the Company also could cause you to lose all or part of your investment.

The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide supply of atrasentan or our other product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our product candidates for patients, if approved, could be delayed or stopped.

We intend to establish manufacturing relationships with a limited number of suppliers to manufacture raw materials, the drug substance and finished product of any product candidate for which we are responsible for preclinical or clinical development. Pursuant to our license agreement with AbbVie, we received a substantial amount of drug product and drug substance to support initiation of our clinical trials of atrasentan; however, we do not yet have a long-term commercial manufacturing agreement for atrasentan with AbbVie or any other CMO. We will need to establish manufacturing relationships for the production of sufficient atrasentan for any potential commercialization. Each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain. As part of any marketing approval, a manufacturer and our processes are required to be qualified by the FDA prior to regulatory approval. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new supplier is relied upon for commercial production. Switching vendors may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

The process of manufacturing drugs is complex, highly-regulated and subject to multiple risks. Manufacturing drugs is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at the facilities of our manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. Moreover, if the FDA determines that our CMOs are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny regulatory approval until the deficiencies are corrected or we replace the manufacturer in our regulatory approvals with a manufacturer that is in compliance. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our CMOs are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day-to-day control over the operations of our CMOs, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if our collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

We believe that we will rely upon a limited number of manufacturers for our product candidates, including atrasentan, for which we have identified single-source suppliers for the various steps of manufacture. This reliance on a limited number of manufacturers and the complexity of drug manufacturing and the difficulty of scaling up a manufacturing process could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our product candidates successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production in a timely manner at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell atrasentan and our other product candidates, we may be unable to generate any revenues.

We currently do not have an organization for the sales, marketing and distribution of atrasentan, BION-1301, CHK-336 and our other product candidates, and the expense of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. To market any products that may be approved, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. With respect to certain of our current programs as well as future programs, we may rely completely on an alliance partner for sales and marketing. In addition, although we intend to establish a sales organization if we are able to obtain approval to market any product candidates, we may enter into strategic alliances with third parties to develop and commercialize atrasentan and other product candidates, including in markets outside of the United States or for other large markets that are beyond our resources, such as the joint venture, SanReno Therapeutics, we formed in late 2021 for the development and commercialization of atrasentan and BION-1301 in China and certain other East-Asian countries. This will reduce the revenue generated from the sales of these products.

Any future strategic alliance partners may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective alliances to enable the sale of our product candidates to healthcare professionals and in geographical regions, including the United States, that will not be covered by our marketing and sales force, or if our potential future strategic alliance partners do not successfully commercialize the product candidates, our ability to generate revenues from product sales will be adversely affected.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

We may not be successful in finding strategic collaborators for continuing development of certain of our future product candidates or successfully commercializing or competing in the market for certain indications.

In the future, we may decide to collaborate with non-profit organizations, universities and pharmaceutical and biotechnology companies for the development and potential commercialization of existing and new product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our expense. If we elect to increase our expenditures to fund development or commercialization activities on our product candidates, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

The success of any potential collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of such collaboration arrangements. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Risks Related to Government Regulation

A Fast Track Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

While we do not intend to seek Fast Track Designation for atrasentan, we may seek such designation for our other product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply to the FDA for Fast Track Designation. The FDA has broad discretion whether to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. The FDA may also withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Even if we receive Fast Track Designation for any of our product candidates, such product candidates may not experience faster development, review or approval processes compared to conventional FDA procedures. Many drugs that have received Fast Track Designation have failed to obtain approval.

We may attempt to secure FDA approval of atrasentan and our other product candidates through the accelerated approval pathway. If we are unable to obtain accelerated approval, we may be required to conduct additional clinical trials beyond those that we currently contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals.

We are developing certain product candidates for the treatment of serious conditions, and therefore may decide to seek approval of such product candidates under the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and provides a meaningful therapeutic benefit over existing treatments based upon a determination that the product candidate has an effect on 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 of or lack of alternative treatments. For the purposes of accelerated approval, a

surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's anticipated effect on irreversible morbidity or mortality or other clinical benefit. In some cases, the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. If the sponsor fails to conduct such studies in a timely manner, or if such post-approval studies fail to verify the drug's predicted clinical benefit, or if other evidence demonstrates that the product candidate is not shown to be safe and effective under the conditions of use, the FDA may withdraw its approval of the drug on an expedited basis.

We intend to use reduction in proteinuria as a surrogate endpoint in our phase 3 ALIGN trial of atrasentan. However, atrasentan may not show a sufficient treatment benefit on the expected surrogate endpoint to satisfy the FDA that the anticipated benefit on loss of renal function will be confirmed in the planned post-marketing phase of the trial. If we decide to submit an NDA seeking accelerated approval or receive an expedited regulatory designation for atrasentan or any of our other product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. If any of our competitors were to receive full approval for an indication for which we are seeking accelerated approval before we receive accelerated approval, the indication we are seeking may no longer qualify as a condition for which there is an unmet medical need and accelerated approval of our product candidate would be more difficult or may not occur.

Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. In addition, Congress is considering various proposals to potentially make changes to the accelerated approval pathway, including proposals to increase the likelihood of withdrawal of approval in such circumstances.

Failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates would result in a longer time period to commercialization of such product candidate, if any, and could increase the cost of development of such product candidate and harm our competitive position in the marketplace.

We may be unsuccessful in obtaining Orphan Drug Designation for our product candidates or transfer of designations obtained by others for future product candidates, and, even if we obtain such designation, we may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity, for atrasentan or our other product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs intended to treat relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting for regulatory approval. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for tax credits for qualified clinical research costs and exemption from prescription drug user fees. Similarly, in the EU, the European Commission grants Orphan Drug Designation after receiving the opinion of the EMA's Committee for Orphan Medicinal Products on an Orphan Drug Designation application. In the EU, Orphan Drug Designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the EU and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or the product would be a significant benefit to those affected). In the EU, Orphan Drug Designation entitles a party to financial incentives such as reduction of fees or fee waivers.

Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or EMA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. If a competitor is able to obtain orphan drug exclusivity prior to us for a product that constitutes the same active moiety and treats the same indications as our product candidates, we may not be able to obtain approval of our drug by the applicable regulatory authority for a significant period of time unless we are able to show that our drug is clinically superior to the approved drug. The applicable period is seven years in the United States and ten years in the EU. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

We have obtained Orphan Drug Designation for atrasentan in the EU and may seek Orphan Drug Designation for atrasentan in the United States and other countries. However, we may not obtain Orphan Drug Designation and even if we do, Orphan Drug Designation does not guarantee future orphan drug marketing exclusivity.

Even after an orphan drug is approved, the FDA can also subsequently approve a later application for the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We may be unsuccessful in obtaining Rare Pediatric Disease Designation for our product candidates or for future product candidates, and, even if we obtain such designation, we may be unable to maintain the benefits associated with such designation, including the potential for use or sale of a future priority review voucher.

The Rare Pediatric Disease Voucher Program is intended to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Although there are existing incentive programs to encourage the development and study of drugs for rare diseases, pediatric populations, and unmet medical needs, this program provides an additional incentive for the development of drugs for rare pediatric diseases, which may be used alone or in combination with other incentive programs. A rare pediatric disease is defined as a disease that is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and is a rare disease or condition as defined in the FD&C Act, which includes diseases and conditions that affect fewer than 200,000 persons in the U.S. and diseases and conditions that affect a larger number of persons and for which there is no reasonable expectation that the costs of developing and making available the drug in the U.S. can be recovered from sales of the drug in the U.S.

The sponsor of a drug application for a rare pediatric disease drug product may be eligible for a voucher that can be used or sold to obtain a priority review for a subsequent drug application submitted under section 505(b)(1) of the FD&C Act or section 351 of the Public Health Service Act after the date of approval of the rare pediatric disease drug product. The rare pediatric disease priority review voucher program was most recently re-authorized by Congress in the Consolidated Appropriations Act of 2021, extending the rare pediatric disease program through September 30, 2024, with the potential for priority review vouchers to be granted through September 30, 2026. Although we have obtained designation of CHK-336 as a rare pediatric disease, we may not meet the eligibility requirements for a priority voucher at the time we seek approval of CHK-336 or we may not meet the current deadline for receiving a priority review voucher, in which case we would not be able to use priority review for a subsequent product of ours or be able to sell such voucher to a third party.

Enacted and future legislation may increase the difficulty and cost for us to commercialize and obtain marketing approval of our product candidates and may affect the prices we may set.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, or ACA, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

There have been executive, legislative and judicial efforts to modify, repeal or otherwise invalidate all or certain aspects of the ACA. By way of example, the Tax Cuts and Jobs Act, or the TCJA, was enacted, effective January 1, 2019, and included, among other things, a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In June 2021, the U.S. Supreme Court held that plaintiffs did not have standing to challenge constitutionality of the individual mandate. It is unclear whether there may be other efforts to challenge, repeal or replace the ACA. We are continuing to monitor any changes to the ACA

that, in turn, may potentially impact our business in the future. In addition, other legislative changes have been proposed and adopted since the ACA was enacted to reduce healthcare expenditures, including aggregate reductions to Medicare payments to providers of 2 percent per fiscal year, which went into effect April 1, 2013 and will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. The Medicare reductions phase back in starting with a 1% reduction in effect from April 1, 2022 to June 30, 2022 before increasing to the full 2% reduction. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Recently there has 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 and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products. For example, in July 2021, President Biden issued an executive order pertaining to drug pricing, which expressed support for legislation allowing direct negotiation in Medicare Part D and inflationary rebates, and directed various executive branch agencies to take actions to lower drug prices and promote generic competition. Several pending legislative efforts, including President Biden's larger Build Back Better legislative agenda and draft bill text, incorporate these drug pricing reforms in addition to inflationary rebates on Part B and Part D drugs that would be payable on commercial and governmental program utilization, policies aimed at redesigning the Medicare Part D benefit and adopting drug price transparency measures. Drug manufacturers who are unwilling to negotiate with Medicare would be subject to additional excise taxes. Additionally, the plan would impose tax penalties on drug manufacturers that increase the prices of drug products faster than the rate of inflation. If elements of the recently announced prescription drug pricing plan become law, our pricing strategy and commercial prospects may be adversely affected. It is unclear to what extent these new proposals or any future legislation or regulations by the Biden administration will have on our business, including our ability to generate revenue and achieve profitability. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law. We may choose to seek an expanded access program for our product candidates, or to utilize comparable rules in other countries that allow the use of a drug, on a named patient basis or under a compassionate use program.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. For example, the FDA may require additional trials in indications for which similar products to ours were previously approved based on smaller clinical trials or less stringent clinical outcome requirements. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

The FDA's ability to review and approve new products may be hindered by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, statutory, regulatory and policy changes and global health concerns.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. 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.

The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions and could greatly impact healthcare and the pharmaceutical industry.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and, subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities using a risk-based prioritization system, and to conduct "mission critical" domestic and foreign inspections. The FDA may pause domestic or foreign inspections again in the future. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our operations and relationships with future customers, providers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with providers, third-party payors and customers will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidates for which we obtain marketing approval.

Restrictions under applicable U.S. federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward 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 Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation:
- federal false claims laws, including the federal False Claims Act, imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, knowingly and willfully executing or attempting to execute 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 Payment Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics, and medical supplies for
 which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report
 payments and other transfers of value provided during the previous year to physicians, as defined by such law, physician assistants, certain
 types of advance practice nurses, and teaching hospitals, as well as certain ownership and investment interests held by such physicians and
 their immediate family, which includes annual data collection and reporting obligations;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the

pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and

• some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of product candidates from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to obtain, maintain and protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark, trade secret and other intellectual property protection of our proprietary technologies and product candidates, which include atrasentan and the other product candidates we have in development, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending our patents and other intellectual property rights against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, importing or otherwise commercializing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development activities before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and may be reliant on our licensors or licensees to do so. Our pending and future patent applications may not result in issued patents. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-license may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether any of our platform advances and product candidates will be protectable or remain protected by valid and enforceable patents. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies.

We depend on intellectual property licensed from third parties, and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated, or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

We are dependent on patents, know-how and proprietary technology licensed from others. Our licenses to such patents, know-how and proprietary technology may not provide exclusive rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our products in the future. The agreements under which we license patents, know-how and proprietary technology from others are complex, and certain provisions in such agreements may be susceptible to multiple interpretations.

For example, we are a party to a license agreement with AbbVie, pursuant to which we in-license worldwide, exclusive rights to atrasentan, including responsibility for our development and commercialization. This agreement imposes various diligence, milestone payment, royalty, insurance and other obligations on us. If we, or our sublicensees, fail to comply with these obligations, AbbVie may

have the right to terminate our license, in which event we would not be able to develop or market atrasentan or any other technology or product candidates covered by the intellectual property licensed under this agreement. In addition, we may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of product candidates we may develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In either event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology or product candidates.

If our licensors fail to adequately protect our licensed intellectual property, our ability to commercialize product candidates could suffer. We do not have complete control over the maintenance, prosecution and litigation of our in-licensed patents and patent applications and may have limited control over future intellectual property that may be in-licensed. For example, we cannot be certain that activities such as the maintenance and prosecution by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. It is possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests.

In addition, the resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant patents, know-how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes that may arise between us and our licensors regarding intellectual property subject to a license agreement could include disputes regarding:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations;
- royalty, milestone or other payment obligations that may result from the advancement or commercial sale of any of our product candidates;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected technology or product candidates.

Our owned and in-licensed patents and patent applications may not provide sufficient protection of our atrasentan product candidate and our other product candidates or result in any competitive advantage.

We have in-licensed issued U.S. patents and foreign patent applications that cover formulations and methods of use related directly to atrasentan from AbbVie. We have filed patent applications intended to specifically cover additional methods of treatment and combinations of atrasentan with other therapies in kidney disease. We cannot be certain that any of these patent applications will issue as patents, and if they do, that such patents will cover or adequately protect atrasentan or that such patents will not be challenged, narrowed, circumvented, invalidated or held unenforceable.

In addition to claims directed toward the technology underlying atrasentan, our owned and in-licensed patents and patent applications contain claims directed to compositions of matter on the active pharmaceutical ingredients, or APIs, in BION-1301, CHK-336 and our other product candidates, as well as methods-of-use directed to the use of such APIs for a specified treatment. Composition-of-matter patents on the API in prescription drug products provide protection without regard to any particular method of use of the API used. Method-of-use patents do not prevent a competitor or other third party from developing or marketing an identical product for an indication that is outside the scope of the patented method. Patents covering methods-of-use are not available in certain foreign countries, in which case we may not be able to prevent competitors or third parties from marketing our product candidates in those countries. Moreover, with respect to method-of-use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, providers may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common, and this type of infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. For example, while our patent applications are pending, we may be subject to a third party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in interference or derivation proceedings, or equivalent proceedings in foreign jurisdictions. Even if patents do successfully issue, third parties may challenge their inventorship, validity, enforceability or scope, including through opposition, revocation, reexamination, post-grant and inter partes review proceedings. An adverse determination in any such submission, proceeding or litigation may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. Moreover, some of our owned and in-licensed patents and patent applications may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in development, testing, and regulatory review of new product candidates, the period of time during which we could market our product candidates under patent protection would be reduced or eliminated.

Since patent applications in the United States and other countries are confidential for a period of time after filing, at any moment in time, we cannot be certain that we were in the past or will be in the future the first to file any patent application related to our product candidates. In addition, some patent applications in the United States may be maintained in secrecy until the patents are issued. As a result, there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim, and we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that, if challenged, our patents would be declared by a court, patent office or other governmental authority to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant in our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, that block our efforts or potentially result in our product candidates or our activities infringing such claims. It is possible that our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to our own products or technology. Those patent applications may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. The possibility also exists that others will develop products that have the same effect as our product candidates on an independent basis that do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our product candidates or their use.

Likewise, our currently owned and in-licensed patents and patent applications, if issued as patents, directed to our proprietary technologies and our product candidates are expected to expire from 2028 through 2041, without taking into account any possible patent term adjustments or extensions. Our earliest in-licensed patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Additionally, we cannot be assured that the USPTO or relevant foreign patent offices will grant any of the pending patent applications we own or in-license currently or in the future. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, financial condition, results of operations and prospects.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the active compositions of our product candidates but that are not covered by the claims of our patents;
- the APIs in our current product candidates will eventually become commercially available in generic drug products, and no patent protection may be available with regard to formulation or method of use;
- our licensors, as the case may be, may fail to meet our obligations to the U.S. government regarding any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- our licensors, as the case may be, might not have been the first to file patent applications for certain inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our currently pending or future patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our owned or in-licensed patents, as the case may be, or parts of our owned or in-licensed patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished patent applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States:
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not adequately cover our product candidates:
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or
 processes that design around our patents, or become hostile to the Company or the patents or patent applications on which they are named as
 inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable or such omitted individuals may grant licenses to third parties;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patent claims;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Our strategy of obtaining rights to key technologies through in-licenses may not be successful.

The future growth of our business will depend in part on our ability to in-license or otherwise acquire the rights to additional product candidates and technologies. Although we have succeeded in licensing technology from AbbVie and others in the past, we cannot assure you that we will be able to in-license or acquire the rights to any product candidates or technologies from third parties on acceptable terms or at all.

For example, our agreements with certain of our third-party research partners provide that improvements developed in the course of our relationship may be owned solely by either us or our third-party research partner, or jointly between us and the third party. If we determine that exclusive rights to such improvements owned solely by a research partner or other third party with whom we collaborate are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party in order to use the improvements and continue developing, manufacturing or marketing our product candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing our product candidates or allow our competitors or others the opportunity to access technology that is important in our business. We also may need the cooperation of any co-owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us.

In addition, in-licensing and acquisition of these technologies is a highly competitive area, and a number of more established companies are also pursuing strategies to license or acquire product candidates or technologies that we may consider attractive. These established companies may have a competitive advantage over the Company due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive the Company to be a competitor may be unwilling to license rights to the Company. Furthermore, we may be unable to identify suitable product candidates or technologies

within our area of focus. If we are unable to successfully obtain rights to suitable product candidates or technologies, our business and prospects could be materially and adversely affected.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, we rely upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with the Company. These agreements provide that all confidential information concerning our research and development, business, or financial affairs developed or made known to the individual or entity during the course of the party's relationship with Chinook Therapeutics are to be kept confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and that are related in our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information (or as otherwise permitted by applicable law), are our exclusive property. In the case of consultants and other third parties, the agreements provide that all inventions conceived in connection with the services provided are our exclusive property. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our secrets. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as the Company's trade secrets, were to be disclosed or misappropriated, such as through a data breach, or if any of that information was independently developed by a competitor, our competitive position could be harmed. Additionally, certain trade secrets and proprietary information may be required to be disclosed in submissions to regulatory authorities. If such authorities do not maintain the confidential basis of such information or disclose it as part of the basis of regulatory approval, our competitive position could be adversely affected.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume our time and other resources. Although we take steps to protect our proprietary information and trade secrets, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access in our trade secrets or disclose our technology, through legal or illegal means. As a result, we may not be able to meaningfully protect the Company's trade secrets. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Third-party claims of intellectual property infringement may prevent, delay or otherwise interfere with our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property or other proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover

various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our field, third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe, misappropriate or otherwise violate our intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims that, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages plus the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights or proprietary technology to us, which it is not required to do, on commercially reasonable terms or at all;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant crosslicenses to intellectual property rights for our product candidates;
- the requirement that we redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time; and
- there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities
 analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects.

Third parties may assert that we are employing their proprietary technology without authorization, including by enforcing its patents against us by filing a patent infringement lawsuit against the Company. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof.

There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, or materials used in or formed during the manufacturing process, or any final product itself, the holders of those patents may be able to block our ability to commercialize our product candidate unless we obtain a license under the applicable patents, or until those patents were to expire or those patents are finally determined to be invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of that patent may be able to block our ability to develop and commercialize the product candidate unless we obtain a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, a license may not be available on commercially reasonable terms, or at all, particularly if such patent is owned or controlled by one of our primary competitors. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to the Company. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee time and resources from our business. In the event of a

successful claim of infringement against the Company, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any license of this nature would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates and we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could significantly harm our business.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful and could result in a finding that such patents are unenforceable or invalid.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Defense of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Conversely, we may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings), or we may choose to challenge a third party's patent in patent opposition proceedings in the Canadian Intellectual Property Office, or CIPO, the European Patent Office, or EPO, or another foreign patent office. Even if successful, the costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, CIPO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. Any of the foregoing could have a material adverse effect on our business financial condition, results of operations and prospects.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We currently have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, patents covering methods-of-use are not available in certain foreign countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we do not have or have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our product candidates in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. We may then have to pursue litigation to defend against these claims. If we fail in defending any claims of this nature, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these types of claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities, and we may not have sufficient financial or other resources to adequately conduct this type of litigation or proceeding. For example, some of our competitors may be able to sustain the costs of this type of litigation or proceeding more effectively than we can because of their substantially greater financial resources. In any case, uncertainties resulting from the initiation and continuation of intellectual property litigation or ot

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

The growth of our business may depend in part on our ability to acquire, in-license or use third-party proprietary rights. For example, our product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing pre-existing pharmaceutical compounds, or we may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patents we may co-own with third parties, we may require licenses to such co-owners' interest in such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties we identify as necessary or important in our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means of our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies

may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business financial condition, results of operations and prospects could suffer.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable laws and rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Were a noncompliance event to occur, our competitors might be able to enter the market, which would have a material adverse effect on our business financial condition, results of operations and prospects.

Changes in patent law in the United States and in non-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain.

Past or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, in March 2013, under the Leahy-Smith America Invents Act, or America Invents Act, the United States moved from a "first to invent" to a "first-to-file" patent system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes continue to evolve as the USPTO continues to promulgate new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the "first-to-file" provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on the specific patents discussed in this filing have not been determined and would need to be reviewed. Moreover, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Additionally, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case, *Assoc. for Molecular Pathology v. Myriad Genetics*, *Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patent-eligible.

Similarly, other cases by the U.S. Supreme Court have held that certain methods of treatment or diagnosis are not patent-eligible. U.S. law regarding patent-eligibility continues to evolve. While we do not believe that any of our owned or in-licensed patents will be found invalid based on these changes to U.S. patent law, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also have a material adverse effect on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our products.

If we do not obtain patent term extension for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during clinical trials and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per product may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. U.S. and ex-U.S. law concerning patent term extensions and foreign equivalents continue to evolve. Even if we were to seek a patent term extension, it may not be granted because of, for example, the failure to exercise due diligence during the testing phase or regulatory review process, the failure to apply within applicable deadlines, the failure to apply prior to expiration of relevant patents, or any other failure to satisfy applicable requirements. Moreover, the applicable time period of extension or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than it requests, our competitors may obtain approval of competing products following our patent expiration sooner than expected, and our business, financial condition, results of operations and prospects could be materially harmed

Some intellectual property that we have in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Inventions contained within some of our in-licensed patents and patent applications may have been made using U.S. government funding or other non-governmental funding. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act, and implementing regulations. We rely on our licensors to ensure compliance with applicable obligations arising from such funding, such as timely reporting, an obligation associated with in-licensed patents and patent applications. The failure of our licensors to meet their obligations may lead to a loss of rights or the unenforceability of relevant patents. For example, the government could have certain rights in such in-licensed patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf for non-commercial purposes. In addition, our rights in such in-licensed government-funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any of the foregoing could harm our business, financial condition, results of operations and prospects significantly.

Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business

We expect to expand our development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of product candidate development, growing our capability to conduct clinical trials, and, if approved, through commercialization of our product candidates. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel, or contract with third parties to provide these capabilities for us. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Future acquisitions or strategic alliances could disrupt our business and harm our financial condition and results of operations.

We may acquire additional businesses or drugs, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be

able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new drugs resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. The risks we face in connection with acquisitions, include:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- coordination of research and development efforts;
- retention of key employees from the acquired company;
- changes in relationships with strategic partners as a result of product acquisitions or strategic positioning resulting from the acquisition;
- cultural challenges associated with integrating employees from the acquired company into our organization;
- the need to implement or improve controls, procedures and policies at a business that prior to the acquisition may have lacked sufficiently effective controls, procedures and policies;
- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violation of laws, commercial disputes, tax liabilities and other known liabilities;
- · unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions or strategic alliances could cause us to fail to realize the anticipated benefits of these transactions, cause us to incur unanticipated liabilities and harm the business generally. There is also a risk that future acquisitions will result in the incurrence of debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or results of operations.

Our employees, principal investigators, CROs, CMOs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, 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. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, 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 comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We will face an inherent risk of product liability exposure related to the testing of atrasentan and our other product candidates in clinical trials and will face an even greater risk if we commercialize any of our product candidates. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in a product, negligence, strict liability or breach of warranty. Claims could also be asserted under U.S. state consumer protection acts. If we cannot successfully defend itself against claims of our product candidates caused injuries, then we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;

- significant time and costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- termination of our collaboration relationships or disputes with our collaborators;
- voluntary product recalls, withdrawals or labeling restrictions; and
- the inability to commercialize any product candidates that we may develop.

While we currently have insurance that we believe is appropriate for our stage of development, we may need to obtain higher levels prior to clinical development or marketing atrasentan or any of our future product candidates. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our ability to utilize our net operating loss carryforwards may be subject to limitations.

To the extent our taxable income exceeds any current year operating losses, we plan to use our net operating loss carryforwards to offset income that would otherwise be taxable. Under Section 382 of the Code, changes in a company's ownership may limit the amount of net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset its future taxable income, if any. This limitation generally applies in the event of a cumulative change in ownership of more than 50 percent within a three-year period. Aduro experienced and Private Chinook likely experienced an ownership change under Section 382 as a result of the Merger. Any such limitation may significantly reduce our ability to utilize net operating loss carryforwards and tax credit carryforwards before they expire. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of Private Chinook's or Aduro's net operating loss carryforwards and other tax attributes, which could have a material adverse effect on our cash flow and results of operations. There is also a risk that due to regulatory changes, such as suspensions on the use of net operating losses, or NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Under the TCJA, as modified by the CARES Act, NOLs and other carryforwards generated in tax years that began after December 31, 2017 may offset no more than 80 percent of current taxable income annually for taxable years beginning after December 31, 2020. Accordingly, we, Private Chinook or Aduro, as applicable, generated or will generate NOLs after the tax year ended December 31, 2017, and we might have to pay more federal income taxes in a subsequent year as a result of the 80 percent taxable income limitation than we would have had to pay under the law in effect before the Tax Act as modified by the CARES Act.

Risks Related to the CVRs

Our outstanding CVRs may expire valueless.

The right of the holders of our contingent value rights, or CVRs, issued prior to the closing of the Merger will be contingent solely upon the occurrence of the milestones described in the CVR agreement and the consideration received being greater than the amounts that could be deducted by us under the CVR Agreement. In April 2021, prior to the disposition period set forth in the CVR agreement, we entered into an agreement with Sairopa, a private company created by Van Herk Royalty B.V. and D.S. Chahal to acquire certain of our non-renal assets in exchange for stock in Sairopa. We will hold our equity interests in Sairopa until there is a liquidity event, upon which 50% of any proceeds, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses, will be distributed to CVR holders, provided such liquidity event occurs during the 10-year CVR period. In the event that no CVR milestones occur within the 10-year CVR period specified in the CVR Agreement or the consideration received is not greater than the amounts that could be deducted by us, no payments will be made under the CVR Agreement, and the CVRs will expire valueless.

We do not have any obligation to develop the non-renal assets, or to expend any effort or resources to divest or otherwise monetize the non-renal assets. Furthermore, the CVRs are unsecured obligations of us and all payments under the CVRs, all other obligations under the CVR Agreement and the CVRs and any rights or claims relating thereto may be subordinated in right of payment to the prior payment in full of all current or future senior obligations of us.

The tax treatment of the CVRs is unclear.

The U.S. federal income tax treatment of the CVRs is unclear. There is no legal authority directly addressing the U.S. federal income tax treatment of the receipt of, and payments under, the CVRs, and there can be no assurance that the IRS would not assert, or that a court would not sustain, a position that could result in adverse U.S. federal income tax consequences to holders of the CVRs.

For example, Aduro did not report the issuance of the CVRs as a current distribution of property with respect to its common stock, but it is possible that the IRS could assert that CVR recipients are treated as having received a distribution of property equal to the fair market value of the CVRs on the date the CVRs are distributed, which could be taxable to such recipients without the corresponding receipt of cash. In addition, it is possible that the IRS or a court could determine that the issuance of the CVRs (and/or any payments thereon) and the reverse stock split constitute a single "recapitalization" for U.S. federal income tax purposes with the CVRs constituting taxable "boot" received in such recapitalization exchange. In such case, the tax consequences of the CVRs and the reverse stock split would differ from those described in the Merger proxy statement, including with respect to the timing and character of income.

Risks Related to our Common Stock

The market price of our common stock is expected to be volatile, and the market price of the common stock may drop in the future.

The market price of our common stock is subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of clinical trials and preclinical studies of our product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- if we do not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about the combined business, or if they issue adverse or misleading opinions regarding our business and common stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations and continued development of our product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with our potential products; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 or otherwise could materially and adversely affect our business and the value of our common stock. Furthermore, the trading price of our common stock may be adversely affected by third-parties trying to drive down the market price. Short sellers and others, some of whom post anonymously on social media, may be positioned to profit if our stock declines and their activities can negatively affect our stock price. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we have a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.

We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

We will incur significant legal, accounting and other expenses as a public company that we did not incur as a private company, including costs associated with public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our management team consists, among others, of the executive officers of Private Chinook prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow it to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

Once we are no longer a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.

We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. We currently qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, which allows us to take advantage of many exemptions from disclosure requirements applicable to smaller reporting companies and non-accelerated filers, including not being required to have our independent auditors attest to its internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Once we are no longer, a smaller reporting company or otherwise qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and may incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Provisions in our charter documents and under Delaware law could make an acquisition more difficult and may discourage any takeover attempts the company stockholders may consider favorable, and may lead to entrenchment of management.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws could delay or prevent changes in control or changes in management without the consent of the board of directors. These provisions include the following:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- a prohibition on stockholder action by written consent, which means that all stockholder action must be taken at an annual or special meeting
 of the stockholders;

- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the Chief Executive Officer or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to the board of directors;
- a requirement that no member of the board of directors may be removed from office by stockholders except for cause and, in addition to any
 other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of voting stock then entitled to vote in the
 election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of voting stock to amend any bylaws by stockholder action or to amend specific provisions of the certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the DGCL, or Section 203. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15 percent or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our certificate of incorporation and bylaws provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, and that federal district court is the exclusive forum for any actions arising under the Exchange Act, which could limit your ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation and bylaws provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on the Company's behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against it arising pursuant to any provisions of the DGCL, its certificate of incorporation or its bylaws, or any action asserting a claim against it that is governed by the internal affairs doctrine. The exclusive forum provision does not apply to actions arising under the Exchange Act. The amended and restated bylaws will also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act. The provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the Company or its directors, officers or other employees, which may discourage such lawsuits against the Company and its directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in the certificate of incorporation and bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations.

We do not expect to pay any cash dividends in the foreseeable future.

Our current expectation is that we will retain future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to the Company's stockholders for approval.

Our executive officers, directors and principal stockholders, in the aggregate, beneficially own a significant portion of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire.

General Risk Factors

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, a global economic downturn, whether due to terrorism, armed conflict (such as the current conflict between

Russia and Ukraine), natural disasters or health crises (such as COVID-19) could cause extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We generally anticipate contracting with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We or the third parties upon whom we depend may be adversely affected by natural disasters and other calamities, including pandemics, such as the global outbreak of COVID-19, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, fire, hurricane, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or other offices, that damaged critical infrastructure, such as our suppliers' manufacturing facilities, or that otherwise disrupted operations, such as data storage, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

Occurrences of epidemics or pandemics, depending on their scale, may cause different degrees of damage to the national and local economies within our geographic focus. Global economic conditions may be disrupted by widespread outbreaks of infectious or contagious diseases, and such disruption may adversely affect clinical development plans. For example, the COVID-19 pandemic could have an adverse effect on the coordination of research and development, our capital raising efforts, and the financial condition of our business, as well as the ability of us to retain key personnel and continue to expand product candidate development and conduct clinical trials. In addition, the impact of COVID-19 is likely to cause substantial changes in consumer behavior and has caused restrictions on business and individual activities, which have are likely to continue to lead to reduced economic activity.

Extraordinary actions taken by international, federal, state and local public health and governmental authorities to contain and combat the outbreak and spread of COVID-19 in regions throughout the world, including travel bans, quarantines, "stay-at-home" orders and similar mandates for many individuals and businesses to substantially restrict daily activities could have an adverse effect on our financial condition and ability to raise financing.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As a result of the COVID-19 pandemic, we may experience reduction in research and development, clinical testing, regulatory compliance activities, and manufacturing activities, and are unable at this time to estimate the extent of the effect of COVID-19 on our business. Further, the extent and duration of the economic slowdown or other adverse effects attributable to COVID-19 remain uncertain at this time. A continued significant economic

slowdown could have a substantial adverse effect on our financial condition, liquidity, and results of operations. If these conditions persist for an extended term, it could have a material adverse effect on our future revenue and sales.

We have broad discretion in the use of our cash and cash equivalents and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We have broad discretion over the use of our cash and cash equivalents. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You may not have the opportunity to influence our decisions on how to use our cash resources.

We must attract and retain highly skilled employees to succeed.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan, harm our results of operations and increase our capabilities to successfully commercialize atrasentan and other product candidates. In particular, we believe that our future success is highly dependent upon the contributions of our senior management, particularly our President and Chief Executive Officer, Eric Dobmeier. The loss of services of Mr. Dobmeier or any of our senior management could delay or prevent the successful development of our product pipeline, completion of our clinical trials or the commercialization of our product candidates, if approved. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates and our business will be limited.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about the company, its business or its market, its stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on it regularly, demand for our common stock could decrease, which in turn could cause its stock price or trading volume to decline.

Our internal computer and information systems, or those used by our CROs, CMOs or other contractors or consultants, may fail or suffer security incidents (e.g., cyber-attacks), which could result in a material disruption of our development programs and may result in extensive and costly legal compliance requirements.

Despite the implementation of appropriate security measures, our internal computer and information systems and those of our current and any future CROs, CMOs and other contractors or consultants may become vulnerable to damage from security incidents (such as data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or information technology incidents caused by threat actors, technological vulnerabilities or human error), unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of data from completed or future preclinical studies or clinical trials could result in significant 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, our competitive position could be harmed and the further development and commercialization of our product candidates could be significantly delayed. System failures or outages, including any potential disruptions due to significantly increased global demand on certain cloud-based systems during the COVID-19 pandemic, could compromise our ability to perform our day-to-day operations, which could harm our ability to conduct business or delay our financial reporting. Such failures could materially adversely affect our operations and internal formation in conduct business or delay our financial reporting.

Although we devote resources designed to protect our information systems, we realize that cyberattacks resulting in a security incident are a threat, and there can be no assurance of our efforts will prevent information security breaches that would result in business, legal, financial, or reputational harm to the Company, or would have a material adverse effect on our results of operations and financial condition. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including personal and financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. The COVID-19 pandemic is generally increasing the attack surface available to criminals, as more companies and individuals work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing.

Federal, state, and foreign government requirements include obligations of companies to notify regulators and/or individuals of security breaches involving personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Even though we may have contractual protections with such vendors, contractors, or other organizations, notifications and follow-up actions related to a security breach could impact our reputation and cause us to incur significant costs. Any failure to prevent or mitigate security breaches or improper access to, use, disclosure or other misappropriation of our data or consumers' personal data could result in significant legal liability, such as under state breach notification laws, federal law (including HIPAA/HITECH), and international law (e.g., GDPR). Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules and possible government oversight. Our failure to comply with such laws or to adequately secure the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our future client base, member base and revenue.

We are subject to a variety of privacy and data security laws, and our failure to comply with them could harm our business.

We maintain a large quantity of sensitive information, including confidential business and patient health information in connection with our preclinical and clinical studies, and are subject to laws and regulations governing the privacy and security of such information. Privacy laws, rules and regulations evolve frequently, and their scope may continually change through new legislation, amendments to existing legislation, and changes in enforcement, and may be inconsistent from one jurisdiction to another. The interpretation and application of consumer, health-related and data protection laws, especially with respect to genetic samples and data, in the United States, the European Union and elsewhere, are often uncertain, contradictory and in flux. We cannot provide assurance that current or future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal data (as necessary); either of these circumstances may prevent us from undertaking or publishing essential research and development, manufacturing, and commercialization, which could have a material adverse effect on our business, results of operations, financial condition and prospects. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices, systems, and compliance procedures in a manner adverse to our business. Any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity and could harm our ability to initiate and complete clinical trials.

In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including health information privacy laws, security breach notification laws, and consumer protection laws. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA/HITECH. Entities that are found to be in violation of HIPAA/HITECH 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. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties. Additionally, governmental agencies like the FTC have adopted, or are considering adopting, laws and regulations concerning personal data and data security. The FTC may also take action against companies for unfair acts or practices for failing to keep promises made in public statements, such as privacy policies. We make public statements about our use and disclosure of personal data through our privacy policy, information described on our website, and in press statements. Although we endeavor to ensure that our public statements are complete and accurate, any failure (real or perceived) by us to comply with our privacy commitments could be considered an "unfair and deceptive" act by the FTC resulting in an FTC consent decree that may include fines and sustained government-mandated audits for a period of 20 years. State Attorneys General may enfo

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. California recently enacted legislation, the 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 and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. A ballot initiative from privacy

rights advocates intended to augment and expand the CCPA called the California Privacy Rights Act, or CPRA, was passed in November 2020 and will take effect in January 2023 (with a look back to January 2022). The CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal data. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. Potential uncertainty surrounding the CCPA and CPRA may increase our compliance costs and potential liability, particularly in the event of a data breach, and could have a material adverse effect on our business. Other states have followed California's lead. The Virginia Consumer Data Protection Act, or VCDPA, which will go into effect in 2023, gives new data protection rights to Virginia residents and imposes additional obligations on controllers and processors of personal data. Colorado has also adopted a new state data protection act titled the Colorado Privacy Act, which is set to take effect on July 1, 2023. As of January 2022, fourteen states have pending consumer privacy legislation under review, which if enacted would add additional costs and expense of resources to maintain compliance.

In Canada, the Personal Information Protection and Electronic Documents Act, or PIPEDA, and similar provincial laws may impose obligations with respect to processing personal information, including health-related information. PIPEDA requires companies to obtain an individual's consent when collecting, using, or disclosing that individual's personal information. Individuals have the right to access and challenge the accuracy of their personal information held by an organization, and personal information may only be used for the purposes for which it was collected. If an organization intends to use personal information for another purpose, it must again obtain that individual's consent. Failure to comply with PIPEDA could result in significant fines and penalties.

In May 2018, the General Data Protection Regulation, or the GDPR, took effect in the European Economic Area, the EEA. The GDPR governs the collection, use, disclosure, transfer, or other processing of personal data of natural persons. Among other things, the GDPR imposes strict obligations on the ability to process health-related and other personal data of data subjects in the EEA, including in relation to use, collection, analysis, and transfer (including cross-border transfer) of such personal data. The GDPR includes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators. The GDPR also includes certain requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects as well as requirements for establishing a lawful basis on which personal data can be processed and a right to lodge a complaint with the government.

The GDPR, as well as law in the UK and Switzerland, also prohibits the international transfer of personal data from the EEA/UK/Switzerland to countries outside of those jurisdictions unless made to a country deemed to have adequate data privacy laws by the European Commission or where a data transfer mechanism has been put in place. We rely on a mixture of mechanisms to transfer personal data to countries outside of the EEA, Switzerland, and the UK, including to the United States and therefore are continuing to evaluate the guidance and mechanisms required to establish adequate safeguards for personal data. Until recently, one such data transfer mechanism was the EU-US Privacy Shield. However, in July 2020 the Court of Justice of the European Union, or CJEU, declared the Privacy Shield to be invalid. The CJEU upheld the validity of the standard contractual clauses, or SCCs, as a legal mechanism to transfer personal data but companies relying on SCCs will continually be subject to guidance from regulators in the EEA and need to evaluate and implement supplementary measures that provide privacy protections additional to those provided under SCCs. In turn, the findings of the CJEU will have significant implications for cross-border data flows. On June 4, 2021, the European Commission adopted new SCCs to apply to international transfers. We will have until December 27, 2022 to update any existing agreements, or any new agreements executed before September 27, 2021, that rely on the former SCCs. If we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we conduct our operations, and we may find it necessary to establish systems in the EEA, Switzerland, and the UK to maintain personal data originating from the EEA and the UK, which may involve substantial expense and distraction from other aspects of our business. As supervisory authorities continue to issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used and/or what safeguards must be implemented, or start taking enforcement action, there will be uncertainty as to how we comply with EEA, Switzerland, and UK privacy laws and we could suffer additional costs, complaints, or regulatory investigations or fines. We may need to implement additional safeguards to further enhance the security of data transferred out of the EEA/Switzerland/UK, conduct data transfer impact assessments, and review existing agreements which could increase our compliance costs, expose us to further regulatory scrutiny and liability, and adversely affect our business. Further, the GDPR provides that countries in the EEA may establish their own laws and regulations further restricting the processing of certain personal data, including genetic data, biometric data, and health data.

Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4 percent of the annual global revenues of the noncompliant company, whichever is greater. Additionally, following the UK's withdrawal from the EU and the EEA, companies must comply with the GDPR and the GDPR as incorporated into UK national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4 percent of global turnover.

We create contractual obligations with third parties with whom we depend in relation to the operation of our business, a number of which process personal data on our behalf. With each such provider we attempt to mitigate the associated risks of using third parties

by performing security assessments and detailed due diligence, entering into contractual arrangements to ensure that providers only process personal data according to our instructions, and that they have sufficient technical and organizational security measures in place. Where we transfer personal data outside the EEA, the UK, or Switzerland to such third parties, we do so while considering the relevant data export requirements, as described above. There is no assurance that these contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage, and transmission of such information. Any violation of data or security laws by our third-party processors could have a material adverse effect on our business and result in the fines and penalties outlined above.

If our operations are found to be in violation of any of the privacy and data protection laws described above or any other laws that apply to us, we may be subject to penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in government healthcare programs, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government, class action litigation and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corrective action plan or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our results of operations. When such events occur (or even alleged), our reputation may be harmed, we may lose current and potential users and the competitive positions of our brand might be diminished, any or all of which could materially adversely affect our business, reputation, operating results, and financial condition.

U.S. federal income tax reform and changes in other tax laws could adversely affect us.

In December 2017, the TCJA, was signed into law, significantly reforming the Code. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of business interest, allows for the expensing of capital expenditures, puts into effect the migration from a "worldwide" system of taxation to a partial "territorial" system, and modifies or repeals many business deductions and credits.

In addition, new legislation or regulation which could affect our tax burden could be enacted by any governmental authority. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results. Additionally, we use our best judgment in attempting to quantify and reserve for these tax obligations. However, a challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions could have a material adverse effect on our business, results of operations or financial condition.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

In connection with the Merger in 2020, we assumed a facility lease for an office and laboratory facility in Berkeley, California totaling approximately 111,000 square feet that has a remaining lease term expiring on December 31, 2029. We have the right to further extend the lease term for up to two renewal terms of five years each, provided that the rental rate would be subject to market adjustment at the beginning of each renewal term. We are subleasing approximately 95,000 square feet of the Berkeley facility as of December 31, 2021 under a sublease agreement, which ultimately will cover the entire leased premises, and which expires at the same time as the underlying lease.

In addition, we lease approximately 23,000 square feet of office space in Vancouver, Canada for which the expiration date is August 31, 2027.

In June 2021, we entered into a sublease agreement for approximately 26,000 square feet of office space located in Seattle, Washington, which we are using for our corporate headquarters, and that has a remaining lease term expiring April 30, 2026.

We believe that our existing facilities are adequate to meet our current needs, and that suitable additional or alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

We are not currently subject to any material 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 Price of Common Stock

Our common stock is traded on the Nasdaq Global Select Market under the symbol "KDNY." From April 15, 2015 to October 5, 2020 our common stock was traded under the symbol "ADRO."

On March 10, 2022, the last reported sale price of our common stock on the Nasdaq Global Select Market was \$13.00 per share.

Holders of Record

As of March 10, 2022, we had 99 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

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.

Recent Sales of Unregistered Securities

None.

Repurchases of Shares or of Company Equity Securities

None.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing precision medicines for kidney diseases. Our pipeline is focused on rare, severe chronic kidney diseases with well-defined clinical pathways. Our lead clinical program is atrasentan, an endothelin A receptor antagonist. In March 2021 we initiated the phase 3 ALIGN trial of atrasentan for IgA nephropathy, or IgAN, and in April 2021 we initiated the phase 2 AFFINITY basket trial for proteinuric glomerular diseases. Our second product candidate, BION-1301, is an anti-APRIL monoclonal antibody also in development for patients with IgAN, and we presented results from the ongoing phase 1/2 trial at the American Society of Nephrology (ASN) Kidney Week in November 2021. We plan to maintain commercial rights for atrasentan and BION-1301 in North America and possibly Europe. In November 2021, we also established SanReno, a joint venture to develop, manufacture and commercialize kidney disease therapies in the Territory. East-Asian populations have a higher incidence and prevalence of IgAN than in the United States and Europe. We believe that a strong local presence in East-Asia may allow us to accelerate the clinical development and maximize the commercial potential of atrasentan and BION-1301 in the region. We are also advancing our third program, CHK-336 towards an expected start of a phase 1 clinical trial in healthy volunteers in the first half of 2022. We are developing CHK-336 for the treatment of primary hyperoxaluria, or PH, as well as secondary hyperoxaluria and idiopathic kidney stone formation. In addition, we are conducting research programs in several other rare, severe chronic kidney diseases. We seek to build our pipeline by leveraging insights from kidney single cell RNA sequencing, human-derived organoids and new translational models, to discover and develop therapeutic candidates with mechanisms of action targeted against key kidney disease pathways. To support these efforts, we have entered into a strategic collaboration with Evotec SE, or Evotec, to jointly identify, characterize and validate novel mechanisms and discover precision medicines for lupus nephritis, IgAN, polycystic kidney disease, or PKD, and other primary glomerular diseases. The collaboration with Evotec will also involve further characterization of pathways and patient stratification strategies for programs currently in Chinook's clinical and preclinical pipeline.

Our approach to precision medicines leverages recent advances in identifying targeted kidney therapies linked to mechanistic biomarkers by the application of systems biology approaches in nephrology. The application of systems biology to nephrology has advanced over the past decade through the study of multiple patient groups across a wide variety of kidney diseases and their associated multilevel data sets, including genome, transcriptome, proteome, metabolome, pathology and prospective long-term clinical characteristics and outcomes. A key objective of these investigations is to define kidney diseases in molecular terms to drive the development of targeted treatments. We believe we are well-positioned to exploit the insights provided into the key molecular drivers and classifiers of kidney diseases by the application of these systems biology tools to nephrology. Our strategy is to use these mechanistic insights to select compelling drug targets and deliver novel and differentiated product candidates for rare and severe kidney diseases with high unmet medical need.

For additional information regarding our product candidates, clinical development candidates and other research and discovery programs, refer to "Overview" within Part I, Item 1. Business in this Annual Report on Form 10-K.

Components of Operating Results

Collaboration and License Revenue

We have not generated any revenue from product sales. Our revenue to date has been primarily derived from our collaboration and license agreements.

SanReno Therapeutics

In November 2021, we entered into a License Agreement with SanReno, or the China License Agreement. The China License Agreement includes the transfer of intellectual property rights in the form of a development and commercialization license in the Territory; manufacturing and supply services; and participation in opt-in global studies with the collaboration party. In exchange for the development and commercialization license, we received non-cash consideration in the form of preferred shares in SanReno. The terms of the China License Agreement also include potential payment to us for the following: progress-dependent milestone payment; royalties on the net sales of a licensed product and reimbursement for certain expenses incurred. As of December 31, 2021, these potential payments are not considered probable of being achieved and they relate to promised goods or services for which revenue will be recognized upon our satisfaction of the underlying performance obligations.

Pre-existing Collaboration Agreements

Prior to the completion of the Merger, Aduro generated revenue from collaboration and license agreements. These collaboration agreements may have included the transfer of intellectual property rights in the form of licenses, promises to provide research and development services and promises to participate on certain development committees with the collaboration party. The terms of such agreements included payment to Aduro of one or more of the following: nonrefundable upfront fees, payment for research and development services, development, regulatory and commercial milestone payments, and royalties on net sales of licensed products.

Potential milestone payments related to development, regulatory or commercial milestone payments may be earned in the future under these preexisting agreements, but all such payments are uncertain and beyond our or our collaborators' control and would be recorded as revenue upon receipt or
over a period following receipt, such as under the CAPM model, if and when such payments are earned. We evaluated the remaining performance
obligations under these pre-existing agreements and concluded that we do not expect to recognize material revenue under these pre-existing agreements in
the near term.

For additional information, refer to Note 11 "Collaboration and License Agreements" of the Notes to the Consolidated Financial Statements under Part II, Item 8, "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K.

Research and Development Expenses

The largest component of our operating expenses is our investment in research and development activities, including the clinical development of our product candidates. Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates, as well as the development of product candidates pursuant to Aduro's pre-existing collaboration and license agreements. Research and development costs include employee-related costs; licensing costs; materials and supplies; contracted research and manufacturing; consulting arrangements; allocated costs, such as facility costs; and other expenses incurred to advance our research and development activities. We recognize all research and development costs as they are incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed.

We expect our research and development expenses to increase in the future as we advance our product candidates into and through clinical trials and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The probability of success for our product candidates and technologies may be affected by a variety of factors including: the quality of our product candidates, early clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never succeed in obtaining regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates.

General and Administrative Expenses

General and administrative expenses include employee-related costs, expenses for outside professional services, and other allocated expenses. Employee-related costs consist of salaries, bonuses, severance and benefits. Consulting and outside services consist of legal, accounting and audit services, insurance expenses, investor relations activities, administrative services and other consulting fees. Allocated expenses consist of rent expense related to our offices and research and development facility.

Change in Fair Value of Contingent Consideration and Contingent Value Rights Liabilities

At the effective time of the Merger, we also entered into an agreement, or CVR Agreement, pursuant to which Aduro's common stockholders of record as of the close of business on October 2, 2020 received one CVR for each outstanding share of Aduro common stock held by such stockholder on such date. Each CVR represents the contractual right to receive payments from us upon the receipt of consideration resulting from milestones and royalties from certain pre-existing agreements and the disposition or licensing of any of Aduro's non-renal assets, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses. Change in the fair value of the contingent consideration and CVR liabilities at each reporting consists of the changes in the values of these contractual rights.

Amortization of Intangible Assets

Amortization of intangible assets, excluding goodwill results from the amortization of finite-lived intangible assets acquired in the Merger. Amortization is over a period of 9 to 17 years, with an original weighted average period of 16.7 years.

Gain on Sale of Assets to Equity Method Investment

In 2021, we entered into an agreement with Sairopa B.V., or Sairopa, to acquire certain of our non-renal assets in exchange for preferred stock in Sairopa. The sale of the non-renal assets to Sairopa resulted in a \$7.2 million gain, which is the difference between the fair value of the equity received and the carrying value of the non-renal assets sold. The gain is reported in our consolidated statements of operations and comprehensive loss during the year ended December 31, 2021.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income and expense, foreign currency gains and losses, and various income or expense items of a non-recurring nature.

Change in Fair Value of Redeemable Convertible Preferred Stock Tranche Liability

As a private company, we issued Series A redeemable convertible preferred stock (Series A stock). The terms of the Series A stock agreement included provisions requiring the investors to purchase, and obligating the Company to deliver, additional shares of redeemable convertible preferred stock at a specified price in the future based on the achievement of certain development-based milestones.

We estimated the fair value of the redeemable convertible preferred stock tranche liability related to each milestone utilizing the income approach using unobservable inputs including (a) future per share value of Series A stock upon achievement of the milestone, (b) estimated term until date of milestone achievement, and (c) probability of milestone achievement. The future per share value of Series A stock upon achievement of the milestone and the probability of milestone achievement for each tranche were calculated on a probability-weighted basis giving equal weighting to public offering and private exit scenarios. The future cash flows were discounted to their fair values as of the valuation date using one or more discount rates, depending on the number of probability-weighted scenarios employed.

Upon issuance, the fair value of the redeemable convertible preferred stock tranche liability was recorded as a reduction in the amounts paid by investors for the purchase of Series A stock.

Upon closing of the Merger, the outstanding redeemable convertible preferred stock tranche rights terminated pursuant to the terms of the Merger agreement.

Income Tax (Expense) Benefit

We are subject to income taxes in the United States and foreign jurisdictions in which we do business. These foreign jurisdictions have statutory tax rates different from those in the United States. Accordingly, our effective tax rates will vary depending on the relative proportion of foreign to U.S. income, the availability of research and development tax credits, changes in the valuation of our deferred tax assets and liabilities and changes in tax laws. We regularly assess the likelihood of adverse outcomes resulting from the examination of our tax returns by the Internal Revenue Service, or IRS, and other tax authorities to determine the adequacy of our income tax reserves and expense. Should actual events or results differ from our current expectations, charges or credits to our income tax expense may become necessary.

Share of Net Loss of Equity Method Investment

Share of net loss of equity method investment represents our share of net loss of the Sairopa investment, which is reported in our consolidated statements of operations and comprehensive loss on a one quarter lag.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

	 Year Ended I	Change	
	2021	2020	\$
		(in thousands)	
Collaboration and license revenue	\$ 51,625	\$ 827	\$ 50,798
Operating expenses:			
Research and development	96,987	36,051	60,936
General and administrative	31,899	19,071	12,828
Change in fair value of contingent consideration			
and contingent value rights liabilities	27,317	1,510	25,807
Amortization of intangible assets	1,687	422	1,265
Total operating expenses	 157,890	57,054	100,836
Gain on sale of assets to equity method investment	7,227	_	7,227
Loss from operations	 (99,038)	(56,227)	(42,811)
Other income (expense), net	(170)	298	(468)
Change in fair value of redeemable convertible			
preferred stock tranche liability	_	(27,696)	27,696
Loss before income taxes and share of net loss of equity	 		
method investment	(99,208)	(83,625)	(15,583)
Income tax (expense) benefit	(2,093)	2,003	(4,096)
Share of net loss of equity method investment	(1,636)		(1,636)
Net loss	\$ (102,937)	\$ (81,622)	\$ (21,315)

Collaboration and License Revenue

Total revenue was \$51.6 million for the year ended December 31, 2021, an increase of \$50.8 million compared to \$0.8 million for the year ended December 31, 2020. The increase in revenue was primarily due to \$41.2 million of non-cash revenue recognized under our license agreement with SanReno and a development milestone of \$10.0 million recognized under our agreement with Merck and Co, Inc., or Merck. The agreement with Merck was acquired through the Merger. For additional information, refer to Note 11 "Collaboration and License Agreements".

Research and Development Expenses

The following tables summarize our research and development expenses by program and by category incurred during the years ended December 31, 2021 and 2020.

	Year Ended December 31,					
		2021 2020			Change	
	(in thousands)					
Product candidates:						
Atrasentan	\$	41,606	\$	16,255	\$	25,351
BION-1301		12,928		1,405		11,523
CHK-336		9,141		4,267		4,874
Other discovery, research and development programs		17,334		6,567		10,767
Subtotal		81,009		28,494		52,515
Stock-based compensation expense		6,007		1,759		4,248
Facility and depreciation costs		4,046		1,282		2,764
Other general research and development expenses		5,925		4,516		1,409
Total research and development expenses	\$	96,987	\$	36,051	\$	60,936

	Year Ended December 31,					
	2021 2020			Change		
	(in thousands)					
Licensing and contract research and manufacturing	\$	51,248	\$	19,488	\$	31,760
Employee-related costs		24,904		9,450		15,454
Supplies used in research and development		2,882		1,863		1,019
Stock-based compensation expense		6,007		1,759		4,248
Facility and depreciation costs		4,046		1,282		2,764
Consulting and outside services		6,531		1,037		5,494
Other		1,369		1,172		197
Total research and development expenses	\$	96,987	\$	36,051	\$	60,936

Research and development expenses were \$97.0 million for the year ended December 31, 2021, an increase of \$60.9 million compared to \$36.1 million for the year ended December 31, 2020. The increase in research and development expenses was primarily due to external clinical and manufacturing expenses related to the atrasentan and BION-1301 clinical programs; higher employee-related costs, including salaries, benefits and stockbased compensation expense, associated with hiring staff to build out our clinical and development capabilities; increased spending for consulting and outside services; and higher facilities and other costs. The year ended December 31, 2021 also includes an upfront fee of \$3.3 million paid to Evotec International GmbH under a research collaboration and license agreement entered into in February 2021.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the years ended December 31, 2021 and 2020:

	Year Ended December 31,				
		2021	2020		Change
	(in thousands)				
Consulting and outside services	\$	10,091	\$	9,170	\$ 921
Employee-related costs		10,448		4,984	5,464
Stock-based compensation expense		6,778		1,852	4,926
Facility and depreciation costs		2,449		1,170	1,279
Other		2,133		1,895	238
Total general and administrative expenses	\$	31,899	\$	19,071	\$ 12,828

General and administrative expenses were \$31.9 million for the year ended December 31, 2021, an increase of \$12.8 million compared to \$19.1 million for the year ended December 31, 2020. The increase in general and administrative expenses was primarily due to higher employee-related costs, including salaries, benefits and stock-based compensation expense associated with the addition of administrative staff to build out our public company infrastructure; higher legal, consulting and other professional services costs; and an increase in facilities and other costs.

Change in fair value of contingent consideration and contingent value rights liabilities

Change in fair value of contingent consideration and contingent value rights liabilities expense was \$27.3 million for the year ended December 31, 2021, an increase of \$25.8 million compared to \$1.5 million for the year ended December 31, 2020. The increase primarily resulted from a change in estimate of the potential future proceeds derived from Aduro's license agreement with Merck and from the sale of certain of our non-renal assets in exchange for preferred shares in Sairopa during the second quarter of 2021. The fair value of the contingent value rights liability also increased during 2021 due to the achievement of a development milestone under the terms of the agreement with Merck, which is payable to the CVR holders, net of permitted deductions. During the second quarter of 2021, Merck informed us that they intend to explore the potential benefits of the product candidate MK-5890, previously out-licensed to Merck by Aduro, in a phase 2 clinical study for a new indication. This could result in potential milestone and royalty payments for the benefit of the CVR holders.

Amortization of intangible assets

Amortization of intangible assets expense increased by \$1.3 million for the year ended December 31, 2021 compared to the year ended December 31, 2020 due to amortization of finite-lived intangible assets acquired in the Merger during the fourth quarter of 2020.

Gain on sale of assets to equity method investment

Gain on sale of assets to equity method investment increased \$7.2 million for the year ended December 31, 2021, resulting from the sale of certain non-renal assets in exchange for stock in Sairopa during the second quarter of 2021. The gain is the difference between the fair value of the equity received and the carrying value of the non-renal assets sold.

Change in fair value of redeemable convertible preferred stock tranche liability

Change in fair value of redeemable convertible preferred stock tranche liability decreased by \$27.7 million for the year ended December 31, 2021 compared to the year ended December 31, 2020, due to the termination of the convertible preferred stock tranche rights pursuant to the terms of the Merger agreement.

Income tax (expense) benefit

We recorded income tax expense of \$2.1 million for the year ended December 31, 2021, primarily resulting from the reduction of deferred tax liabilities related to our foreign entities.

Share of net loss of equity method investment

Share of net loss of equity method investment increased by \$1.6 million for the year ended December 31, 2021 compared to the year ended December 31, 2020, resulting from our share of net loss of the Sairopa investment, net of any taxes.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2021, we had \$355.1 million in cash, cash equivalents and marketable securities. We expect that our research and development and general and administrative expenses will increase, and, as a result, we anticipate that we will continue to incur increasing losses in the foreseeable future. We believe that our cash, cash equivalents and marketable securities as of December 31, 2021 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months.

In November 2021, we completed an underwritten public offering of 9.5 million shares of our common stock at a price to the public of \$14.00 per share, which included the exercise in full of the underwriters' option to purchase an additional 1.7 million shares of our common stock. In addition, we sold to certain investors pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 3.6 million shares of common stock at a purchase price of \$13.9999 per pre-funded warrant, which represents the per share public offering price for the common stock less the \$0.0001 per share exercise price for each such warrant. The Pre-Funded Warrants are exercisable at any time after the date of issuance and do not expire. A holder of Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 4.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of Pre-Funded Warrants may increase or decrease this percentage, but not in excess of 19.99%, by providing at least 61 days' prior notice to Chinook. The underwritten public offering resulted in gross proceeds to us of \$183.5 million, before \$11.3 million of transaction costs.

In April 2021, we entered into an "at-the-market" sales agreement (the "2021 Sales Agreement") with Cantor Fitzgerald & Co. and SVB Leerink LLC, through which we may offer and sell shares of our common stock having an aggregate offering of up to \$75.0 million through our sales agents, Cantor Fitzgerald & Co. and SVB Leerink LLC. We will pay the sales agents a commission of up to 3% of the gross proceeds of sales made through the 2021 Sales Agreement. In 2021, we sold 2.2 million shares for net proceeds of \$33.9 million under the 2021 Sales Agreement. As of December 31, 2021, we have \$40.0 million remaining under the 2021 Sales Agreement.

Funding Requirements

We have not generated any revenue from product sales, and we do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval of and commercialize any of our product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. Accordingly, we anticipate that we will need substantial additional funding in connection with our continuing operations.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to finance our future cash needs primarily through the issuance of additional equity, borrowings and strategic alliances with partner companies. To the extent that we raise additional capital through the issuance of additional equity, including through our at-the-market offering program or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include

liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market our product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	 Year Ended December 31,				
	 2021		2020		
	(in thousands)				
Net cash provided by (used in):					
Operating activities	\$ (102,744)	\$	(55,848)		
Investing activities	(112,639)		109,672		
Financing activities	209,524		124,292		
Effect of exchange rate changes	157		27		
Net change in cash, cash equivalents, and restricted					
cash	\$ (5,702)	\$	178,143		

Operating Activities

Net cash used in operating activities was \$102.7 million for the year ended December 31, 2021, an increase of \$46.9 million compared to \$55.8 million for the year ended December 31, 2020. The increase was primarily due to an increased operating loss resulting from increased research and development and general and administrative spending.

Investing Activities

Net cash used in investing activities was \$112.6 million for the year ended December 31, 2021, an increase of \$222.3 million compared to \$109.7 million cash provided by investing activities for the year ended December 31, 2020. The increase was primarily due to net purchases of marketable securities during the year ended December 31, 2021. Additionally, cash provided by investing activities in the prior year included the receipt of cash and cash equivalents acquired in connection with the Merger and net proceeds from maturities of marketable securities, with no corresponding amounts during the year ended December 31, 2021.

Financing Activities

Net cash provided by financing activities was \$209.5 million for the year ended December 31, 2021, an increase of \$85.2 million compared to \$124.3 million for the year ended December 31, 2020. The increase was primarily due to aggregate net proceeds of \$206.1 million received from the sale of common stock in the November 2021 underwritten public offering and the at-the-market sales agreement; option exercises during the year ended December 31, 2021, which increased over the prior period by \$2.1 million; and an increase in proceeds from the employee stock purchase plan. These increases were partially offset by net proceeds from the issuance of redeemable convertible preferred stock in the prior year.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Business Combination

Accounting for acquisitions requires extensive use of estimates and judgment to measure the fair value of the identifiable tangible and intangible assets acquired, including in-process research and development and liabilities assumed. Additionally, we must determine whether an acquired entity is considered a business or a set of net assets because the excess of the purchase price over the fair value of net assets acquired can only be recognized as goodwill in a business combination. We accounted for the Merger with Aduro as a business combination under the acquisition method of accounting. Consideration paid to acquire Aduro was measured at fair value and included the exchange of Aduro's common stock, assumption of Aduro stock options and warrants, and assumption of contingent value rights.

We allocated the purchase price to the acquired tangible and intangible assets and assumed liabilities of Aduro based on their estimated fair values as of the acquisition date. The allocation of the purchase price resulted in recognition of intangible assets related to an acquired license agreement, an inplace sublease broker commission, in-process research and development and goodwill. The fair value of the identifiable intangible assets is based on detailed valuations using information and assumptions such as the timing and estimated costs to complete the in-process projects, projecting regulatory approvals, developing an appropriate discount rate and estimating future cash flows.

Contingent Value Rights and Contingent Consideration Liabilities

The estimated fair value of the contingent value rights and contingent consideration liabilities, initially measured and recorded on the Merger date, are considered to be Level 3 instruments. The contingent value rights and contingent consideration liabilities are recorded at fair value at the end of each reporting period with changes in estimated fair values recorded in change in fair value of contingent consideration and contingent value rights liabilities in the consolidated statements of operations and comprehensive loss. In determining the fair value of the CVR and the contingent consideration liabilities, we used the income approach, primarily discounted cash flow models. The discounted cash flow models require the use of significant judgment, estimates and assumptions, including estimated revenues and costs, the probability of technical and regulatory success, and discount rates.

Intangible Assets

Our intangible assets include an acquired out-license agreement and indefinite-life in-process research and development assets ("IPR&D") acquired in the Merger with Aduro. The acquired out-license agreement represents the estimated fair value of an agreement with Merck and Co, Inc. ("Merck") related to a product candidate currently being studied in phase 2 clinical testing. The IPR&D represents the estimated fair value as of the acquisition date of two substantive in-process projects that have not reached technological feasibility: the BION-1301 product candidate currently being tested in a phase 1 clinical trial and the non-renal assets intended to be disposed of. The primary basis for determining technological feasibility of these assets is, in the case of BION-1301 and the Merck agreement, obtaining regulatory approval. In the case of the non-renal assets, it is completing transactions for the out-license or sale of the assets. The fair value of the Merck out-license agreement and in-process BION-1301 research and development intangible assets were determined using probability-weighted discounted cash flow models, including a multi-period excess earnings method and use of a Monte Carlo simulation. Projecting discounted future cash flows requires management to make significant estimates regarding future revenue and expenses, probability of technological and regulatory success, revenue volatility and discount rates. The discount rate used is determined at the time of acquisition and includes a rate of return which accounts for the time value of money, as well as risk factors reflecting the economic risk that the projected cash flows may not be realized. The fair value of the non-renal IPR&D intangible assets were determined using a probability-weighted discounted cash flow model, including assumptions regarding probabilities, timing and prices for the sale or out-license of these assets.

We review our intangible assets at least annually, on October 1 of each year, for possible impairment. Intangible assets are reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the assets below their carrying values. Our intangible assets totaled \$62.6 million at December 31, 2021.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates. Research and development costs include employee-related costs; licensing costs, materials and supplies, contracted research and manufacturing, consulting arrangements; allocated costs, such as facility costs; and other expenses incurred to advance our research and development activities. We recognize all research and development costs as they are incurred. In-licensing fees and other costs to acquire technologies that are utilized in research and development, and that are not expected to have alternative future use, are expensed when incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed. For service contracts that include a nonrefundable prepayment for future service, the upfront payment is deferred and recognized in the consolidated statements of operations and comprehensive loss as the services are rendered.

Estimated Fair Value of Redeemable Convertible Preferred Stock Tranche Liability

We had a liability related to future tranche options for purchase of our Series A redeemable convertible preferred stock. Such redeemable convertible preferred stock tranche rights terminated upon the closing of the Merger. The tranche options were accounted for as a liability at its estimated fair value at the inception of the obligation and was remeasured to fair value as of each balance sheet date, with the related re-measurement adjustment recognized as a component of other income (expense) in the consolidated statements of operations and comprehensive loss. The estimated fair value of the tranche options was determined using an option pricing model that considered the redeemable convertible preferred stock price, the exercise price of the option, the estimated time period the option would have been outstanding, the volatility of the underlying stock, the risk-free interest rate associated with the life of the option, and the dividend yield of the underlying Series A redeemable convertible preferred stock. The value derived from the option pricing model was adjusted for the probability of the related milestones not being met. Our management used its judgment to estimate many of these variables. We recorded adjustments to the estimated fair value of the redeemable convertible preferred stock tranche liability until which time the tranche options expired upon closing of the Merger.

Stock-Based Compensation Expense

We measure and recognize compensation expense for all stock-based awards granted to employees and non-employees based on the estimated fair value of the award on the date of grant.

We use the Black-Scholes option pricing model to measure the fair value of stock option awards when they are granted. We make several estimates in determining stock-based compensation and these estimates generally require significant analysis and judgment to develop, including (i) the expected share price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) the expected dividend yield. Prior to the Merger, due to the lack of company-specific historical and implied volatility data, we based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded, which have characteristics similar to those of Private Chinook, including stage of product development and focus on the life science industry. For options granted after the Merger, we are using historical volatility of Aduro's and the Company's common stock, as it approximates the volatility of the formerly utilized peer group. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The expected term for options granted to employees represents the weighted-average period the awards are expected to remain outstanding and our estimates were determined using the simplified method. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. We use an assumed dividend yield of zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

Stock-based compensation expense for restricted stock and stock options is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. We record forfeitures as incurred.

For the years ended December 31, 2021 and 2020, stock-based compensation expense was \$12.8 million and \$3.6 million, respectively. As of December 31, 2021, we had \$34.6 million of total unrecognized stock-based compensation costs, which we expect to recognize over a weighted-average period of 2.5 years.

Revenue Recognition

At inception, we determine whether contracts are within the scope of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606"). For contracts that are determined to be within the scope of ASC Topic 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which we expect to be entitled to receive in exchange for these goods and services, which is determined by applying the following five steps:

- (i) identifying the contract with the customer;
- (ii) identifying the performance obligations in the contract;
- (iii) determining the transaction price;
- (iv) allocating the transaction price to the performance obligations in the contract; and
- (v) recognizing revenue when or as we satisfy a performance obligation.

We only apply the five-step model to contracts when we determine that collection of substantially all consideration for goods and services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

Performance obligations promised in a contract are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct and are distinct in the context of the contract. To the extent a contract includes multiple promised goods and services, we apply judgment to determine whether promised goods and services are both capable of being distinct and distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation.

Determining the transaction price requires significant judgment. The transaction price in the contract is measured at fair value and reflects the consideration we expect to be entitled to in exchange for the goods and services. In the transaction price, variable consideration is only included to the extent that it is highly probable that a significant future reversal in the amount of cumulative revenue recognized under the contract will not occur. The transaction price is allocated to each performance obligation according to their stand-alone selling prices ("SSP") and is recognized when control of the goods or services are transferred to the customer, either over time or at a point in time, depending on the specific terms and conditions in the contracts. Judgment is required to determine the SSP. In instances where the SSP is not directly observable, such as when a license or service is not sold separately, the SSP is determined using information that may include market conditions and other observable inputs.

In November 2021, we entered into a License Agreement with SanReno ("China License Agreement"). In addition, we assumed several existing collaboration agreements in conjunction with the Merger. These agreements may include the transfer of intellectual property rights in the form of licenses and obligations to provide research and development services, participate on certain development committees with the collaboration party and to provide manufacturing supply. The terms of such agreements generally include payment in the form of cash or equity securities to us for one or more of the following: development and commercialization licenses; research and development services; manufacturing supply; development, regulatory and commercial milestone fees; and royalties on net sales of licensed products. Judgment is required to determine whether the license to our intellectual property is distinct from the research and development services or participation on development committees.

As of the closing of the Merger, we considered all remaining performance obligations under the assumed agreements to determine appropriate revenue recognition. For agreements that include development, regulatory or commercial milestone payments, we evaluated whether the milestones are considered probable of being reached and concluded that all such milestones are not within the control of us or the licensee, such as regulatory approvals, and are not considered probable of being achieved until those approvals are received or the underlying activity has been completed. Accordingly, any future milestone payments received under the assumed agreements will be analogized to ASC Topic 606 and recorded as revenue upon or over a period following receipt, if such milestone payments are received.

We also assumed an existing out-license agreement with Merck under which all performance obligations of Aduro were completed prior to the Merger. We are eligible to receive future contingent payments pursuant to Merck's achievement of certain development, commercial and net sales milestones for a product candidate. In addition, we are eligible to receive royalties based on net sales of the product. Any such milestones and royalties earned will be payable by us to the CVR holders, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses.

Income Taxes

Income taxes are accounted for using an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the consolidated financial statement and tax bases of assets and liabilities at the applicable enacted tax rates. We establish a valuation allowance for deferred tax assets if it is more likely than not that these items will expire before we are able to realize its benefits or that future deductibility is uncertain.

We recognize the tax benefit from uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax position is measured based on the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement. We recognize interest and penalties related to income tax matters in income tax expense if incurred.

Recent Accounting Pronouncements

For information regarding recent accounting pronouncements, refer to Note 2 "Summary of Significant Accounting Policies" of the Notes to the Consolidated Financial Statements under Part II, Item 8 of this report.

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

A smaller reporting company is not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data.

CHINOOK THERAPEUTICS, INC. INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Chinook Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Chinook Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' equity (deficit) and of cash flows for the years then ended, including 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 as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (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 of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters 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.

Valuation of the Contingent Value Rights and Contingent Consideration Liabilities

As described in Notes 2, 3, and 5 to the consolidated financial statements, the Company completed its merger with Aduro Biotech, Inc. in 2020 and recorded liabilities for contingent value rights and contingent consideration liabilities. The contingent value rights and contingent consideration liabilities are recorded at fair value at the end of each reporting period, and determined by management using the income approach, primarily using discounted cash flow models. Management applied significant judgment in determining the fair value of the contingent value rights and contingent consideration liabilities, which involved the use of significant estimates and assumptions including estimated revenues

and costs, the probability of technical and regulatory success and discount rates. The fair value of the contingent value rights and the contingent consideration liabilities as of December 31, 2021 is \$34.6 million and \$5.2 million, respectively.

The principal considerations for our determination that performing procedures relating to the valuation of the contingent value rights and contingent consideration liabilities is a critical audit matter are (i) the significant judgment by management when determining the fair value of the contingent value rights and contingent consideration liabilities and (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management's significant assumption relating to the probability of technical and regulatory success.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, (i) reading and evaluating the agreements relating to the contingent value rights and contingent consideration liabilities; (ii) testing management's process for determining the fair value of the contingent value rights and contingent consideration liabilities; (iii) evaluating the appropriateness of the discounted cash flow models; and (iv) evaluating the reasonableness of the significant assumption used by management related to the probability of technical and regulatory success. The probability of technical and regulatory success was evaluated by considering external market and industry data.

/s/ PricewaterhouseCoopers LLP Seattle, Washington March 17, 2022

We have served as the Company's auditor since 2019.

Chinook Therapeutics, Inc. Consolidated Balance Sheets (in thousands, except per share amounts)

		December 31,			
		2021		2020	
Assets					
Current assets:					
Cash and cash equivalents	\$	181,724	\$	187,750	
Marketable securities		105,113		59,622	
Accounts receivable		10,061		262	
Prepaid expenses and other current assets		3,741		6,447	
Total current assets		300,639		254,081	
Marketable securities		68,215		3,000	
Property and equipment, net		18,935		20,626	
Restricted cash		2,074		1,750	
Operating lease right-of-use assets		55,385		55,673	
Investment in equity securities		41,200			
Equity method investment		8,205			
Intangible assets, net		26,009		27,696	
In-process research & development		36,550		39,295	
Goodwill		117		22,441	
Other assets		6,474		4,440	
Total assets	<u>\$</u>	563,803	\$	429,002	
Liabilities and Stockholders' Equity					
Current liabilities:					
Accounts payable	\$	8,580	\$	3,995	
Accrued and other current liabilities		17,104		15,674	
Operating lease liabilities		4,401		3,045	
Contingent value rights liability		10,000		_	
Deferred revenue				95	
Total current liabilities		40,085		22,809	
Contingent value rights liability - non-current		24,591		13,780	
Contingent consideration liability		5,160		1,800	
Deferred tax liabilities		735		16,377	
Operating lease liabilities, net of current maturities		39,589		38,709	
Other long-term liabilities				905	
Total liabilities		110,160		94,380	
Commitments and contingencies (Note 12)			-		
Stockholders' equity:					
Preferred stock, \$0.0001 par value; 10,000 shares authorized as of					
December 31, 2021 and 2020; no shares issued and outstanding					
as of December 31, 2021 and 2020		_		_	
Common stock, \$0.0001 par value; 300,000 shares authorized as of					
December 31, 2021 and 2020; 54,761 and 42,282 shares issued					
and outstanding as of December 31, 2021 and 2020, respectively		5		4	
Additional paid-in capital		685,459		463,436	
Accumulated deficit		(231,766)		(128,829)	
Accumulated other comprehensive income (loss)		(55)		11	
Total stockholders' equity		453,643		334,622	
Total liabilities and stockholders' equity	<u>\$</u>	563,803	\$	429,002	

Chinook Therapeutics, Inc. Consolidated Statements of Operations and Comprehensive Loss (in thousands, except per share amounts)

		Years ended December 31,				
		2021		2020		
Collaboration and license revenue	\$	51,625	\$	827		
Operating expenses:						
Research and development		96,987		36,051		
General and administrative		31,899		19,071		
Change in fair value of contingent consideration and contingent value rights liabilities		27,317		1,510		
Amortization of intangible assets		1,687		422		
Total operating expenses		157,890		57,054		
Gain on sale of assets to equity method investment		7,227		<i>57</i> ,054		
Loss from operations		(99,038)		(56,227)		
Other income (expense):		(55,050)		(30,227)		
Other income (expense), net		(170)		298		
Change in fair value of redeemable convertible preferred stock tranche liability		(170)		(27,696)		
Loss before income taxes and share of net loss of equity method investment		(00.200)				
		(99,208)		(83,625)		
Income tax (expense) benefit		(2,093)		2,003		
Share of net loss of equity method investment	<u></u>	(1,636)		(04 (02)		
Net loss	\$	(102,937)	\$	(81,622)		
Net loss per share attributable to common stockholders, basic and diluted	\$	(2.26)	\$	(6.20)		
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted		45,607		13,168		
Other comprehensive income (loss):						
Foreign currency translation adjustments, net of tax of \$0		44		39		
Unrealized loss on marketable securities, net of tax of \$0		(110)		(21)		
Total other comprehensive income (loss)		(66)		18		
Comprehensive loss	\$	(103,003)	\$	(81,604)		

Chinook Therapeutics, Inc. Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) (in thousands)

	Redee Conve Preferre Shares	ertible	Commo	n Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
Balances at December 31, 2019	7,597	\$ 19,835	4,502	\$ —	6,095	\$ (47,207)	\$ (7)	\$ (41,119)
Issuance of common stock upon exercise of stock options, issuance of common stock under Employee Stock Purchase Plan, and vesting of restricted stock units	_	_	94	_	446	_	_	446
Repurchase of unvested restricted stock awards	_	_	(72)	_	_	_	_	_
Issuance of Series A redeemable convertible preferred stock, net of issuance costs	4,237	14,479		_	_	_	_	
Reclassification of redeemable convertible preferred stock tranche liability upon exercise	-	9,723	_	_	_	_	_	_
Conversion of redeemable convertible preferred stock to common stock	(11,834)	(44,037)	11,834	1	44,036	_	_	44,037
Reclassification of redeemable preferred stock tranche liability to additional paid-in capital upon termination of rights	_	_		_	50,706	_	_	50,706
Issuance of common stock pursuant to subscription agreements prior to Merger	_	_	9,583	1	109,413	_	_	109,414
Aduro outstanding common stock assumed as a result of the Merger	_	_	16,307	2	248,629	_	_	248,631
Issuance of common stock for financial advisory services in connection with the Merger	_	_	34	_	500	_	_	500
Stock-based compensation expense Other comprehensive gain	_	_ _	_	_	3,611	_	— 18	3,611 18
Net loss	_	_	_	_	_	(81,622)	_	(81,622)
Balances at December 31, 2020		<u> </u>	42,282	\$ 4	\$ 463,436	\$ (128,829)	\$ 11	\$ 334,622
Issuance of common stock upon exercise of stock options and warrants, issuance of common stock under Employee Stock Purchase Plan, and vesting of								
restricted stock units Issuance of common stock under the at-the-market sales agreement, net of	<u> </u>	_	724		3,106	_	_	3,106
issuance costs Issuance of common stock and accompanying pre-funded warrants in underwritten public offering, net	_	_	2,216	_	33,891	_	_	33,891
of issuance costs	_	_	9,539	1	172,241	_	_	172,242
Stock-based compensation expense	_	_	_	_	12,785	_	_	12,785
Other comprehensive loss	_	_	_	_	_	_	(66)	(66)
Net loss						(102,937)		(102,937)
Balances at December 31, 2021		<u> </u>	54,761	\$ 5	\$ 685,459	\$ (231,766)	<u>\$ (55)</u>	\$ 453,643

Chinook Therapeutics, Inc. Consolidated Statements of Cash Flows (in thousands)

Cash Flows from Operating Activities2021Net loss\$ (102,937)Adjustments to reconcile net loss to net cash used in operating activities:(41,200)Reversal of non-cash consideration related to revenue(3,065)Amortization of finance lease right-of-use asset—Amortization of intangible assets1,687Gain on disposal of property and equipment—Non-cash operating lease expense5,688Stock-based compensation expense12,785	\$ (81,6) 9 4 (1,1,4)
Net loss\$ (102,937)Adjustments to reconcile net loss to net cash used in operating activities:(41,200)Reversal of non-cash consideration related to revenue(3,065)Depreciation and amortization expense3,065Amortization of finance lease right-of-use asset—Amortization of intangible assets1,687Gain on disposal of property and equipment—Non-cash operating lease expense5,688Stock-based compensation expense12,785	9 4 (
Adjustments to reconcile net loss to net cash used in operating activities: Reversal of non-cash consideration related to revenue (41,200) Depreciation and amortization expense 3,065 Amortization of finance lease right-of-use asset — Amortization of intangible assets 1,687 Gain on disposal of property and equipment — Non-cash operating lease expense 5,688 Stock-based compensation expense 12,785	9 4 (
Reversal of non-cash consideration related to revenue (41,200) Depreciation and amortization expense 3,065 Amortization of finance lease right-of-use asset — Amortization of intangible assets 1,687 Gain on disposal of property and equipment — Non-cash operating lease expense 5,688 Stock-based compensation expense 12,785	4 (1,4
Depreciation and amortization expense 3,065 Amortization of finance lease right-of-use asset — Amortization of intangible assets 1,687 Gain on disposal of property and equipment — Non-cash operating lease expense 5,688 Stock-based compensation expense 12,785	4 (1,4
Amortization of finance lease right-of-use asset Amortization of intangible assets Gain on disposal of property and equipment Non-cash operating lease expense Stock-based compensation expense 12,785	4 (1,4
Amortization of intangible assets Gain on disposal of property and equipment Non-cash operating lease expense Stock-based compensation expense 1,687 5,688 5,688 12,785	4 (1,4
Gain on disposal of property and equipment Non-cash operating lease expense Stock-based compensation expense 12,785	(1,4
Non-cash operating lease expense 5,688 Stock-based compensation expense 12,785	1,4
Stock-based compensation expense 12,785	,
Change in fairnal and an able annually annually and the design of the little	3,6
Change in fair value of redeemable convertible preferred stock tranche liability Change in fair value of contingent consideration and contingent value rights liabilities 27,317	27,6 1,5
	1,5
	-
Financial advisory expenses paid through issuance of common stock Deferred income taxes 2,093	5
	(2,0
Gain on sale of assets to equity method investment (7,227) Share of net loss of equity method investment 1,636	
Changes in operating assets and liabilities: Accounts receivable (9,799)	8
Accounts receivable (9,799) Prepaid expenses and other assets 675	(7,9
Accounts payable 4,547	(7,9
Accounts payable 4,547 Accrued and other liabilities 1,972	
	(8
Operating lease liabilities (3,162) Deferred revenue (95)	(4
	(5
Net cash used in operating activities (102,744)	(55,8
Cash Flows from Investing Activities	=.0
Cash, cash equivalents and restricted cash acquired in connection with the Merger	74,9
Purchases of marketable securities (232,343)	(16,5
Proceeds from marketable securities 121,315	52,0
Purchases of property and equipment (1,878)	(7
Proceeds from sale of property and equipment 267	1
Net cash provided by (used in) investing activities (112,639)	109,6
Cash Flows from Financing Activities	
Proceeds from issuance of common stock pursuant to subscription agreements prior to Merger, net of offering costs	109,4
Proceeds from issuance of common stock and accompanying pre-funded warrants in underwritten public offering,	
net of issuance costs 172,527	
Proceeds from exercise of stock options and warrants and from employee stock purchase plan 3,106	4
Proceeds from at-the-market-sales agreement, net of issuance costs 33,891	44.
Proceeds from issuance of redeemable convertible preferred stock and related tranche rights, net of issuance costs	14,4
Repayment of finance lease liability	
Net cash provided by financing activities 209,524	124,2
Effect of exchange rate changes on cash, cash equivalents and restricted cash 157	
Net increase (decrease) in cash, cash equivalents and restricted cash (5,702)	178,1
Cash, cash equivalents and restricted cash at beginning of period	11,3
Cash, cash equivalents and restricted cash at end of period \$ 183,798	\$ 189,5
Reconciliation of Cash, Cash Equivalents and Restricted Cash	
Cash and cash equivalents \$ 181,724	\$ 187,7
Restricted cash 2,074	1,7
Total cash, cash equivalents and restricted cash \$ 183,798	\$ 189,5
Supplemental Cash Flow Information	
Supplemental Cash Flow Modifiation (Cash paid for amounts included in the measurement of lease liabilities \$ 6,270	\$ 1,3
Supplemental Disclosure of Non-Cash Investing and Financing Activities	\$ 1,3
Purchases of property and equipment included in accounts payable and in accrued and other current liabilities \$ 174	\$ 4
Furtherses of property and equipment included in accounts payable and in account of the further in administration of the further in accounts payable and in account of the further individual in account payable and in account payab	1,4
Issuance costs incurred but unpaid 286	1,4
Investment in equity securities acquired through non-cash consideration 41,200	
Fair value of net assets acquired in Merger —	185,9
Conversion of redeemable convertible stock to common stock upon closing of the Merger —	44.0
Financial advisory expenses paid through issuance of common stock —	44,0
Termination of redeemable convertible preferred stock tranche liability —	9,7
Termination of reactinate convertible preferred stock training industry	9,7

Chinook Therapeutics, Inc. Notes to Consolidated Financial Statements

1. Description of Business

Chinook Therapeutics, Inc. (the "Company", "Chinook", "we", "our", or "us") is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing precision medicines for kidney diseases. On October 5, 2020, Aduro Biotech, Inc. ("Aduro") completed its merger with Chinook Therapeutics U.S., Inc. ("Private Chinook"), pursuant to the terms of a merger agreement dated as of June 1, 2020, and amended on August 17, 2020, by which a wholly owned subsidiary of Aduro merged with and into Private Chinook, with Private Chinook continuing as a wholly owned subsidiary of Aduro (the "Merger"). Immediately following the Merger, Aduro changed its name to "Chinook Therapeutics, Inc." and the business conducted by Private Chinook became the primary business conducted by the Company. Refer to Note 3 "Reverse Merger and Contingent Value Rights" in the accompanying notes to the consolidated financial statements.

Our lead clinical program is atrasentan, an endothelin receptor antagonist that was in-licensed from AbbVie in late 2019. In March 2021, we initiated the phase 3 ALIGN trial of atrasentan for IgA nephropathy ("IgAN") and in April 2021, we initiated the phase 2 AFFINITY basket trial of atrasentan for proteinuric glomerular diseases. Our second product candidate, BION-1301, is an anti-APRIL monoclonal antibody also in development for patients with IgAN. Our pipeline also includes CHK-336, an oral small molecule LDHA inhibitor planned to enter clinical trials in the first half of 2022 for the treatment of primary hyperoxaluria. In addition, we are building our precision medicine pipeline through research and discovery programs for other rare, severe chronic kidney diseases. We were incorporated in Delaware and are headquartered in Seattle, Washington.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements and related disclosures have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and follow the requirements of the Securities and Exchange Commission (the "SEC") for annual reporting. The consolidated financial statements include the accounts of Chinook Therapeutics, Inc. and our wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported amounts of expenses during the reporting periods. Such estimates include the valuation of intangible assets, acquired property and equipment, investments, contingent value rights ("CVR") liability, contingent consideration liability, redeemable convertible preferred stock tranche liability, lease right-of-use assets, and lease obligations, as well as accruals for research and development activities, stock-based compensation expense, and income taxes. Actual results could differ from those estimates.

Segments

We operate and manage our business as one reportable and operating segment, which is the business of discovering, developing and commercializing precision medicines for kidney diseases. Our President and Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance.

Risks and Uncertainties

We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, reliance on single-source vendors and collaborators, availability of raw materials, patentability of our products and processes and clinical efficacy and safety of our products under development, compliance with government regulations and the need to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical studies, clinical trials and regulatory approval, prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting.

Our product candidates are still in development and, to date, none of our product candidates have been approved for sale and, therefore, we have not generated any revenue from product sales.

There can be no assurance that our research and development will be successfully completed, that adequate protection for our intellectual property will be obtained or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if our product development efforts are successful, it is uncertain when, if ever, we will generate revenue from product sales. We operate in an environment of rapid technological change and substantial competition from other pharmaceutical and biotechnology companies. In addition, we are dependent upon the services of our employees, consultants and other third parties.

Moreover, the current COVID-19 pandemic, which is impacting worldwide economic activity, poses risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time which may delay the start-up and conduct of our clinical trials, and negatively impact manufacturing and testing activities performed by third parties. Any significant delays may impact the use and sufficiency of our existing cash reserves, and we may be required to raise additional capital earlier than we had previously planned. We may be unable to raise additional capital if and when needed, which may result in further delays or suspension of our development plans. The extent to which the pandemic will impact our business will depend on future developments that are highly uncertain and cannot be predicted at this time.

Business Combination

Accounting for acquisitions requires extensive use of estimates and judgment to measure the fair value of the identifiable tangible and intangible assets acquired, including in-process research and development and liabilities assumed. Additionally, we must determine whether an acquired entity is considered a business or a set of net assets because the excess of the purchase price over the fair value of net assets acquired can only be recognized as goodwill in a business combination. We accounted for the Merger with Aduro as a business combination under the acquisition method of accounting pursuant to Accounting Standards Codification ("ASC") Topic 805, *Business Combinations*. Consideration paid to acquire Aduro was measured at fair value and included the exchange of Aduro's common stock, assumption of Aduro stock options and warrants, and assumption of CVR. Refer to Note 3 "Reverse Merger and Contingent Value Rights" for more information.

Cash and Cash Equivalents

We consider all highly liquid investments with maturities of three months or less at the time of acquisition to be cash equivalents. Cash and cash equivalents consist of cash held in bank accounts, money market funds, commercial paper, corporate debt securities, and U.S. government and agency securities. The recorded carrying amount of cash equivalents approximates their fair value.

Restricted Cash

We maintain a letter of credit as security for a facility lease that expires in 2029. The letter of credit is collateralized by a certificate of deposit in the amount of \$1.8 million, which is classified as long-term restricted cash in our consolidated balance sheets. Additionally, we maintain a letter of credit as a security deposit for a facility lease that expires in 2026. The letter of credit is collateralized by a certificate of deposit in the amount of \$0.3 million, which is classified as long-term restricted cash which is classified as long-term restricted cash in our consolidated balance sheets.

Marketable Securities

We classify our marketable securities as available-for-sale, which are reported at estimated fair value with unrealized gains and losses included in accumulated other comprehensive loss in stockholders' equity. Realized gains, realized losses and declines in the value of securities determined to be other-than-temporary, are included in other income (expense), net. The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Amortization of premiums and accretion of discounts are included in other income (expense), net. Interest earned on all securities is included in other income (expense), net. Marketable securities with maturities of less than one year, where management's intent is to use the investments to fund current operations, or to make them available for current operations, are classified as current.

If the estimated fair value of a debt security is below its carrying value, we evaluate whether it is more likely than not that we will sell the security before its anticipated recovery in market value and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. We also evaluate whether or not we intend to sell the investment. If the impairment is considered to be other-than-temporary, the security is written down to its estimated fair value. In addition, we consider whether credit losses exist for any securities. A credit loss exists if the present value of cash flows expected to

be collected is less than the amortized cost basis of the security. Other-than-temporary declines in estimated fair value and credit losses are charged against other income (expense).

Marketable securities are classified within Level 2 of the fair value hierarchy as the valuation is obtained from third-party services, which utilize industry standard valuation models, including both income-based and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate the fair value. Refer to Note 5 "Fair Value Measurements" for more information.

Concentration of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash, cash equivalents, available-for-sale securities and accounts receivable. We are exposed to credit risk from our deposits of cash and cash equivalents in excess of amounts insured by the Federal Deposit Insurance Corporation. Substantially all of our cash, cash equivalents and available-for-sale securities are maintained at major financial institutions of high credit standing. We monitor the financial creditworthiness of the issuers of our investments and limit the concentration in individual securities and types of investments that exist within our investment portfolio. Generally, all of our investments carry high credit quality ratings, in accordance with our investment policy. At December 31, 2021, we do not believe there is a significant financial risk from non-performance by the issuers of our cash, cash equivalents, and marketable securities. We have no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Fair Value of Financial Instruments

We established the fair value of our assets and liabilities using the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date and established a fair value hierarchy based on the inputs used to measure fair value. Cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued and liabilities are carried at cost, which approximates fair value due to their short maturities. Additionally, we have CVR and contingent consideration liabilities, which are recorded at fair value at the end of each reporting period with changes in estimated fair values recorded in the consolidated statements of operations and comprehensive loss. The fair values of the CVR and contingent consideration liabilities are based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. Refer to Note 5 "Fair Value Measurements" for more information.

There were no assets or liabilities measured at fair value on a nonrecurring basis during the years ended December 31, 2021 and 2020.

Redeemable Convertible Preferred Stock Tranche Liability

We determined that our obligations to issue additional shares of redeemable convertible preferred stock upon the achievement of certain milestones or at the option of the respective holders of such shares represented freestanding financial instruments. These instruments were initially measured at fair value and were subject to remeasurement with changes in fair value recognized in the consolidated statements of operations and comprehensive loss until they were exercised or settled. Upon closing of the Merger, the outstanding redeemable convertible preferred stock tranche rights terminated and all redeemable convertible preferred stock issued converted to common stock.

Refer to Note 12 "Commitments and Contingencies" for more information.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets. Upon retirement or sale of assets, the cost and the related accumulated depreciation or amortization of the respective assets are removed from the consolidated balance sheet and any resulting gain or loss is reflected in the consolidated statements of operations and comprehensive loss. Additions and improvements that increase the value or extend the life of an asset are capitalized. Repairs and maintenance costs are expensed as incurred.

The useful live of property and equipment are as follows:

Description	Estimated Useful Life (in years)
Research and lab equipment	5
Computer equipment and software	3
Furniture and fixtures	5
Leasehold improvements	Shorter of useful life or lease term

Goodwill and Intangible Assets

Goodwill represents the excess of the consideration transferred over the estimated fair value of assets acquired and liabilities assumed in a business combination. Intangible assets with indefinite useful lives are related to acquired in-process research and development ("IPR&D") projects and are measured at their respective fair values as of the acquisition date.

Our intangible assets primarily include an acquired out-license agreement and indefinite-life IPR&D acquired in the Merger with Aduro. The acquired out-license agreement represents the estimated fair value of an agreement with Merck & Co., Inc. ("Merck"). The IPR&D represents the estimated fair value as of the acquisition date of two substantive in-process projects that have not reached technological feasibility. The fair value of an acquired out-licensed agreement and IPR&D acquired in a business combination is recorded on our consolidated balance sheets at the acquisition date fair value and is determined by estimating future revenue and expenses, probability of technological and regulatory success, revenue volatility and discount rates, and discounting the projected net cash flows to present value.

Goodwill and intangible assets with indefinite useful lives are not amortized but are tested for impairment annually on October 1 or more frequently if we become aware of any events or changes that would indicate the fair values of the assets are below their carrying amounts. Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and are amortized based on their respective estimated useful lives at that point in time.

Impairment of Long-Lived Assets

We assess the impairment of long-lived assets, primarily property and equipment, whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. When such events occur, we determine whether there has been an impairment in value by comparing the asset's carrying value with its fair value, as measured by the anticipated undiscounted net cash flows of the asset. If an impairment in value exists, the asset is written down to its estimated fair value, as measured by anticipated discounted cash flows of the asset or market data. We have not recognized any impairment losses through December 31, 2021.

Leases

Leases related to our facilities are classified as operating leases.

We determine if an arrangement is a lease at inception. We have made a policy election to not separate lease and non-lease components for our real estate leases to the extent they are fixed. Non-lease components that are not fixed are expensed as incurred as variable lease expense. Our facility leases typically include variable non-lease components, such as common-area maintenance costs. Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities on our consolidated balance sheets. Operating lease ROU assets represent our right to use an underlying asset for the lease term and operating lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term. As our leases do not provide an implicit rate, we use our incremental borrowing rate, obtained from our bank and the financial statements of a known public company and adjusted for an appropriate level of risk based on the remaining term of the lease and our current financial condition, in determining the present value of lease payments. The operating lease ROU asset also includes any prepaid lease payments made and excludes lease incentives. Our leases may include options to extend or terminate the lease; lease terms are only adjusted for these options when it is reasonably certain that we will exercise such options to extend or terminate the lease expense is recognized on a straight-line basis over the lease term.

Assumptions made by us at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

We have subleased a substantial portion of our leased facilities under agreements considered to be operating leases according to ASC Topic 842, *Leases*. We have not been legally released from our primary obligations under the original lease and, therefore, we continue to account for the original lease as we did before commencement of the subleases. We record both fixed and variable payments received from the sublessees in our consolidated statements of operations and comprehensive loss on a straight-line basis as an offset to rent expense.

Investment in Equity Securities

Our investment in equity securities represents an ownership interest held by us in an unconsolidated entity, SanReno Therapeutics ("SanReno"). Refer to Note 9 "Investment in Equity Securities" for additional information. Accounting Standard Update ("ASU") 2016-01 requires equity securities to be recorded at cost and adjusted to fair value at each reporting period. However, the guidance allows for a measurement alternative, which is to record investments at cost, less impairment, if any, and subsequently adjust for observable price changes of identical or similar investments of the same issuer. The measurement alternative is used when an investment does not qualify for the equity method of the practical expedient in ASC Topic 820, *Fair Value Measurement* ("ASC Topic 820"), which estimates fair value using the net asset value per share.

Due to the lack of readily determinable fair values for such investment, we account for this investment under the measurement alternative at cost, less impairment. We perform a qualitative impairment assessment on our investment recorded under the measurement alternative quarterly. The investment is re-measured on a non-recurring basis as the investment is re-measured upon future observable price changes(s) in an orderly transaction(s), or upon impairment, if any. If the investment is determined to be other-than-temporarily impaired, an impairment charge is recorded against such investment and reflected in the consolidated statements of operations and comprehensive loss. There were no impairments of this investment during the year ended December 31, 2021.

Dividends from our investment in equity securities, if declared, are reflected in the consolidated statements of operations and comprehensive loss. There were no dividends declared during the year ended December 31, 2021.

Equity Method Investment

We report our investments in unconsolidated entities, over whose operating and financial policies we have the ability to exercise significant influence but not control, under the equity method of accounting. Judgment regarding the level of influence over our equity method investment includes considering key factors such as ownership interest, representation on the board of directors, and participation in policy-making decisions. Our equity method investment is reported at cost and adjusted each period for our share of the investee's income or loss, which is reported in our consolidated statements of operations and comprehensive loss on a one quarter lag.

We evaluate our equity method investments for impairment whenever events or changes in circumstances indicate that the carrying value of our investment may not be recoverable. If it is determined that a decline in the fair value of our investment is not temporary, and if such reduced fair value is below its carrying value, an impairment is recorded. Determining fair value involves significant judgment. Our estimates consider available evidence including, but not limited, to general economic conditions and other relevant factors. We did not record any impairments related to our equity method investment for the year ended December 31, 2021.

Revenue Recognition

At inception, we determine whether contracts are within the scope of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606"). For contracts that are determined to be within the scope of ASC Topic 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which we expect to be entitled to receive in exchange for these goods and services, which is determined by applying the following five steps:

- (i) identifying the contract with the customer;
- (ii) identifying the performance obligations in the contract;
- (iii) determining the transaction price;
- (iv) allocating the transaction price to the performance obligations in the contract; and
- (v) recognizing revenue when or as we satisfy a performance obligation.

We only apply the five-step model to contracts when we determine that collection of substantially all consideration for goods and services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

Performance obligations promised in a contract are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct and are distinct in the context of the contract. To the extent a contract includes multiple promised goods and services, we apply judgment to determine whether promised goods and services are both capable of being distinct and distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation.

Determining the transaction price requires significant judgment. The transaction price in the contract is measured at fair value and reflects the consideration we expect to be entitled to in exchange for the goods and services. In the transaction price, variable consideration is only included to the extent that it is highly probable that a significant future reversal in the amount of cumulative revenue recognized under the contract will not occur. The transaction price is allocated to each performance obligation according to

their stand-alone selling prices ("SSP") and is recognized when control of the goods or services are transferred to the customer, either over time or at a point in time, depending on the specific terms and conditions in the contracts. Judgment is required to determine the SSP. In instances where the SSP is not directly observable, such as when a license or service is not sold separately, the SSP is determined using information that may include market conditions and other observable inputs.

In November 2021, we entered into a License Agreement with SanReno ("China License Agreement"). In addition, we assumed several existing collaboration agreements in conjunction with the Merger. These agreements may include the transfer of intellectual property rights in the form of licenses and obligations to provide research and development services, participate on certain development committees with the collaboration party and to provide manufacturing supply. The terms of such agreements generally include payment in the form of cash or equity securities to us for one or more of the following: development and commercialization licenses; research and development services; manufacturing supply; development, regulatory and commercial milestone fees; and royalties on net sales of licensed products. Judgment is required to determine whether the license to our intellectual property is distinct from the research and development services or participation on development committees.

As of the closing of the Merger, we considered all remaining performance obligations under the assumed agreements to determine appropriate revenue recognition. For agreements that include development, regulatory or commercial milestone payments, we evaluated whether the milestones are considered probable of being reached and concluded that all such milestones are not within the control of us or the licensee, such as regulatory approvals, and are not considered probable of being achieved until those approvals are received or the underlying activity has been completed. Accordingly, any future milestone payments received under the assumed agreements will be analogized to ASC Topic 606 and recorded as revenue upon or over a period following receipt, if such milestone payments are received.

We also assumed an existing out-license agreement with Merck under which all performance obligations of Aduro were completed prior to the Merger. We are eligible to receive future contingent payments pursuant to Merck's achievement of certain development, commercial and net sales milestones for a product candidate. In addition, we are eligible to receive royalties based on net sales of the product. Any such milestones and royalties earned will be payable by us to the CVR holders, net of deductions permitted under the agreement with the CVR holders, including taxes and certain other expenses.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates. Research and development costs include employee-related costs; licensing costs, materials and supplies, contracted research and manufacturing, consulting arrangements; allocated costs, such as facility costs; and other expenses incurred to advance our research and development activities. We recognize all research and development costs as they are incurred. In-licensing fees and other costs to acquire technologies that are utilized in research and development, and that are not expected to have alternative future use, are expensed when incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed. For service contracts that include a nonrefundable prepayment for future service, the upfront payment is deferred and recognized in the consolidated statements of operations and comprehensive loss as the services are rendered.

Income Taxes

Income taxes are accounted for using an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the consolidated financial statement and tax bases of assets and liabilities at the applicable enacted tax rates. We establish a valuation allowance for deferred tax assets if it is more likely than not that these items will expire before we are able to realize its benefits or that future deductibility is uncertain.

We recognize the tax benefit from uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax position is measured based on the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement. We recognize interest and penalties related to income tax matters in income tax expense if incurred.

Fair value of Common Stock

Prior to the Merger, management estimated the fair value of our common stock consistent with the methods outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Determining the best estimated fair value of our common stock required significant judgment and management

considered several factors, including our stage of development, equity market conditions affecting comparable public companies, significant milestones and progress of research and development efforts.

Stock-Based Compensation

We measure and recognize compensation expense for all stock-based awards granted to employees and non-employees based on the estimated fair value of the award on the date of grant.

We use the Black-Scholes option pricing model to measure the fair value of stock option awards when they are granted. We make several estimates in determining stock-based compensation and these estimates generally require significant analysis and judgment to develop, including (i) the expected share price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) the expected dividend yield. Prior to the Merger, due to the lack of company-specific historical and implied volatility data, we based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded, which have characteristics similar to those of Private Chinook, including stage of product development and focus on the life science industry. For options granted after the Merger, we are using historical volatility of Aduro's and our common stock, as it approximates the volatility of the formerly utilized peer group. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The expected term for options granted to employees represents the weighted-average period the awards are expected to remain outstanding and our estimates were determined using the simplified method. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. We use an assumed dividend yield of zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

Stock-based compensation expense for restricted stock and stock options is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. We record forfeitures as incurred.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. The other comprehensive loss disclosed in our consolidated statements of operations and comprehensive loss for the years ended December 31, 2021 and 2020 consists of foreign currency translation adjustments and unrealized gains (losses) on marketable securities.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and pre-funded warrants outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock, pre-funded warrants and potentially dilutive securities outstanding for the period. The pre-funded warrants are included in the computation of basic and diluted net loss per common share as the exercise price is negligible and the pre-funded warrants are fully vested and exercisable. For purposes of the diluted net loss per share calculation, the common stock subject to repurchase, unvested restricted stock units, unvested restricted stock awards, options to purchase common stock, and warrants are considered to be potentially dilutive securities.

Foreign Currency

Our functional currency is the U.S. dollar and the functional currency of our foreign subsidiaries is either the Canadian dollar or the U.S. dollar. For subsidiaries with the functional currency of the Canadian dollar, assets and liabilities are translated to U.S. dollars using the exchange rates at the balance sheet date and expenses are translated using the monthly average exchange rates in effect during the period in which the transactions occur. Foreign currency translation adjustments are recorded as a component of accumulated other comprehensive income (loss) within stockholders' equity. Remeasurement adjustments are recorded in other income (expense), net. The effect of foreign currency exchange rates on cash and cash equivalents was not material for any of the periods presented.

Monetary assets and liabilities in the non-functional currency of our subsidiaries are remeasured using exchange rates in effect at the end of the period. Costs in the non-functional currency are remeasured using average exchange rates for the period, except for costs related to those balance sheet items that are remeasured using historical exchange rates. The resulting transaction gains and losses are included in the consolidated statements of operations and comprehensive loss as incurred and have not been material for all periods presented.

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. This ASU replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes will result in earlier recognition of credit losses. The standard is effective for smaller reporting companies in fiscal years beginning after December 15, 2022 with early adoption permitted for all periods beginning after December 15, 2018. We do not plan to early adopt ASU No. 2016-13 and are currently evaluating the impact the adoption of this ASU will have on our consolidated financial statements.

In May 2021, the FASB issued ASU No. 2021-04, Earnings Per Share (Topic 260), *Debt—Modifications and Extinguishments (Subtopic 470-50)*, *Compensation—Stock Compensation (Topic 718)*, and *Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815- 40)*, which provides guidance on modifications or exchanges of a freestanding equity-classified written call option (such as a warrant) that is not within the scope of another Topic. This new standard provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The standard is effective for smaller reporting companies in fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted. We will adopt ASU 2021-04 on January 1, 2022. We do not expect that adoption of the standard will have a material impact on our consolidated financial statements.

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12 – *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.* The standard update simplifies the accounting for income taxes by removing certain exceptions to the general principles in ASC 740 and also improves consistent application by clarifying and amending existing guidance. The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. We adopted the standard on January 1, 2021 and concluded that adoption of the standard did not have a material impact on our consolidated financial statements.

3. Reverse Merger and Contingent Value Rights

We completed our Merger with Aduro on October 5, 2020 and we acquired 100 percent equity interest in Private Chinook by issuing 16.3 million shares of common stock. Based upon the terms of the merger agreement dated June 1, 2020 and amended August 17, 2020, Private Chinook was determined to be the acquiring company for accounting purposes, and the transaction was accounted for as a reverse acquisition under the acquisition method of accounting for business combinations in accordance with U.S. GAAP. Accordingly, the assets and liabilities of Aduro were recorded at estimated fair value as of the merger closing date.

At the effective time of the Merger, we issued shares of our common stock to Private Chinook stockholders, at an exchange rate of 0.292188 shares of Aduro common stock for each share of Private Chinook common stock outstanding immediately prior to the Merger, including shares sold in the Pre-Closing Financing and all shares of Series A redeemable convertible preferred stock which converted into Private Chinook's shares of common stock on a one-for-one basis prior to closing of the Merger (the "Exchange Ratio"). We also assumed all the stock options outstanding under the Private Chinook 2019 Equity Incentive Plan. Unless otherwise noted herein, references to our common share and per-share amounts give retroactive effect to the Exchange Ratio.

In August 2020, Private Chinook entered into subscription agreements (the "Pre-Closing Financing") with certain existing and new investors, pursuant to which we agreed to sell, and the investors agreed to purchase, an aggregate of \$115.0 million of our common stock. On October 5, 2020, immediately prior to the closing of the Merger, investors purchased 9.6 million shares of common stock, at a price of \$12.00 per share, in the Pre-Closing Financing.

At the effective time of the Merger, we also entered into an agreement pursuant to which Aduro's common stockholders of record as of the close of business on October 2, 2020 received one CVR for each outstanding share of Aduro common stock held by such stockholder on such date (the "CVR Agreement"). Each CVR represents the contractual right to receive payments from us upon the receipt of consideration resulting from milestones and royalties from certain pre-existing agreements and the disposition or licensing of any of Aduro's non-renal assets, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses.

During the year ended December 31, 2021, we identified and recorded measurement period adjustments primarily for taxes, which impacted deferred tax liabilities, the fair value of the CVR liability, and other liabilities related to the Merger. The measurement period adjustments were the result of additional analyses performed and information identified during 2021 based on facts and circumstances that existed as of the Merger date.

Consideration Transferred

The fair value of the consideration transferred was based on the most reliable measure, which was determined to be the market price of Aduro shares of common stock as of the acquisition date. The fair value of the consideration transferred consisted of the following (in thousands):

	 ir Value at cquisition Date	Measuremen Period Adjustment		Adjusted Fair Value at Acquisition Date	
Value of shares of the combined company					
owned by Aduro equity holders (1)	\$ 238,003	\$	_	\$	238,003
Fair value of Aduro stock options and warrants -					
pre-combination services (2)	10,628		_		10,628
Estimated fair value of CVR (3)	12,270		(2,696)		9,574
Total fair value of consideration	\$ 260,901	\$	(2,696)	\$	258,205

- (1) Comprised of 16.3 million shares of common stock outstanding at the date of the Merger based on the closing price of \$14.595 per share on October 5, 2020.
- (2) Upon closing of the Merger, any Aduro stock option, warrant, or unvested restricted stock unit held by an Aduro employee who remained employed by Aduro as of immediately prior to the Merger, that is outstanding and unexercised as of immediately prior to the Merger, for accounting purposes was converted into a stock-based compensation award, or a Replacement Award, of the Company and is subject to the same terms and conditions after the Merger as the terms and conditions applicable to the corresponding Aduro stock-based compensation award. The amount included in Merger consideration represents the pre-combination service portion of the estimated fair value of the Replacement Awards issued to Aduro employees.
- (3) Immediately prior to closing of the Merger, Aduro granted its stockholders one CVR for each share of Aduro common stock. This CVR gives the holder a right to receive certain cash proceeds from potential future proceeds derived from Aduro's license agreement with Merck and other non-renal assets for up to ten years.

Purchase Price Allocation

As Private Chinook was the accounting acquirer in the Merger, the purchase price was allocated to the acquired tangible and intangible assets and assumed liabilities of Aduro based on the estimated fair values as of the acquisition date. The excess of the acquisition consideration paid over the estimated fair values of net assets acquired was recorded as goodwill in our consolidated balance sheets. Our determination of the estimated fair values of the assets acquired and liabilities assumed included the consideration of third-party valuation estimates relating to the value of the acquired intangible assets, leasehold improvements, property and equipment, a favorable lease and the CVRs.

The following summarizes the estimated fair value of the assets acquired and the liabilities assumed at the acquisition date (in thousands):

	ir Value at cquisition Date	Measurement Period Adjustments		Ĭ	usted Fair Value at iisition Date
Assets:					
Cash and cash equivalents	\$ 73,159	\$	_	\$	73,159
Marketable securities	98,057		_		98,057
Accounts receivable	1,122		_		1,122
Prepaids and other current assets	1,757		_		1,757
Property and equipment, net	19,039		_		19,039
Operating lease right-of-use assets	53,704		_		53,704
Intangible assets	28,118		_		28,118
IPR&D	39,295		_		39,295
Goodwill	22,441		(22,324)		117
Restricted cash	1,750		_		1,750
Other assets	295		_		295
Total assets acquired	 338,737		(22,324)		316,413
Liabilities:					
Accounts payable	2,280		_		2,280
Accrued clinical trial and manufacturing expenses	1,632		_		1,632
Accrued compensation	6,854		_		6,854
Accrued and other current liabilities	6,092		(690)		5,402
Deferred revenue, current	660		_		660
Operating lease liability, current	2,230		_		2,230
Existing contingent consideration	1,800		(450)		1,350
Deferred tax liabilities	18,372		(17,735)		637
Operating lease liabilities, non-current	36,474		_		36,474
Other non-current liabilities	1,442		(753)		689
Total liabilities assumed	77,836		(19,628)		58,208
Net Fair Value	\$ 260,901	\$	(2,696)	\$	258,205

We determined that the historical values of Aduro's current assets and current liabilities approximate fair value at the date of the acquisition based on the short-term nature of such items, except for as noted below.

Acquired property and equipment anticipated to be used was valued using a cost approach, where fair value was estimated as replacement cost less depreciation factors that represented the condition of the assets. Acquired property and equipment intended to be disposed of was valued at their estimated liquidation value.

The fair value of the acquired renal ("BION-1301") IPR&D intangible asset of \$32.4 million was determined using a probability-weighted discounted cash flow model prepared under the multi-period excess earnings method. The fair value of the acquired Merck license agreement intangible assets of \$26.7 million and the related CVR liability of \$8.1 million were valued under the income method using a probability-weighted discounted cash flow model and a Monte Carlo simulation model. We applied significant judgment in estimating the fair value of the acquired intangible assets and related contingent value rights, which involved the use of significant estimates and assumptions. Significant estimates and assumptions used in the valuation of the acquired BION-1301 IPR&D intangible asset related to future revenues and expenses, probabilities of technological and regulatory success and discount rate. Significant estimates and assumptions used in the valuation of the acquired Merck license agreement intangible assets and related contingent value rights related to future revenues and revenue volatility, probabilities of technological and regulatory success and discount rates. The fair value of the non-renal IPR&D intangible assets were determined using a probability-weighted discounted cash flow model, including assumptions regarding probabilities, timing and prices for the sale or out-license of these assets.

Favorable terms of an acquired lease were recorded as part of the operating lease ROU asset and was valued using a with-and-without income approach method.

Deferred revenue was valued based upon the estimated remaining costs to fulfill the legal performance obligation, plus a reasonable profit margin, which was expected to be satisfied within a year from the date of the Merger.

The existing contingent consideration liability related to the former shareholders of BioNovion Holdings BV was valued using a probability-weighted discounted cash flow assessment that considers probability and timing of future payments.

Goodwill is the excess of the consideration transferred over the fair values of assets acquired and liabilities assumed, which primarily reflects the future economic benefit arising from other assets acquired that could not be individually identified and separately recognized.

Our transaction costs were \$4.5 million, which were expensed as incurred.

4. Cash, Cash Equivalents and Marketable Securities

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

	December 31, 2021								
	A	Amortized Cost		Unrealized Gains		Inrealized Losses		Estimated Fair Value	
Cash and cash equivalents:									
Cash	\$	44,499	\$	_	\$	_	\$	44,499	
Money market funds		117,023		_		_		117,023	
Commercial paper		16,898		_		(1)		16,897	
Corporate debt securities		3,306				(1)		3,305	
Total cash and cash equivalents	\$	181,726	\$		\$	(2)	\$	181,724	
Marketable securities:									
Commercial paper	\$	34,978	\$	_	\$	(10)	\$	34,968	
U.S. government and agency securities		85,309		1		(88)		85,222	
Corporate debt securities		53,172		4		(38)		53,138	
Total marketable securities	\$	173,459	\$	5	\$	(136)	\$	173,328	

	December 31, 2020									
	Amortized Cost		Unrealized Gains		U	nrealized Losses		Estimated Fair Value		
Cash and cash equivalents:										
Cash	\$	5,659	\$	_	\$	_	\$	5,659		
Money market funds		113,592		_		_		113,592		
Certificate of deposit		157		_		_		157		
Commercial paper		40,844		_		_		40,844		
U.S. government and agency securities		27,498		_		_		27,498		
Total cash and cash equivalents	\$	187,750	\$	_	\$	_	\$	187,750		
Marketable securities:										
Commercial paper	\$	35,089	\$	_	\$	_	\$	35,089		
U.S. government and agency securities		26,026		6		(3)		26,029		
Corporate debt securities		1,504		_		_		1,504		
Total marketable securities	\$	62,619	\$	6	\$	(3)	\$	62,622		

The amortized cost and estimated fair value of our available-for-sale marketable securities by contractual maturity are summarized below as of December 31, 2021 (in thousands):

	Amortized Cost		U	Inrealized Gains	1	Unrealized Losses	Estimated Fair Value	
Mature in one year or less	\$	105,184	\$	1	\$	(72)	\$	105,113
Mature after one year through two years		68,275		4		(64)		68,215
Total available-for-sale marketable securities	\$	173,459	\$	5	\$	(136)	\$	173,328

None of our marketable securities were in a continuous unrealized loss position as of December 31, 2021. We review the individual securities in our portfolio to determine whether a decline in a security's fair value below the amortized cost basis is other-than-temporary. We determined that as of December 31, 2021 and 2020, there were no investments in our portfolio that were other-than-temporarily impaired.

5. Fair Value Measurements

We record certain financial assets and liabilities at fair value in accordance with the provisions of ASC Topic 820 on fair value measurements. As defined in the guidance, fair value, defined as an exit price, represents the amount that would be received to sell an asset or pay to transfer a liability in an orderly transaction between market participants. As a result, fair value is a market-based approach that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering these assumptions, the guidance defines a three-tier valuation hierarchy that prioritizes the inputs used in the valuation methodologies in measuring fair value.

- Level 1: Unadjusted quoted prices in active, accessible markets for identical assets or liabilities.
- Level 2: Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly.
 - Level 3: Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable activity.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The determination of a financial instrument's level within the fair value hierarchy is based on an assessment of the lowest level of any input that is significant to the fair value measurement. We consider observable data to be market data which is readily available, regularly distributed or updated, reliable and verifiable, not proprietary, and provided by independent sources that are actively involved in the relevant market.

The following tables present information about our financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	December 31, 2021									
		Level 1		Level 2		Level 2 Level 3		Level 3		Total
<u>Assets</u>										
Cash equivalents:										
Cash and money market funds	\$	161,522	\$	_	\$	_	\$	161,522		
Commercial paper		_		16,897				16,897		
Corporate debt securities				3,305				3,305		
Total cash and cash equivalents		161,522		20,202		_		181,724		
Marketable securities:										
Commercial paper		_		34,968				34,968		
U.S. government and agency securities		_		85,222		_		85,222		
Corporate debt securities		_		53,138		<u> </u>		53,138		
Total marketable securities		_		173,328		_		173,328		
Total fair value of assets	\$	161,522	\$	193,530	\$	_	\$	355,052		
<u>Liabilities</u>					_					
Contingent value rights liability	\$	_	\$	_	\$	34,591	\$	34,591		
Contingent consideration liability		_		_		5,160		5,160		
Total fair value of liabilities	\$		\$	_	\$	39,751	\$	39,751		

	December 31, 2020									
	Level 1		Level 2		Level 3			Total		
<u>Assets</u>										
Cash and cash equivalents:										
Cash and money market funds	\$	119,251	\$	_	\$	_	\$	119,251		
Certificate of deposit				157		_		157		
Commercial paper		_		40,844		_		40,844		
U.S. government and agency securities		_		27,498		_		27,498		
Total cash and cash equivalents		119,251		68,499				187,750		
Marketable securities:										
Commercial paper		_		35,089		_		35,089		
U.S. government and agency securities		_		26,029		_		26,029		
Corporate debt securities		_		1,504		_		1,504		
Total marketable securities				62,622				62,622		
Total fair value of assets	\$	119,251	\$	131,121	\$	_	\$	250,372		
<u>Liabilities</u>			_							
Contingent value rights liability	\$	_	\$	_	\$	13,780	\$	13,780		
Contingent consideration liability		_		_		1,800		1,800		
Total fair value of liabilities	\$	_	\$	_	\$	15,580	\$	15,580		

Money market funds are included within Level 1 of the fair value hierarchy because they are valued using quoted market prices. Other cash equivalents and marketable securities, such as commercial paper, U.S. government and agency securities, and corporate debt securities, as well as certificate of deposit, are classified within Level 2 of the fair value hierarchy as the valuation is obtained from third-party pricing services, which utilize industry standard valuation models, including both income-based and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate the fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, estimated interest rates based on the issuer credit rating and term, and other observable inputs.

The following table presents a summary of the changes in the fair value of the Company's Level 3 financial instruments (in thousands):

	ngent Value ts Liability	Co	Contingent nsideration Liability
Fair Value as of December 31, 2019	\$ _	\$	_
Assumed in the Merger	12,270		1,800
Change in fair value upon remeasurement	1,510		_
Fair Value as of December 31, 2020	13,780		1,800
Change in fair value upon remeasurement	23,507		3,810
Measurement period adjustment	(2,696)		(450)
Fair Value as of December 31, 2021	\$ 34,591	\$	5,160

The fair values of the CVR and contingent consideration liabilities are based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. In determining the fair value of the CVR and the contingent consideration liabilities, we used the income approach, primarily discounted cash flow models. The discounted cash flow models require the use of significant judgment, estimates and assumptions, including estimated revenues and costs, the probability of technical and regulatory success, and discount rates. For the year ended December 31, 2021 and 2020, the aggregate change in fair value of the CVR and the contingent consideration liabilities was \$27.3 million and \$1.5 million, respectively, and was recorded in the consolidated statement of operations and comprehensive loss. The change in the fair value during the periods resulted from a change in estimate of the potential future proceeds derived from Aduro's license agreement with Merck. Additionally, the change in fair value during the 2021 period resulted from the sale of certain of our non-renal assets in exchange for preferred shares in Sairopa B.V. ("Sairopa") during the second quarter of 2021. We will hold the shares in Sairopa until there is a liquidation event at which time, in accordance with the CVR agreement, 50% of any net proceeds will accrue to the benefit of the CVR holders, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses. Refer to Note 10 "Equity Method Investment" for more information. In addition, we identified measurement period adjustments during 2021 which reduced the CVR and contingent consideration liabilities. Refer to Note 3 "Reverse Merger and Contingent Value Rights" for more information.

6. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	 December 31,						
	2021		2020				
Research and lab equipment	\$ 3,366	\$	3,616				
Computer equipment and software	1,497		948				
Furniture and fixtures	1,224		1,099				
Leasehold improvements	16,976		16,111				
Total property and equipment	 23,063		21,774				
Total accumulated depreciation	(4,128)		(1,148)				
Property and equipment, net	\$ 18,935	\$	20,626				

Depreciation and amortization expense for property and equipment for the years ended December 31, 2021 and 2020 was \$3.1 million and \$1.1 million, respectively. Approximately \$2.9 million of our property and equipment as of December 31, 2021 is located in Canada.

7. Goodwill and Intangible Assets

Goodwill

The gross carrying amount and net book value of goodwill was \$0.1 million at December 31, 2021, all of which resulted from the Merger. During the year ended December 31, 2021, we identified and recorded measurement period adjustments primarily for taxes related to the Merger, which reduced goodwill by \$22.3 million from the preliminary purchase price allocation. The measurement period adjustments were the result of additional analysis performed and information identified during 2021 based on facts and circumstances that existed as of the Merger date. Refer to Note 3 "Reverse Merger and Contingent Value Rights" for more information.

We test goodwill for impairment on an annual basis or more frequently if an impairment indicator exists. To determine if an impairment has occurred, we perform a quantitative test in which the fair value of a single reporting unit is compared to its carrying value. If the carrying value of the reporting unit exceeds the fair value of the reporting unit, we record an impairment loss equal to that difference.

Intangible assets

The gross carrying amounts and net book value of intangible assets were as follows (in thousands):

	December 31, 2021						
		Carrying nount		cumulated nortization		Net Book Value	
Intangible assets with finite lives:				_		_	
Acquired license agreement	\$	26,685	\$	1,968	\$	24,717	
In-place lease		1,433		141		1,292	
Total intangible assets with finite lives		28,118		2,109		26,009	
Acquired IPR&D assets		36,550				36,550	
Total intangible and acquired IPR&D assets	\$	64,668	\$	2,109	\$	62,559	

	December 31, 2020								
		s Carrying Amount		Accumulated Amortization	Net Book Value				
Intangible assets with finite lives:									
Acquired license agreement	\$	26,685	\$	398	\$	26,287			
In-place lease		1,433		24		1,409			
Total intangible assets with finite lives		28,118		422		27,696			
Acquired IPR&D assets		39,295		_		39,295			
Total intangible and acquired IPR&D assets	\$	67,413	\$	422	\$	66,991			

Intangible assets are carried at cost less accumulated amortization and impairment. Amortization is over periods of 9 to 17 years, with an original weighted average period of 16.7 years, and the amortization expense is recorded in operating expenses. We test our Acquired IPR&D assets for impairment on an annual basis, or more frequently if an impairment indicator exists.

Acquired IPR&D decreased by \$2.7 million from the sale of certain of our non-renal assets in exchange for stock during the year ended December 31, 2021. Refer to Note 10 "Equity Method Investment" for more information.

Amortization expense was \$1.7 million and \$0.4 for the years ended December 31, 2021, and 2020, respectively. Based on finite-lived intangible assets recorded as of December 31, 2021, the estimated future amortization expense for the next five years is as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2022	\$ 1,722
2023	1,733
2024	1,733
2025	1,733
2026	1,733
Thereafter	17,355

8. Accrued Liabilities and Other

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

	December 31,					
		2021		2020		
Research and development costs	\$	8,397	\$	8,135		
Compensation and benefits		6,455		4,530		
Sublease rent and security deposit		1,067		1,400		
Business taxes and licensing fees		421		898		
Consulting and outside services		424		499		
Other		340		212		
Total accrued and other current liabilities	\$	17,104	\$	15,674		

9. Investment in Equity Securities

On November 24, 2021, we entered into agreements related to the formation of SanReno, a corporation established to develop, manufacture and commercialize kidney disease therapies in mainland China, Hong Kong, Macau, Taiwan and Singapore (collectively, the "Territory"). In connection with the formation of SanReno and pursuant to the China License Agreement entered into between Chinook and SanReno on November 24, 2021, Chinook granted SanReno exclusive licenses under certain intellectual property to develop and commercialize atrasentan and BION-1301 in the Territory for use in all human indications. In return, Chinook received 40.0 million preferred shares in SanReno representing 50% ownership of the outstanding voting securities and a warrant to purchase a total of 5.0 million common shares of SanReno at an exercise price of \$0.01 per share upon the attainment of regulatory exclusivity for atrasentan in the Territory. Such warrant will only be exercisable if and provided that SanReno obtains, before the 10-year anniversary of the closing of the formation of SanReno, the regulatory exclusivity for atrasentan in China for at least three years commencing from the New Drug Application approval by the National Medical Product Administration of China. The warrant will have a five-year exercise period after it becomes exercisable upon satisfaction of the exercise conditions and was valued at \$1.2 million on the grant date based on the probability of exercise of the warrant and the market for such instruments. An investor syndicate led by Frazier Healthcare Partners and Pivotal bioVenture Partners China, along with existing Chinook investors Versant Ventures and Samsara BioCapital, has invested \$40.0 million in exchange for the remaining 50% of the outstanding voting securities of SanReno. Refer to Note 11 "Collaboration and License Agreements" for more information regarding the China License Agreement.

In connection with the formation of SanReno, on November 24, 2021, Chinook also entered into a Shareholders Agreement (the "Shareholders Agreement") providing for certain rights and obligations of SanReno and its shareholders. Pursuant to the Shareholders Agreement, Chinook has the right to designate an individual for election to the board of directors of SanReno and SanReno has agreed that certain specified events (including certain liquidation events) shall require the approval of shareholders of SanReno holding a supermajority of SanReno's Series A preferred shares. The Shareholders Agreement terminates by mutual consent of the parties, and automatically terminates upon the dissolution of SanReno or immediately prior to the consummation of a qualified initial public offering.

We accounted for the investment in SanReno in accordance with the provisions of ASC Topic 321, *Investments – Equity Securities*, and elected to use the measurement alternative therein. As such, the investment is valued at \$41.2 million as of December 31, 2021, which was the total of the aggregate cost value of the 40.0 million preferred shares in SanReno received by us on the date of the closing of the formation of SanReno and the grant date value of the warrant. The investment will be re-measured upon future observable prices changes(s) in orderly transaction(s) or upon impairment, if any. Refer to Note 2 "Summary of Significant Accounting Policies" for more information regarding our Investment in Equity Securities accounting policies. There were no impairments of this investment during the year ended December 31, 2021.

We are entitled to non-cumulative dividends at 8% of our initial investment, payable when and if declared by the board of directors of SanReno. Dividends from our investment in equity securities, if declared, are reflected in the consolidated statements of operations and comprehensive loss. There were no dividends declared during the year ended December 31, 2021.

10. Equity Method Investment

On April 2, 2021, we entered into a definitive agreement with Sairopa B.V., a private company created by Van Herk Royalty B.V. and D.S. Chahal (the "Sairopa Investors") to acquire certain non-renal assets of Chinook in exchange for preferred stock in Sairopa. We will hold such shares until such time as there is a liquidation event, as defined in the shareholders agreement, in Sairopa. In accordance with the CVR agreement, 50% of any net proceeds received from this transaction by way of a liquidation event of Sairopa by October 4, 2030, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses, will accrue to the benefit of the CVR holders.

As of December 31, 2021, we own a 44% interest in Sairopa. We determined that we have the ability to exercise significant influence over Sairopa but do not have a controlling interest. Therefore, the investment in Sairopa was accounted for using the equity method. Judgment regarding the level of influence over each equity method investment includes considering key factors such as ownership interest, representation on the board of directors, and participation in policy-making decisions. The Sairopa Investors provided an initial capitalization of 12.5 million Euros. We recorded the equity method investment at \$10.0 million, which is the fair value of the equity received by us in exchange for the non-renal assets. The sale of the non-renal assets to Sairopa resulted in a \$7.2 million gain, which is the difference between the fair value of the equity received and the carrying value of the non-renal assets sold. The gain is reported in our consolidated statement of operations and comprehensive loss during the year ended December 31, 2021.

Our equity method investment is reported at cost and adjusted each period for our share of the investee's income or loss, which is reported in our consolidated statements of operations and comprehensive loss on a one quarter lag. We assess our equity method investment for impairment whenever events or changes in circumstances indicate that the carrying value of the investment may not be recoverable. Refer to Note 2 "Summary of Significant Accounting Policies" for information regarding our Equity Method Investment accounting policies.

11. Collaboration and License Agreements

SanReno Therapeutics

In November 2021, we entered into the China License Agreement, pursuant to which we granted SanReno exclusive licenses under certain intellectual property to develop, manufacture and commercialize for atrasentan and BION-1301 in the Territory. Refer to Note 9 "Investment in Equity Securities" for further details on the agreements executed with SanReno. We evaluated the China License Agreement under ASC Topic 606 and determined that the China License Agreement represents a contract with a customer. We identified the following performance obligations: (i) the licenses to develop, manufacture and commercialize atrasentan and BION-1301; (ii) our obligation to transfer know-how for the licensed product candidates ("Technology Transfers"); (iii) manufacturing and supply services; and (iv) opt-in global studies.

We determined that the preferred shares we received in SanReno of \$40.0 million plus the warrant granted to us of \$1.2 million constituted the entire consideration to be included in the total transaction price at the outset of the arrangement. Further, in determination of the performance obligations under the license agreements, the stand-alone selling prices of the performance obligations and our responsibility in the development activities have also been considered. Accordingly, the licenses, Technology Transfers, manufacturing and supply services, and opt-in global studies are all considered distinct performance obligations.

Since both licensed product candidates are in the later stages of development, we determined that both licenses have significant stand-alone functionalities as of contract inception. SanReno can begin deriving benefit from the licenses prior to the Technology Transfers being completed. The Technology Transfers will be completed upon request of SanReno and are separate from the transfer of the licenses, which occurred at contract inception. We also considered that we are not contractually obligated to perform research and development activities that significantly affect SanReno's ability to benefit from the licensed product candidates, and SanReno has full use of the licenses.

The estimated standalone selling price for the Technology Transfers was determined by estimating the costs of satisfying the performance obligation, plus an appropriate margin for such services. Pursuant to the China License Agreement, SanReno will reimburse the manufacturing and supply services at cost plus a mark-up and will reimburse the opt-in global studies at cost, which represent pass-through fees from third-party vendors, including clinical research organization.

Revenue attributable to the licenses and Technology Transfers was recognized during fiscal year 2021 as the licenses were delivered upon contract inception and the amount of the total transaction price allocated to the Technology Transfers was not material. Revenue attributable to the manufacturing and supply services and opt-in global studies will be recognized as incurred.

We are also eligible to receive a progress-dependent milestone payment of up to approximately \$25.0 million with respect to BION-1301. Under the China License Agreement, SanReno is also obligated to pay Chinook royalty payments at a percentage in the low teens based on net sales of atrasentan in the Territory on the portion of annual net sales in excess of a pre-determined amount, which royalty will be payable until the expiration of all licensed patents covering the sale of atrasentan in the Territory. The China License Agreement expires on a licensed product-by-licensed product basis on the latest of: (i) the expiration of the royalty term for atrasentan, (ii) the expiration of the last valid claim of a licensed patent for BION-1301 in the Territory. The parties may terminate the China License Agreement pursuant to terms specified in the agreement. Chinook and SanReno also have reciprocal rights of first negotiation in their respective territories for certain future kidney disease products developed or in-licensed by either company. Chinook retains full rights to atrasentan and BION-1301 outside of the Territory.

The potential progress-dependent cash milestone payment that we are eligible to receive was excluded from the total transaction price, as the milestone amount is fully constrained based on the probability of achievement. Accordingly, any future milestone payment received under the agreement will be recorded upon or over a period following receipt. Further, we will apply the exception under ASC Topic 606 for variable consideration related to sales-or-usage based royalties received in exchange for licensed intellectual property associated with atrasentan, therefore the royalties are not included in the transaction price until the licensee sells product.

During the year ended December 31, 2021, we recognized revenue of \$41.2 million under the China License Agreement. No progress-dependent milestone payments and royalties were received during the year ended December 31, 2021.

AbbVie Ireland Unlimited Company

On December 16, 2019, we entered into a license agreement (the "License Agreement") with AbbVie Ireland Unlimited Company ("AbbVie"), which granted us an exclusive license to develop and commercialize atrasentan, an endothelin receptor antagonist. Under the agreement, we assumed all global development and commercialization responsibilities for atrasentan. In consideration of the license and rights granted under the License Agreement, we made an upfront cash payment and issued 2.0 million shares of common stock for total consideration of \$6.7 million to AbbVie. We concluded that this transaction should be accounted for as an asset purchase, and as such, recorded the associated expense within research and development expenses in the consolidated statements of operations and comprehensive loss, as the product has not reached technological feasibility and does not have alternative future use. Under the License Agreement, we are obligated to make contingent development, regulatory and commercial milestone payments, of up to a maximum of \$135.0 million in the aggregate, as well as pay royalties on the worldwide net sales of licensed products ranging from upper-single-digit to high-teen percentages.

We did not recognize any milestone payments for the years ended December 31, 2021 and 2020. As of December 31, 2021 and 2020, we did not have any payable or receivable balances associated with the License Agreement.

Merck

In connection with Merger, we became party to an agreement with Merck. The agreement sets forth the parties' respective obligations for development, commercialization, regulatory and manufacturing and supply activities for antibody product candidates. All performance obligations of Aduro were completed prior to the Merger. We are eligible to receive future contingent payments, including up to \$287.0 million in potential development milestone payments, and up to \$135.0 million in commercial and net sales milestones for a product candidate. In addition, we are eligible to receive royalties at percentages in the mid-single digits to low teens based on net sales of the product. Future milestone payments and royalties will be recognized as revenue when earned as we have no performance obligations under this agreement. Any such milestones and royalties earned prior to October 4, 2030 will be payable by us to the CVR holders, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses. In the fourth quarter of 2021, we recognized revenue of \$10.0 million upon notification of the achievement of a development milestone under the terms of the agreement with Merck, which is payable to the CVR holders, net of permitted deductions.

Eli Lilly and Company

In connection with the Merger, we assumed an ongoing research collaboration and exclusive license agreement with Eli Lilly and Company ("Lilly") for the research and development of novel immunotherapies for autoimmune and other inflammatory diseases. Our only remaining performance obligation under the agreement was to perform research services through 2021, for which we were reimbursed up to a specified amount. We are eligible to receive future contingent milestone payments of up to approximately \$464.9 million per licensed product and tiered royalties on net sales at percentages in the single digits. We determined that the potential milestone payments are not considered probable of being achieved and, accordingly, such milestones will be recognized as revenue when earned.

For the year ended December 31, 2021 and 2020, we recognized revenue of \$0.4 million and \$0.8 million, respectively, under the Lilly agreement.

Novartis Pharmaceuticals Corporation

In connection with the Merger, we assumed an ongoing collaboration and license agreement with Novartis Pharmaceuticals Corporation ("Novartis") for the development and potential commercialization of product candidates in the field of oncology. On April 1, 2021, we received notice that Novartis terminated for convenience the Collaboration and License Agreement, dated March 12, 2015.

As a result of the termination, the only remaining activity under this agreement is reimbursement resulting from development costs that are shared between us and Novartis. We record any amounts paid to Novartis under the agreement as research and development expenses and any amounts received from Novartis as an offset to research and development expenses. For the year ended December 31, 2021, the amounts recognized under the agreement with Novartis were not material.

12. Commitments and Contingencies

Redeemable Convertible Preferred Stock Tranche Liability

In February 2019, as amended in July 2019, we entered into a Series A financing transaction, pursuant to which we were authorized to issue up to 18,992,220 shares of Series A redeemable convertible preferred stock having a per share par value of \$0.0001, at a purchase price of \$3.4225 per share.

The terms of the Series A redeemable convertible preferred stock agreement include provisions requiring the investors to purchase, and obligating us to deliver, additional shares of redeemable convertible preferred stock at a specified price in the future based on the achievement of certain development-based milestones by us. The investors are also able to waive the milestone requirements, which provides the investors with an option to purchase additional Series A redeemable convertible preferred stock if the milestone is not met. The rights to purchase additional shares were recorded as a tranche liability at the estimated fair value of the obligation on the date of issuance with the carrying values adjusted at each reporting date for any changes in the estimated fair values. For the year ended December 31, 2020, we recorded \$27.7 million, for the change in the fair value of the redeemable convertible preferred stock tranche liability.

Upon closing of the Merger, the outstanding redeemable convertible preferred stock tranche rights terminated and all redeemable convertible preferred stock that had been issued converted to common stock. The estimated fair value of the tranche rights at the time of termination was \$50.7 million, which was recorded as an increase to additional paid-in capital as a deemed capital contribution from the Series A redeemable convertible preferred stockholders.

Leases

We have a total of four operating leases as of December 31, 2021 with remaining lease terms of approximately 5 to 8 years.

In June 2021, we entered into a sublease agreement for office space in Seattle, Washington ("Seattle Sublease"), which we expect to use as our corporate headquarters. The Seattle Sublease commenced on July 1, 2021 and continues for a period of 58 months. The aggregate estimated base rent payments due over the remaining term of the Seattle Sublease is approximately \$5.3 million.

As of December 31, 2021, we are subleasing approximately 95,000 square feet in one of our facilities. Sublease income was \$6.2 million and \$1.4 million for the years ended December 31, 2021 and 2020, respectively, which was netted against rent expense. Total sublease income to be earned, in aggregate, will be approximately \$65.8 million over the remaining term of the sublease agreement.

The maturity of the Company's operating lease liabilities at December 31, 2021 was as follows (in thousands):

Undiscounted Lease Payments	Amounts
2022	\$ 7,481
2023	7,693
2024	7,848
2025	8,007
2026	7,156
Thereafter	18,918
Total undiscounted lease payments	57,103
Present value adjustment	(13,113)
Total net lease liability	43,990
Net lease liability - current	 4,401
Net lease liability - non-current	39,589
Total net lease liability	\$ 43,990

Rent expense recognized for operating leases was \$8.8 million and \$2.9 million for the years ended December 31, 2021 and 2020, respectively. Variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases were \$2.4 million and \$0.8 million for the years ended December 31, 2021 and 2020, respectively.

The following summarizes additional information related to operating leases:

	December 31, 2021	December 31, 2020
Weighted-average remaining lease terms (in years)		
Operating leases	7.4	8.8
Weighted-average discount rate		
Operating leases	7.5%	7.1%

Indemnification Agreements

In the ordinary course of business, we enter into agreements that may include indemnification provisions. Pursuant to such agreements, we may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments we could be required to make under these provisions is not determinable. We have never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. We have also entered into indemnification agreements with our directors and officers that require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. We currently maintain directors' and officers' liability insurance.

Legal Proceedings

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. Management believes that there are no actions pending against us currently, the ultimate disposition of which would have a material adverse effect on our results of operations, financial condition or cash flows.

Other Commitments

We have various manufacturing, clinical, research and other contracts with vendors in the conduct of the normal course of its business. All contracts are terminable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, we would only be obligated for the products or services that we had received at the time the termination became effective as well as non-cancelable and non-refundable obligations, including payment obligations for costs or expenses incurred by the vendor for products or services before the termination became effective. In the case of terminating a clinical trial agreement at a particular site, we would also be obligated to provide continued support for appropriate medical procedures at that site until completion or termination.

13. Common Stock

Common stockholders are entitled to dividends if and when declared by the Board of Directors (the "Board") subject to the prior rights of preferred stockholders, if any. As of December 31, 2021, and 2020, no dividends on common stock had been declared by the Board.

Issuance of Securities through an Underwritten Public Offering

In November 2021, we completed an underwritten public offering of 9.5 million shares of our common stock at a price to the public of \$14.00 per share, which included the exercise in full of the underwriters' option to purchase an additional 1.7 million shares of our common stock. In addition, we sold to certain investors pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 3.6 million shares of common stock at a purchase price of \$13.9999 per pre-funded warrant, which represents the per share public offering price for the common stock less the \$0.0001 per share exercise price for each such warrant. The Pre-Funded Warrants are exercisable at any time after the date of issuance and do not expire. A holder of Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 4.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of Pre-Funded Warrants may increase or decrease this percentage, but not in excess of 19.99%, by providing at least 61 days' prior notice to Chinook. The underwritten public offering resulted in gross proceeds to us of \$183.5 million, before \$11.3 million of transaction costs.

We evaluated the Pre-Funded Warrants for liability or equity classification in accordance with the provisions of ASC Topic 480, *Distinguishing Liabilities from Equity*, and determined that equity treatment was appropriate because the Pre-Funded Warrants did not meet the definition of liability instruments. The Pre-funded Warrants are classified as a component of permanent equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the share of common stock with which they were issued, are immediately exercisable, do not include repurchase rights, cash settlement, or other put provisions, and permit the holders to receive a fixed number of shares of common stock upon exercise. In addition, the Pre-funded Warrants do not provide any guarantee of value or return. We valued the Pre-funded Warrants to purchase 3.6 million shares of common stock at an aggregate value of \$50.0 million. The value of \$13.9999 per pre-funded warrant was measured on the grant date based on the common stock price in the underwritten public offering of \$14.00 per share, less the \$0.0001 per share exercise price of the warrant. As of December 31, 2021, none of the Pre-funded Warrants have been exercised.

At-the-Market Sales Agreement

In April 2021, we entered into an "at-the-market" sales agreement (the "2021 Sales Agreement"), with Cantor Fitzgerald & Co. and SVB Leerink LLC, through which we may offer and sell shares of our common stock having an aggregate offering of up to \$75.0 million through our sales agents, Cantor Fitzgerald & Co. and SVB Leerink LLC. We will pay the sales agents a commission of up to 3% of the gross proceeds of sales made through the 2021 Sales Agreement. In 2021, we sold 2.2 million shares for net proceeds of \$33.9 million under the 2021 Sales Agreement. As of December 31, 2021, we have \$40.0 million remaining under the 2021 Sales Agreement, which is subject to the continued effectiveness of our shelf registration statement on Form S-3 (Registration No. 333-255099) that expires on April 7, 2024, or upon an effective replacement shelf registration statement.

Warrants

We assumed certain common stock warrants in the Merger. At December 31, 2021, warrants outstanding were not material.

Restricted Stock Awards ("RSAs")

We sold 0.6 million shares of restricted common stock to founding employees, directors and investors for \$0.00034 per share. In the event continuous service terminates, the restricted shares sold to employees and directors include a provision whereby we have the option to repurchase unvested shares at the lower of the amount paid at grant or the fair market value as of repurchase date.

Activity with respect to restricted stock was as follows:

	RSAs Out	RSAs Outstanding			
	Number of RSAs (in thousands)	Weighted Average Grant Date Fair Value Per Share			
Balance, December 31, 2020	196	\$ 0.00034			
Vested	(97)	\$ 0.00034			
Balance, December 31, 2021	99	\$ 0.00034			

The fair value of restricted stock vested during the years ended December 31, 2021 and 2020 was \$1.4 million and less than \$0.1 million, respectively.

14. Stock-Based Compensation

Equity Incentive Plans

In February 2019, Private Chinook adopted the 2019 Equity Incentive Plan (the "2019 Plan").

In connection with the Merger, we assumed Aduro's two equity incentive plans, the 2015 Equity Incentive Plan (the "2015 Plan") and the 2009 Stock Incentive Plan (the "2009 Plan" and collectively the "Aduro Plans"). No additional grants may be made from the 2009 Plan; however, shares subject to awards granted under the 2009 Plan remain subject to the terms of the 2009 Plan. The number of shares subject to and the exercise prices applicable to these outstanding options were adjusted to reflect the one-for-five reverse stock split.

As of December 31, 2021 and 2020, there were 1.4 million and 0.9 million shares available for future grant, respectively. On January 1 of each year through 2025, the number of shares authorized for issuance under the 2015 Plan automatically increases by an amount equal to the lower of (i) 4 percent of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or (ii) a lower number determined by the Board of Directors

The 2019 Plan, the 2015 Equity Incentive Plan, and the 2009 Stock Incentive Plan (collectively, "The Plans") are administered by the Board of Directors, or a committee of the Board of Directors, which determines the types of awards to be granted, including the number of shares subject to the awards, the exercise price and the vesting schedule. The exercise price of incentive stock options and nonqualified stock options will be no less than 100 percent of the fair value per share of the Company's common stock on the date of grant. Options generally vest with respect to 25 percent of the shares one year after the options' vesting commencement date and the remainder ratably on a monthly basis over the following three years. Options granted under the Plans have a maximum term of 10 years. Restricted stock units ("RSU") generally vest with respect to one-third of the shares one year after the RSUs' vesting commencement date and remainder ratably on an annual basis over the following two years.

In connection with the Merger, we assumed Aduro's 2015 employee stock purchase plan ("2015 ESPP"). Under the 2015 ESPP, our employees may purchase common stock through payroll deductions at a price equal to 85% of the lower of the fair market value of the stock at the beginning of the offering period or at the end of each applicable purchase period. The 2015 ESPP generally provides for offering periods of six months in duration with purchase periods ending on either May 15 or November 15. ESPP purchases are settled with common stock from the 2015 ESPP previously authorized and available pool of shares. As of December 31, 2021, there were 0.7 million shares available for future issuance under the ESPP. On January 1 of each year through 2025, the number of shares authorized for issuance under the ESPP, automatically increases by an amount equal to the lower of (i) 1 percent of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or (ii) a lower number determined by the Board of Directors.

Stock option activity under the Plans is set forth below:

_	Outstanding	Awar	ds		
	Number of Shares Underlying Outstanding Options (in thousands)		Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance—December 31, 2020	5,514	\$	13.24	6.84	\$ 38,433
Granted	1,499		15.22		
Exercised	(525)		4.61		
Canceled or forfeited	(646)		29.55		
Balance—December 31, 2021	5,842	\$	12.73		
Options exercisable December 31, 2021	2,459	\$	14.83	4.74	\$ 17,255
Vested and expected to vest, December 31, 2021	5,842	\$	12.73	7.00	\$ 34,928

The aggregate intrinsic values of options outstanding, exercisable, and vested and expected to vest were calculated as the difference between the exercise price of the options and the market price for shares of our common stock as of December 31, 2021. Options for 0.5 million and less than 0.1 million shares of our common stock were exercised during the years ended December 31, 2021 and 2020, respectively, with an intrinsic value of \$5.4 million and \$0.8 million, respectively.

RSU activity under the Plans is set forth below:

	RSUs Outstanding			
	Number of RSUs (in thousands)	A Gr Fair	eighted- verage ant Date Value Per Share	
Balance, December 31, 2020	441	\$	14.51	
Granted	588		14.87	
Vested	(141)		14.52	
Forfeited	(65)		14.69	
Balance, December 31, 2021	823	\$	14.76	

The total fair value of RSUs that vested in the years ended December 31, 2021 and 2020 was \$1.9 million and \$0.1 million, respectively. The fair value of RSUs is determined on the date of grant based on the market price of our common stock on that date.

Valuation Assumptions

The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option-pricing model and the resulting weighted-average grant date fair value were as follows:

	 Years Ended December 31,			
	 2021	2020)	
Assumptions:				
Expected term (in years)	6.1	6.1		
Volatility	78.8%	77.6% -	90.0%	
Risk-free interest rate	0.9%	0.1% -	0.9%	
Dividend yield	0%	0%		
Fair Value:				
Weighted-average grant date fair value per share	\$ 10.34	\$	9.99	

The weighted-average assumptions used to estimate the fair value of our common stock to be issued under the 2015 ESPP using a Black-Scholes option-pricing model and the resulting weighted-average grant date fair value were as follows:

	 Years Ended December 31,			
	2021		2020	
Assumptions:				
Expected term (in years)	0.5		0.5	
Volatility	63.3%		81.5% - 12	27.5%
Risk-free interest rate	0.1%		0.1% - 0.0	.2%
Dividend yield	_		_	
Fair Value:				
Weighted-average grant date fair value per share	\$	5.16	\$	5.42

Stock-Based Compensation Expense

Total stock-based compensation expense recognized was as follows (in thousands):

	 Years Ended December 31,		
	 2021		2020
Research and development	\$ 6,007	\$	1,759
General and administrative	6,778		1,852
Total stock-based compensation expense	\$ 12,785	\$	3,611

Total unrecognized stock-based compensation expense and the expected period over which such expense will be recognized are as follows (\$ in millions):

	As of Decen	nber 31, 2021
Stock-options Stock-options		
Unrecognized stock compensation expense	\$	24.7
Weighted-average remaining vesting period (years)		2.7
RSU		
Unrecognized stock compensation expense	\$	9.7
Weighted-average remaining vesting period (years)		2.1
ESPP		
Unrecognized stock compensation expense	\$	0.2
Weighted-average remaining vesting period (years)		0.4

15. Defined Contribution Plans

In 2019, we implemented a defined contribution plan (the "401(k) Plan") for our full-time, U.S. based employees, with eligibility commencing in the month following an employee's hire date. Employee contributions to the 401(k) Plan are based on a percentage of the employee's gross compensation, limited by IRS guidelines for such plans. The 401(k) Plan provides for matching and discretionary contributions by us, which are made in the subsequent year. Matching contributions were \$0.3 million and less than \$0.1 million, for the years ended December 31, 2021 and 2020, respectively.

In 2019, we implemented a defined contribution plan (the "RRSP Matching Program") for our full-time, Canadian employees, with eligibility commencing on the employee's hire date. Employee contributions to the RRSP Matching Program are processed according to the instructions of each employee, with no cap on the amount each employee may contribute. Employees are individually responsible for ensuring their contributions from all sources do not exceed their individual RRSP contribution limit for the year, as defined by the Canada Revenue Agency. The RRSP Matching Program provides for matching contributions by us on a 1-to-1 basis within a prescribed limit for each calendar year. Matching contributions were \$0.1 million and less than \$0.1 million for the years ended December 31, 2021 and 2020, respectively.

In 2020, in connection with the Merger, we assumed a defined contribution plan (the "Aduro 401(k) Plan") for Aduro's full-time, U.S. based employees, continuing employment with the Company. Employee contributions to the Aduro 401(k) Plan were based on a percentage of the employee's gross compensation, limited by IRS guidelines for such plans. The Aduro 401(k) Plan provided for matching and discretionary contributions, which were made in the subsequent year. Matching contributions were \$0.2 million for the period beginning at the time of the Merger through December 31, 2020.

16. Income Taxes

Loss before income taxes was as follows (in thousands):

	 Years ended December 31,			
	2021	2020		
Domestic	\$ (59,702)	\$ (68,63)	6)	
Foreign	(41,142)	(14,98	9)	
Loss before income tax (expense) benefit	\$ (100,844)	\$ (83,62)	5)	

The federal, state, and foreign income tax (expense) benefit consists of the following:

	Years ended December 31,		
		2021	2020
Current:			
U.S. – Federal	\$	_	\$ —
U.S. – State		_	_
Foreign		_	_
Total current			
Deferred:			
U.S. – Federal		(1,690)	1,607
U.S. – State		98	234
Foreign		(501)	162
Total deferred		(2,093)	2,003
Total income tax (expense) benefit	\$	(2,093)	\$ 2,003

The effective tax rate of the provision for income taxes differed from the federal statutory rate as follows:

	Years ended Dec	ember 31,
	2021	2020
Federal tax benefit at statutory rate	21.0%	21.0%
State taxes, net of federal benefit	1.1%	0.2%
Change in valuation allowance	(13.8%)	(12.0%)
Foreign rate differential	(4.4%)	1.0%
Redeemable convertible preferred stock tranche liability	0.0%	(7.0%)
U.S. impact of foreign operations	(4.5%)	0.0%
Other	(1.5%)	(0.9%)
Effective income tax rate	(2.1%)	2.3%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The significant components of deferred tax assets and liabilities consisted of the following (in thousands):

	December 31,			
	2021 2020			2020
Deferred tax assets:				
Net operating loss carryforwards	\$	53,923	\$	16,781
Accruals and reserves		1,350		928
Contingent payments		3,350		_
Stock-based compensation expense		2,821		2,134
Business tax credits		2,450		1,372
Other		2,523		_
Lease liabilities		9,824		10,010
Gross deferred tax assets		76,241		31,225
Valuation allowance		(59,762)		(15,017)
Total deferred tax assets, net of valuation allowance		16,479		16,208
Deferred tax liabilities:			_	
Fixed asset basis		(2,142)		(2,541)
Right of use asset		(12,299)		(13,318)
Intangible asset basis		(2,773)		(16,726)
Total deferred tax liabilities		(17,214)		(32,585)
Net deferred tax assets and liabilities	\$	(735)	\$	(16,377)

We are required to reduce our deferred tax assets by a valuation allowance if it is more likely than not that some or all of our deferred tax assets will not be realized. We must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of the valuation allowance, if any, we assess the likelihood that we will be able to recover our deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical consolidated cumulative losses, we determined that, based on all available evidence, there was substantial uncertainty as to whether we would recover a majority of our recorded net deferred taxes in future periods. As a result, we recorded a valuation allowance against the U.S. net deferred tax assets at December 31, 2021 and 2020. The valuation allowance increased by \$44.7 million and \$10.0 million during the years ended December 31, 2021 and 2020, respectively.

At December 31, 2021, we have generated net operating loss ("NOL") carryforwards (before tax effects) for federal, state and foreign income tax purposes of \$186.2 million, \$80.4 million and \$29.6 million, respectively. The federal, state and foreign NOL carryforwards will begin to expire in 2029, 2039 and 2039, respectively, if not utilized. In addition, we have foreign business tax credits of \$2.4 million to offset future income tax liabilities, which will start to expire in 2039, if not utilized.

Our ability to utilize NOL carryforwards or other tax attributes, such as research tax credits, in any taxable year may be limited if we have experienced an ownership change under Section 382 of the Internal Revenue Code (the Code) of 1986, as amended. The Merger resulted in such an ownership change and, accordingly, our NOL carryforwards and certain other tax attributes will be subject to further limitations on their use. We assessed whether we had an ownership change, as defined by Section 382 of the Code from our formation through December 31, 2021. Based upon this assessment, we experienced an ownership change on October 5, 2020. Due to these ownership changes, reductions were made to our NOL and tax credit carryforwards under these rules. Additional ownership changes in the future could result in additional limitations on our NOL and tax credit carryforwards.

Uncertain Tax Positions

We account for uncertainty in income taxes in accordance with ASC Topic 740. Tax positions are evaluated in a two-step process, whereby we first determine whether it is more likely than not that a tax position will be sustained upon examination by the tax authority, including resolutions of any related appeals or litigation processes, based on technical merit. If a tax position meets the more-likely-than-not recognition threshold, it is then measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured as the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement.

The following table summarizes the activity related to our unrecognized benefits (in thousands):

	Year Ended December 31,			
		2021		2020
Balance at beginning of year	\$	753	\$	753
Additions based on tax positions related to prior year		_		_
Reductions based on tax positions related to prior year		(753)		_
Additions based on tax positions related to current year		_		_
Reductions based on tax positions related to current year		_		_
Balance at end of year	\$		\$	753

Our policy is to classify interest and penalties associated with unrecognized tax benefits as income tax expense. We had no interest or penalty accruals associated with uncertain tax benefits in our consolidated balance sheets and consolidated statement of operations and comprehensive loss for the year ended December 31, 2021. We do not have any tax positions for which it is reasonably possible that the total amount of gross unrecognized tax benefits will significantly change within 12 months of December 31, 2021.

We file federal, state and foreign income tax returns in jurisdictions with varying statutes of limitations. Due to our net operating loss carryforwards, our income tax returns remain subject to examination by federal, state and foreign tax authorities for all tax years.

17. Net Loss Per Common Share

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders, which excludes unvested restricted shares and shares which are legally outstanding, but subject to repurchase by us (in thousands, except share amounts):

	Years Ended December 31,			
		2021		2020
Numerator:				
Net loss attributable to common stockholders	\$	(102,937)	\$	(81,622)
Denominator:				
Weighted-average shares outstanding		45,755		13,463
Less: weighted-average unvested restricted shares and				
shares subject to repurchase		(148)		(295)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and				
diluted		45,607		13,168
Net loss per share attributable to common stockholders,				
basic and diluted	\$	(2.26)	\$	(6.20)

As of December 31, 2021, 3.6 million Pre-Funded Warrants to purchase common stock, issued in connection with the November 2021 public offering, were included in the weighted-average shares outstanding used in the calculation of basic and diluted net loss per share. Refer to Note 13 "Common Stock" for more information.

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the period presented because including them would have been antidilutive (in thousands):

December 31,	
2021 2	2020
Unvested RSUs 823	441
Unvested RSAs 99	196
Common stock warrants —	9
Options to purchase common stock 5,842	5,514
Total 6,764	6,160

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

None

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures.

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this Annual Report on Form 10-K. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were not effective at a reasonable assurance level due to the material weaknesses identified in our internal control over financial reporting as of December 31, 2021, as described below, which our management views as an integral part of our disclosure controls and procedures.

Following identification of the material weaknesses and prior to filing this Annual Report on Form 10-K, we completed substantive procedures for the year ended December 31, 2021. Based on these procedures, management concluded that our consolidated financial statements included in this Form 10-K have been prepared in accordance with U.S. GAAP. Our Chief Executive Officer and Chief Financial Officer have certified that, based on their knowledge, the financial statements, and other financial information included in this Form 10-K, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this Form 10-K.

Management's 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 Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is a process 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. In making this assessment, our management used the criteria set forth by the *Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013)*. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. We identified the following control deficiencies that constituted material weaknesses in our internal control over financial reporting as of December 31, 2021:

- (i) We did not design or maintain an effective control environment commensurate with our financial reporting requirements due to lack of sufficient accounting and finance professionals with the appropriate level of skill, experience and training commensurate with our financial reporting requirements. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, insufficient segregation of duties in our finance and accounting functions. This contributed to additional material weaknesses;
- (ii) We did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting reporting and disclosures, including controls over the preparation and review of account reconciliations, journal entries and period end financial reporting; and
- (iii) We did not design and maintain controls over the operating effectiveness of information technology general controls for information systems that are relevant to the preparation of our financial statements, specifically including controls over program change management; user access, including segregation of duties; and computer operations.

These material weaknesses could result in a misstatement of accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

Based on these material weaknesses, management concluded that we did not maintain effective internal control over financial reporting as of December 31, 2021.

This Annual Report on Form 10-K does not include a report of our independent registered public accounting firm on the effectiveness of internal control over financial reporting due to an exemption for smaller reporting companies established by the rules of the SEC.

Remediation Efforts

Our management, under the supervision of our President and Chief Executive Officer and our Chief Financial Officer, has undertaken a plan to remediate the material weaknesses identified above. The remediation efforts summarized below, which are in the process of being implemented, are intended to address the identified material weaknesses.

- (i) In November 2020, we hired a permanent Chief Financial Officer with substantial experience in the biotechnology industry, whose responsibilities include working with existing employees and third-party consultants to improve the design, implementation, execution and supervision of the company's internal control over financial reporting.
- (ii) We have hired additional finance, accounting and information technology employees with appropriate experience, certification, education and training. This includes a senior information technology leader and additional accounting staff, who are already onboard, as well as a senior accounting leader who joined us in March 2021. This individual has significant experience in technical accounting matters and internal controls commensurate with public company reporting requirements. During the second quarter of 2021, we hired additional qualified personnel to critical accounting leadership roles, who we expect to significantly contribute to the remediation of our material weaknesses.
- (iii) We integrated the accounting systems of Private Chinook and Aduro in 2021, and are updating our formal accounting policies, procedures and controls, including preparation and review of account reconciliations, review of journal entries and controls over period end financial reporting, as well as information technology general controls. During the second quarter of 2021, we implemented procedures for the preparation and review of reconciliations and journal entries, in addition to implementing procedures over several other areas that support our financial reporting. We will continue to enhance or modify these procedures and controls in future periods as needed. We also engaged third-party system service providers, who we plan to utilize in the future to implement certain information technology general controls associated with our accounting general ledger.
- (iv) We have assigned responsibilities among our expanded staff to enable improved segregation of duties. During the third and fourth quarters of 2021, we continued the evaluation of systems and processes for proper segregation of duties. Additionally, during the fourth quarter of 2021, we implemented a third-party system which is being leveraged in our procurement process and has contributed to certain automated system controls supporting segregation of duties within the procurement process.

In addition to the items above, during the second quarter of 2021, we engaged a third-party service provider to complete an independent risk assessment of our internal control over financial reporting to evaluate sources of potential risks to our financial statements. This also included an assessment of key systems supporting financial reporting in order to improve the design and operating effectiveness of information technology general controls. As a result of this risk assessment, we identified and designed key controls across several processes supporting internal control over financial reporting and developed a workplan for remediation of the enhancements identified. During the third quarter of 2021, we engaged an additional third-party service provider to assess and provide feedback on the design of our controls within several process areas impacting financial reporting, including information technology general controls.

We believe that the implementation of the above steps has already allowed us to make progress on addressing a number of the deficient controls within our internal control environment, which will help facilitate the remediation of the material weaknesses identified above. As we continue to evaluate and work to improve our internal control over financial reporting, we will take additional measures to address control deficiencies, or we may modify certain of the remediation measures described above. However, we require additional time to complete the design and implementation of our remediation plans and demonstrate the effectiveness of our remediation efforts. The material weaknesses cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in internal control over financial reporting.

Other than the changes described above, there were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances, and may not prevent or detect misstatements. In addition, 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. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such actions will be sufficient to provide us with effective internal control over financial reporting.

Item 9B. Other Information.
None.

 ${\bf Item~9C.~Disclosure~Regarding~Foreign~Jurisdictions~that~Prevent~Inspections.}$

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated herein by reference to the Company's definitive proxy statement relating to the 2022 annual meeting of stockholders, or 2022 Proxy Statement, to be filed with the Securities and Exchange Commission, or SEC, within 120 days of the Company's fiscal year ended December 31, 2021.

Item 11. Executive Compensation.

The information required by this item is incorporated herein by reference to the 2022 Proxy Statement, to be filed with the SEC within 120 days of the Company's fiscal year ended December 31, 2021.

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

The information required by this item is incorporated herein by reference to the 2022 Proxy Statement, to be filed with the SEC within 120 days of the Company's fiscal year ended December 31, 2021.

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

The information required by this item is incorporated herein by reference to the 2022 Proxy Statement, to be filed with the SEC within 120 days of the Company's fiscal year ended December 31, 2021.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated herein by reference to the 2022 Proxy Statement, to be filed with the SEC within 120 days of the Company's fiscal year ended December 31, 2021.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

- (a) The following documents are filed as part of this report:
- 1. Financial Statements

Information in response to this Item is included in Part II, Item 8 of 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

See Index to Exhibits below.

INDEX TO EXHIBITS

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Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith		
2.1^	Agreement and Plan of Merger and Reorganization, dated June 1, 2020, by and among Aduro Biotech, Inc., Aspire Merger Sub, Inc., and Chinook Therapeutics U.S., Inc.	8-K	001-37345	2.1	06/02/2020			
2.2	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated August 17, 2020, by and among Aduro Biotech, Inc., Aspire Merger Sub, Inc., and Chinook Therapeutics U.S., Inc.	8-K	001-37345	2.1	08/18/2020			
3.1	Restated Certificate of Incorporation of the Registrant.	8-K	001-37345	3.1	04/20/2015			
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, dated October 1, 2020.	8-K	001-37345	3.1	10/01/2020			
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, dated October 5, 2020.	S-8	333-249351	4.6	10/06/2020			
3.4	Amended and Restated Bylaws of the Registrant.	S-1/A	333-202667	3.5	04/06/2015			
3.5	Amendment to Amended and Restated Bylaws, dated July 16, 2020	8-K	001-37345	3.1	07/17/2020			
4.1	Form of Registrant's Common Stock certificate.	S-1/A	333-202667	4.1	04/06/2015			
4.2	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	10-K	001-37345	4.2	04/07/2021			
10.1+	Aduro Biotech 2009 Stock Incentive Plan.	S-1	333-202667	10.5	03/11/2015			
10.2+	Forms of Stock Option Agreement and Notice of Grant of Stock Option under the 2009 Stock Plan.	S-1	333-202667	10.6	03/11/2015			
10.3+	2015 Equity Incentive Plan.	S-1/A	333-202667	10.7	04/06/2015			
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Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.4+	Forms of Stock Option Agreement and Notice of Grant of Stock Option under the 2015 Equity Incentive Plan.	S-1/A	333-202667	10.8	04/06/2015	
10.5+	2015 Employee Stock Purchase Plan.	S-1/A	333-202667	10.9	04/06/2015	
10.6+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement.	8-K	001-37345	10.1	09/14/2016	
10.7+	Chinook 2019 Equity Incentive Plan and forms of award agreements thereunder	S-8	333-249351	99.1	10/06/2020	
10.14+	Form of Consulting Agreement.	8-K	001-35890	10.4	10/7/2020	
10.15	Form of Indemnification Agreement.	8-K	001-35890	10.5	10/7/2020	
10.16+	Form of Employment Agreement (US).	8-K	001-35890	10.6	10/7/2020	
10.17+	Form of Employment Agreement (Canada).	8-K	001-35890	10.7	10/7/2020	
10.19#^	License Agreement, dated December 16, 2019, by and between Chinook Therapeutics U.S., Inc. and AbbVie Ireland Unlimited Company.	S-4	333-239989	10.1	7/22/2020	
10.20	Contingent Value Rights Agreement, dated October 2, 2020, by and between Aduro Biotech, Inc. and Computershare Trust Company, N.A.	10-Q	001-37345	10.8	11/5/2020	
10.21#	Office/Laboratory Lease between Seventh Street Properties VII, LLC and Aduro Biotech, Inc., dated September 11, 2015.	10-Q	001-37345	10.1	11/23/2015	
10.22#	Sublease between the Registrant and Perfect Day, Inc., dated August 25, 2020	10-Q	001-37345	10.9	11/5/2020	
10.23+	Form of Inducement Stock Option Agreement	10-K	001-37345	10.23	04/07/2021	
10.24	Sublease between the Registrant and Wireless Advocates LLC dated May 24, 2021.	10-Q	001-37345	10.24	08/12/2021	
10.25#^	SanReno Shareholder's Agreement between the Registrant and SanReno Therapeutics Holdings Limited and SanReno Therapeutics (Hong Kong) Limited, a wholly owned subsidiary of SanReno Therapeutics Holdings Limited, dated November 24, 2021.					X
10.26#^	SanReno License Agreement between the Registrant and SanReno Therapeutics Holdings Limited and SanReno Therapeutics (Hong Kong) Limited, a wholly owned subsidiary of SanReno Therapeutics Holdings Limited, dated November 24, 2021.					X
10.27	Separation Agreement between the Registrant and Alan Glicklich, dated January 26, 2022.					X
21.1	Subsidiaries of the Registrant					X
23.1	Consent of PricewaterhouseCoopers, LLP, independent registered public accounting firm.					X
	12	23				

	<u>-</u>		Incorporated by F	Reference		
Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
24.1	Power of Attorney (included in the signature page hereto).					X
31.1	Certification of Principal Executive Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.					X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer, as required by rules 13a-14(a) and 15d-14(a) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).					X
101.INS	Inline XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					

Indicates management contract or compensatory plan, contract or agreement.

Item 16. Form 10-K Summary.

None.

[#] Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.

[^] Registrant has omitted schedules and exhibits pursuant to Item 601(b)(2) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.

^{*} The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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 Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Seattle, State of Washington, on the 17th day of March 2022.

CHINOOK THERAPEUTICS, INC.

By: /s/ Eric L. Dobmeier
Eric L. Dobmeier
President and Chief Executive Officer
(principal executive officer)

By: /s/ Eric H. Bjerkholt
Eric H. Bjerkholt
Chief Financial Officer
(principal financial and accounting officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Eric L. Dobmeier and Eric H. Bjerkholt, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Eric L. Dobmeier	President and Chief Executive Officer	March 17, 2022
Eric L. Dobmeier	(principal executive officer)	
/s/ Eric H. Bjerkholt	Chief Financial Officer	March 17, 2022
Eric H. Bjerkholt	(principal financial and accounting officer)	
/s/ Srinivas Akkaraju	Director	March 17, 2022
Srinivas Akkaraju		
/s/ Jerel Davis	Director	March 17, 2022
Jerel Davis		
/s/ William M. Greenman	Director	March 17, 2022
William M. Greenman		
/s/ Michelle Griffin	Director	March 17, 2022
Michelle Griffin		
/s/ Ross Haghighat	Director	March 17, 2022
Ross Haghighat		
/s/ Dolca Thomas	Director	March 17, 2022
Dolca Thomas		

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO CHINOOK THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

SHAREHOLDERS AGREEMENT

This SHAREHOLDERS AGREEMENT (this "<u>Agreement</u>") is entered into on December 8, 2021 (the "<u>Effective Date</u>"), by and among:

- 1. SanReno Therapeutics Holdings Limited, an exempted company incorporated under the laws of the Cayman Islands (the "Company");
- 2. SanReno Therapeutics (Hong Kong) Limited, a limited company incorporated under the laws of Hong Kong and a wholly owned subsidiary of the Company (the "<u>HK Subsidiary</u>");
- 3. each Person set forth in <u>Schedule I</u> attached hereto (each, an "<u>Investor</u>" and collectively, the "<u>Investors</u>"); and
- 4. each of the individuals who will join as a party to this Agreement pursuant to <u>Section 14.4</u>, as set forth in <u>Schedule II</u> attached hereto (each an "<u>Ordinary Shareholder</u>" and collectively the "<u>Ordinary Shareholders</u>").

Each of the parties to this Agreement is referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

- A The Group (as defined below) intends to engage in the businesses of the research, development, manufacturing, sales and commercialization of products targeting kidney diseases (the "Business").
- B Chinook Therapeutics, Inc., a Delaware corporation ("<u>Chinook</u>"), and the HK Subsidiary have entered into that certain License Agreement dated as of November 24, 2021 (the "<u>License Agreement</u>").
- The Investors have agreed to purchase, severally and not jointly, from the Company, and the Company has agreed to sell to the Investors, certain Series A Preferred Shares (as defined below) for cash payment or the rights granted under the License Agreement, as the case may be, on the terms and conditions set forth in the Series A Preferred Share Purchase Agreement dated as of November 24, 2021, by and among the Company and the Investors (the "Purchase Agreement").
- D The Purchase Agreement provides that the execution and delivery of this Agreement shall be a condition precedent to the consummation of the transactions contemplated by the Purchase Agreement.
- E The Parties desire to enter into this Agreement and make the respective representations, warranties, covenants and agreements set forth herein on the terms and conditions set forth herein.

Shareholders Agreement

NOW, THEREFORE, in consideration of the foregoing recitals, the mutual promises hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties intending to be legally bound hereto hereby agree as follows:

1. Definitions.

- **1.1** The following terms shall have the meanings ascribed to them below:
- "<u>Accounting Standards</u>" means International Financial Reporting Standards as promulgated from time to time by the International Accounting Standards Board (the "<u>IASB</u>"), applied on a consistent basis.
- "Action" means any charge, claim, action, complaint, petition, investigation, appeal, suit, litigation, grievance, inquiry or other proceeding, whether administrative, civil, regulatory or criminal, whether at law or in equity, or otherwise under any applicable Law, and whether or not before any mediator, arbitrator or Governmental Authority.
- "Affiliate" means, with respect to a Person, any other Person that, directly or indirectly, Controls, is Controlled by or is under common Control with such Person, including, without limitation, any general partner, managing member, officer, director or trustee of such Person, or any private equity fund, venture capital fund, financial investment firm, collective investment vehicle or holding company formed for investment purposes now or hereafter existing that is Controlled by one or more general partners, managing members or investment adviser of, or shares the same management company or investment adviser with, such Person. For purposes of these Articles, an "Affiliate" of an Investor does not include any Group Company.
- "Anti-Corruption Laws" means all anti-corruption and anti-bribery laws and regulations, including the applicable Laws and regulations of the Cayman Islands, the PRC, the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering, terrorism, corrupt payment, offer, promise, or authorization of the payment or transfer of anything of value (including gifts or entertainment), directly or indirectly, to any Public Official, commercial entity, or any other Person to obtain a business advantage.
- "Applicable Securities Laws" means (a) with respect to any offering of securities in the U.S., or any other act or omission within that jurisdiction, the securities laws of the U.S., including the Exchange Act and the Securities Act, and any applicable Law of any state of the U.S., and (b) with respect to any offering of securities in any jurisdiction other than the U.S., or any related act or omission in that jurisdiction, the applicable Laws of that jurisdiction.
 - "Board" or "Board of Directors" means the board of directors of the Company.
- "Business Day" means any day that is not a Saturday, Sunday, legal holiday or other day on which commercial banks are required or authorized by law to be closed in the Cayman Islands, Hong Kong, the PRC or the United States.

"CFC" means a controlled foreign corporation as defined in the Code.

"Charter Documents" means, with respect to a particular legal entity, the articles or certificate of incorporation, formation or registration (including, if applicable, certificates of change of name), memorandum of association, articles of association, bylaws, articles of organization, limited liability company agreement, trust deed, trust instrument, operating agreement, joint venture agreement, business license, or similar or other constitutive, governing, or charter documents, or equivalent documents, of such entity.

"Chinook" has the meaning set forth in the Recitals.

"Closing" has the meaning set forth in the Purchase Agreement.

"Code" means the U.S. Internal Revenue Code, as amended.

"Commission" means (a) with respect to any offering of securities in the U.S., the Securities and Exchange Commission of the U.S. or any other federal agency at the time administering the Securities Act, and (b) with respect to any offering of securities in a jurisdiction other than the U.S., the regulatory body of the jurisdiction with authority to supervise and regulate the offering or sale of securities in that jurisdiction.

"Competitor" means [***].

"Contract" means a contract, agreement, understanding, indenture, note, bond, loan, instrument, lease, mortgage, franchise, license, commitment, purchase order or other legally binding arrangement, whether written or oral.

"Control" of a given Person means the power or authority, whether exercised or not, to direct the business, management and policies of such Person, directly or indirectly, whether through the ownership of voting securities, by Contract or otherwise; <u>provided</u> that such power or authority shall conclusively be presumed to exist upon possession of beneficial ownership or power to direct the vote of more than 50% of the votes entitled to be cast at a meeting of the members or shareholders of such Person or power to control the composition of a majority of the board of directors of such Person. The terms "Controlled" and "Controlling" have meanings correlative to the foregoing.

"Convertible Securities" means any bonds, debentures, notes or other evidences of indebtedness, or any warrants (including the Warrant), shares or any other securities convertible into, exercisable for, or exchangeable for, Ordinary Shares, including Preferred Shares but excluding Options.

"Deemed Liquidation Event" has the meaning given to such term in the Memorandum and Articles.

"Director" means a director serving on the Board and, as applicable, each Subsidiary Board.

"Equity Securities" means, with respect to any Person that is a legal entity, any and all shares of capital stock, membership interests, units, profits interests, ownership interests, equity interests, registered capital, and other equity securities of such Person, and any right, warrant, option, call, commitment, conversion privilege, preemptive right or other right to acquire any of the foregoing, or security convertible into, exchangeable or exercisable for any of the foregoing, or any Contract providing for the acquisition of any of the foregoing.

- "Exchange Act" means the U.S. Securities Exchange Act of 1934, as amended.
- "<u>Form F-3</u>" means Form F-3 promulgated by the Commission under the Securities Act or any successor form or substantially similar form then in effect.
- "Form S-3" means Form S-3 promulgated by the Commission under the Securities Act or any successor form or substantially similar form then in effect.
 - "Frazier" means Frazier Life Sciences X, L.P.
- "<u>Fully-Diluted Basis</u>" means the total issued and outstanding Ordinary Shares on a fully diluted basis (assuming full conversion and exercise of all of the issued and outstanding Preferred Shares, the issued or granted options and other incentive equity awards under the Incentive Plan, the issued and outstanding Warrant and other issued and outstanding convertible and exercisable securities).
- "Governmental Authority" means any federal, state, national, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).
- "Governmental Order" means any applicable order, ruling, decision, verdict, decree, writ, subpoena, mandate, precept, command, directive, consent, approval, award, judgment, injunction or other similar determination or finding by, before or under the supervision of any Governmental Authority.
- "Group Company" means each of the Company and the HK Subsidiary, together with each Subsidiary of any of the foregoing, in each case including the predecessor of such entity, and "Group" refers to all of Group Companies collectively.
- "<u>Holders</u>" means the holders of Registrable Securities who are parties to this Agreement from time to time, and their permitted transferees that become parties to this Agreement from time to time.
 - "Hong Kong" means the Hong Kong Special Administrative Region of the PRC.
- "Incentive Plan" means the SanReno Therapeutics Holdings Limited share incentive plan to be adopted by the Board and approved by the Shareholders, as amended and restated from time to time.
- "Initiating Holders" means, with respect to a request duly made under <u>Section 2.1</u> or <u>Section 2.2</u> to Register any Registrable Securities, the Holders initiating such request.
 - "IPO" means the first firm-commitment underwritten public offering by the Company of Ordinary Shares.
- "<u>Law</u>" or "<u>Laws</u>" means any and all provisions of any applicable constitution, treaty, statute, law, regulation, ordinance, code, rule, or rule of common law, any governmental approval, concession, grant, franchise, license, agreement, directive, requirement, or other governmental restriction or any similar form of decision of, or determination by, or any

interpretation or administration of any of the foregoing by, any Governmental Authority, in each case as amended, and any and all applicable Governmental Orders.

"<u>Lead Investor</u>" means each of Chinook, Frazier and Pivotal for as long as such Investor, together with its Affiliates, continues to hold at least [***].

"Major Investor" means each Investor that (a) holds, together with its Affiliates, an aggregate of at least [***] Ordinary Shares issued or issuable upon conversion of Preferred Shares or exercise of the Warrant that has become exercisable pursuant to the terms thereof (as adjusted for any share dividends, combinations, reclassifications or splits effected after the Effective Date), and (b) is not a [***].

"Memorandum and Articles" means the Memorandum of Association of the Company and the Articles of Association of the Company, as each may be amended and/or restated from time to time.

"Options" means rights, restricted share units, options or warrants to subscribe for, purchase or otherwise acquire Ordinary Shares or Convertible Securities.

"Ordinary Share Equivalents" means any Equity Security which is by its terms convertible into or exchangeable or exercisable for Ordinary Shares or other share capital of the Company, including without limitation, the Preferred Shares.

"Ordinary Shares" means the ordinary shares, par value US\$0.001 per share, of the Company.

"Person" means any individual, corporation, partnership, limited partnership, proprietorship, association, limited liability company, firm, trust, estate or other enterprise or entity.

"PFIC" means a passive foreign investment company as defined in the Code.

"Pivotal" means Greatest Guide Limited.

"PRC" means the People's Republic of China, but solely for the purposes of this Agreement, excluding Hong Kong, the Macau Special Administrative Region and the Islands of Taiwan.

"Preferred Shares" means the Series A Preferred Shares.

"<u>Public Official</u>" means (a) any executive, official, or employee of a Governmental Authority, political party or member of a political party, political candidate; (b) executive, employee or officer of a public international organization; or (c) director, officer or employee or agent of a wholly owned or partially state-owned or controlled enterprise, including a PRC state-owned or controlled enterprise.

"Qualified IPO" means a firm commitment underwritten public offering of Ordinary Shares, with per share offering price of no less than US\$[***] (as adjusted for any share dividends, combinations, reclassifications or splits effected after the Effective Date), generating gross proceeds to the Company of no less than US\$[***] before deduction of underwriting commissions and expenses.

"Registrable Securities" means (a) the Ordinary Shares issued or issuable upon conversion of the Preferred Shares, (b) the Ordinary Shares issued or issuable upon exercise of the Warrant, (c) any Ordinary Shares of the Company issued or issuable as a dividend or other distribution with respect to, in exchange for, or in replacement of, the shares referenced in (a) or (b) herein, and (d) any Ordinary Shares owned or hereafter acquired by the Investors; excluding in all cases, however, any of the foregoing sold by a Person in a transaction other than an assignment pursuant to Section 14.3. For purposes of this Agreement, Registrable Securities shall cease to be Registrable Securities when such Registrable Securities have been disposed of pursuant to an effective Registration Statement.

"Registration" means a registration effected by preparing and filing a Registration Statement and the declaration or ordering of the effectiveness of that Registration Statement; and the terms "Register" and "Registered" have meanings concomitant with the foregoing.

"Registration Statement" means a registration statement prepared on Form F-1, F-3, S-1, or S-3 under the Securities Act, or on any comparable form in connection with registration in a jurisdiction other than the U.S.

"Representatives" means, with respect to any Party, such Party's Affiliates, officers, directors, general partners, members, employees, investment bankers, financial advisors, accountants, legal counsel, consultants, and other agents and representatives.

"Requisite Holders" means the holders of at least [***] of the outstanding Series A Preferred Shares, voting together as a single class.

"Samsara" means Samsara BioCapital, L.P.

"Sanctioned Country" means any country or region that is, or has been in the last five years, the subject or target of a comprehensive embargo under Trade Controls.

"Sanctions" means any national and supranational laws, regulations, decrees, orders, or other acts with force of law of the United States, the United Kingdom, or the European Union, or United Nations Security Council resolutions, concerning trade and economic sanctions including embargoes; the freezing or blocking of assets of targeted Persons; or other restrictions on exports, investment, payments, or other transactions targeted at particular Persons or countries, including any Laws threatening to impose such trade and economic sanctions on any Person for engaging in proscribed or targeted behavior.

"Securities Act" means the U.S. Securities Act of 1933, as amended.

"Series A Preferred Shares" means the Series A preferred shares, par value US\$0.0001 per share, of the Company with the rights and privileges as set forth in the Memorandum and Articles.

"Shareholder" means a holder of any Shares.

"Share Sale" means a transaction or series of related transactions in which a Person, or a group of related Persons, acquires any Equity Securities of the Company such that, immediately after such transaction or series of related transactions, such Person or group of related Persons holds Equity Securities of the Company representing [***] or more of the outstanding voting power of the Company.

"Shares" means, collectively, Ordinary Shares and Preferred Shares.

"Subsidiary" means, with respect to any given Person, any other Person that is Controlled directly or indirectly by such given Person.

"Trade Controls" means all U.S. and non-U.S. laws relating to (a) economic, trade, and financial sanctions, including those administered and enforced by OFAC, the U.S. Department of State, the European Union, HM Treasury of the United Kingdom, any European Union Member State, and the United Nations; (b) export, import, reexport, transfer, and retransfer controls, including those administered and enforced by the U.S. Department of Commerce Bureau of Industry and Security, U.S. Customs and Border Protection, the European Union, HM Treasury of the United Kingdom, any European Union Member State, and the United Nations; (c) antiboycott requirements; and (d) the prevention of money laundering.

"Transaction Documents" has the meaning set forth in the Purchase Agreement.

"United States" or "U.S." means the United States of America.

"Versant" means Versant Vantage II, L.P.

"Warrant" means that certain Warrant to Purchase Ordinary Shares issued by the Company to Chinook on the Effective Date.

1.2 Other Defined Terms. The following terms shall have the meanings defined for such terms in the Sections set forth below:

Additional Number Agreement Approved Sale **CEO** Director Chinook Chinook [***] Chinook [***] Company Confidential Information Co-Sale Notice Covered Employee Direct U.S. Investor Dispute **Drag Holders Effective Date Exempt Registrations Exercising Shareholder** First Participation Notice Frazier [***] Frazier [***] **Group Affiliates HK Subsidiary ICC** Rules Indirect U.S. Investor Investor/Investors

Preamble Section 11.1 Section 9.1(a)(iv) Recitals Section 9.1(a)(i) Section 9.5 Preamble Section 13.6(a) Section 10.3(a) Section 13.8 Section 13.5(c) Section 14.6(a) Section 11.1 Preamble Section 3.5 Section 10.2(c)(iii) Section 7.4(a) Section 9.1(a)(ii) Section 9.5 Section 13.1(b) Preamble Section 14.6(a) Section 13.5(c) Preamble

Section 7.4(b)

Investor Director/Investor Directors Section 9.1(a)(iii) Joint [***] Section 9.5 License Agreement Recitals **New Securities** Section 7.3 Observer/Observers Section 9.5 Offered Shares Section 10.2(a) **Option Period** Section 10.2(c)(i) Ordinary Shareholder/Ordinary Shareholders Preamble Other Restriction Agreements Section 10.1(f) Oversubscription Participants Section 7.4(b) **Participating Investor** Section 7.4(a) Party/Parties Preamble Permitted Transferee and Permitted Transferees Section 10.1(g) Section 13.5(c) **PFIC Shareholder** Pivotal [***] Section 9.1(a)(iii) Pivotal [***] Section 9.5 Preemptive Pro Rata Share Section 7.2 Preemptive Right Section 7.1 **Prohibited Transfer** Section 10.5 Purchase Agreement **Recitals** Restricted Holder Section 10.1(a) **Restricted Party** Section 13.8 **ROFR Pro Rata Share** Section 10.2(c)(ii) Second Notice Section 10.2(c)(iii) Second Participation Notice Section 7.4(b) Second Participation Period Section 7.4(b)

Selling Shareholder Section 10.3(a) Shareholder Representative Section 11.1(g) Subsidiary Board Section 9.1(b) Transfer Section 10.1(a) Transfer Notice Section 10.2(a) Transferee Section 10.2(a) Transferor Section 10.2(a) Violation Section 5.1(a)

1.3 Interpretation. For all purposes of this Agreement, except as otherwise expressly herein provided, (a) words importing the singular number include the plural number and vice versa, (b) words importing the masculine gender include the feminine gender, (c) references to provisions of any law or regulation shall be construed as references to those provisions as amended, modified, re-enacted or replaced from time to time, (d) unless otherwise specified, all references in this Agreement to designated "Sections" and other subdivisions are to the designated Sections and other subdivisions of the body of this Agreement, (e) the terms "herein", "hereof", and other similar words refer to this Agreement as a whole and not to any particular section, subsection, paragraph, clause, or other subdivision, (f) all references in this Agreement to designated Schedules, Exhibits and Appendices are to the Schedules, Exhibits and Appendices attached to this Agreement, (g) the term "voting power" refers to the number of votes attributable to the Shares (on an as-converted basis) in accordance with the terms of the Memorandum and Articles, (h) the term "or" is not exclusive, (i) the term "including" will be deemed to be followed by, "without limitation", (j) the terms "shall", "will", and "agrees" are mandatory, and the term "may" is permissive, (k) the term "day" means "calendar day",

and "month" means calendar month, (l) the phrase "directly or indirectly" means directly, or indirectly through one or more intermediate Persons or through contractual or other arrangements, and "direct or indirect" has the correlative meaning, (m) references to this Agreement, any other Transaction Documents and any other document shall be construed as references to such document as the same may be amended, supplemented or novated from time to time, (n) each representation, warranty, agreement, and covenant contained herein will have independent significance, regardless of whether also addressed by a different or more specific representation, warranty, agreement, or covenant, (o) all accounting terms not otherwise defined herein have the meanings assigned under the Accounting Standards, and (p) all references to "HK\$" are to the currency of Hong Kong and all references to "US\$" are to currency of the U.S. (and each shall be deemed to include reference to the equivalent amount in other currencies).

2. Demand Registration.

- Registration Other Than on Form F-3 or Form S-3. Subject to the terms of this Agreement, at any time or from time to time after the earlier of (a) the [***] anniversary of the Effective Date or (b) the date that is [***] months after the closing of the IPO, Holders holding [***] or more of the voting power of the then outstanding Registrable Securities held by all Holders may request in writing that the Company effect a Registration of at least [***] of the Registrable Securities then outstanding (or a lesser percentage if the anticipated aggregate offering price, net of underwriting discounts and commissions, is in excess of US\$[***]). Upon receipt of such a request, the Company shall (x) within ten (10) days after the date such request is given, give written notice of the proposed Registration to all other Holders and (y) as soon as practicable, and in any event within sixty (60) days after the date such request is given by the Initiating Holders, use its reasonable best efforts to cause the Registrable Securities specified in the request, together with any Registrable Securities of any Holder who requests in writing to join such Registration within thirty (30) days after the Company's delivery of written notice, to be Registered and qualified for sale and distribution in such jurisdiction as the Initiating Holders may request. The Company shall be obligated to consummate no more than two (2) Registrations pursuant to this Section 2.1 that have been declared and ordered effective.
- **Registration on Form F-3 or Form S-3.** The Company shall use its reasonable best efforts to qualify for registration on Form F-3 or Form S-3. Subject to the terms of this Agreement, if the Company qualifies for registration on Form F-3 or Form S-3 (or any comparable form for Registration in a jurisdiction other than the United States), Holders of at least [***] of the Registrable Securities then outstanding may request the Company to file, in any jurisdiction in which the Company has had a registered underwritten public offering, a Registration Statement on Form F-3 or Form S-3 (or any comparable form for Registration in a jurisdiction other than the United States), including any registration statement filed under the Securities Act providing for the registration of, and the sale on a continuous or a delayed basis by the Holders of, all of the Registrable Securities pursuant to Rule 415 under the Securities Act and/or any similar rule that may be adopted by the Commission. Upon receipt of such a request, the Company shall (a) within ten (10) days after the such request is given, give written notice of the proposed Registration to all other Holders and (b) as soon as practicable, and in any event within forty-five (45) days after the date such request is given by the Initiating Holders, use its reasonable best efforts to cause the Registrable Securities specified in the request, together with any Registrable Securities of any Holder who requests in writing to join such Registration within thirty (30) days after the Company's delivery of written notice, to be

Registered and qualified for sale and distribution in such jurisdiction. The Company shall be obligated to consummate no more than two Registrations that have been declared and ordered effective within any twelve (12)-month period pursuant to this Section 2.2.

2.3 Right of Deferral.

(a) The Company shall not be obligated to Register or qualify Registrable Securities pursuant to this Section 2:

- (i) if, within ten (10) days of the receipt of any request of the Holders to Register any Registrable Securities under Section 2.1 or Section 2.2, the Company gives notice to the Initiating Holders of its bona fide intention to effect the filing for its own account of a Registration Statement of Ordinary Shares within sixty (60) days of receipt of that request; provided that the Company is actively employing in good faith its reasonable best efforts to cause that Registration Statement to become effective within sixty (60) days of receipt of that request; provided, further, that the Holders are entitled to join such Registration in accordance with Section 3 (other than an Exempt Registration);
- (ii) during the period starting with the date of filing by the Company of, and ending six (6) months following the effective date of any Registration Statement pertaining to Ordinary Shares of the Company other than an Exempt Registration; <u>provided</u> that the Holders are entitled to join such Registration in accordance with Section 3:
- (iii) in any jurisdiction in which the Company would be required to execute a general consent to service of process in effecting such Registration or qualification, unless the Company is already subject to service of process in such jurisdiction; or
- (iv) with respect to the registration on Form F-3 or Form S-3 (or any comparable form for Registration in a jurisdiction other than the U.S.), if Form F-3 or Form S-3 is not available for such offering by the Holders, or if the Holders, together with the holders of any other securities of the Company entitled to inclusion in such registration, propose to sell Registrable Securities and such other securities (if any) at an aggregate price to the public of less than US\$[***].
- (b) If, after receiving a request from Holders pursuant to Section 2.1 or Section 2.2, the Company furnishes to the Holders a certificate signed by the chief executive officer of the Company stating that, in the good faith judgment of the Board, it would be materially detrimental to the Company or its members for a Registration Statement to be filed in the near future, then the Company shall have the right to defer such filing for a period during which such filing would be materially detrimental, <u>provided</u> that the Company may not utilize this right for more than ninety (90) days on any one occasion or more than once during any twelve (12)-month period; <u>provided</u>, <u>further</u>, that the Company may not Register any other its Securities during such period (except for Exempt Registrations).

2.4 Underwritten Offerings.

(a) If, in connection with a request to Register Registrable Securities under <u>Section 2.1</u> or <u>Section 2.2</u>, the Initiating Holders seek to distribute such Registrable Securities

in an underwritten offering, they shall so advise the Company as a part of the request, and the Company shall include such information in the written notice to the other Holders described in <u>Section 2.1</u> and <u>Section 2.2</u>. In such event, the right of any Holder to include its Registrable Securities in such Registration shall be conditioned upon such Holder's participation in such underwritten offering and the inclusion of such Holder's Registrable Securities in the underwritten offering (unless otherwise mutually agreed by the Initiating Holders and such Holder) to the extent provided herein. All Holders proposing to distribute their securities through such underwritten offering shall enter into an underwriting agreement in customary form with the underwriter or underwriters of internationally recognized standing selected for such underwritten offering by the Company and reasonably acceptable to the holders of at least [***] of the voting power of all Registrable Securities proposed to be included in such Registration; provided, however, that no Holder (or any of their assignees) shall be required to make any representations. warranties or indemnities, or provide any information or documentation, except as such representations, warranties, indemnitees, information or documentation relate to such Holder's ownership of shares and authority to enter into the underwriting agreement and to such Holder's intended method of distribution, and the liability of such Holder shall be several and not joint, and limited to an amount equal to the net proceeds from the offering received by such Holder. Notwithstanding any other provision of this Agreement, if the managing underwriter advises the Company and Holders of Registrable Securities that otherwise would be underwritten pursuant hereto that marketing factors (including the aggregate number of securities requested to be Registered, the general condition of the market, and the status of the Persons proposing to sell securities pursuant to the Registration) require a limitation of the number of Registrable Securities to be underwritten in a Registration pursuant to Section 2.1 or Section 2.2, the number of Registrable Securities that may be included in the underwriting shall be allocated among such Holders of Registrable Securities, in proportion (as nearly as practicable) to the number of Registrable Securities owned by each Holder or in such other proportion as shall mutually be agreed to by all such selling Holders; provided, however, that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all other Equity Securities are first entirely excluded from the underwriting; provided, further, that any Initiating Holder shall have the right to withdraw its request for Registration from the underwriting by written notice to the Company and the underwriters delivered at least ten days prior to the effective date of the Registration Statement, and such withdrawal request for Registration shall not be deemed to constitute one of the Registration rights granted pursuant to Section 2.1 or Section 2.2, as the case may be. If any Holder disapproves the terms of any underwriting, the Holder may elect to withdraw therefrom by written notice to the Company and the underwriters delivered at least ten days prior to the effective date of the Registration Statement. Any Registrable Securities excluded or withdrawn from such underwritten offering shall be withdrawn from the Registration. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to a Holder to the nearest one hundred (100) shares.

(b) For purposes of <u>Sections 2.1</u> and <u>2.2</u>, a Registration shall not be counted as "effected" if, as a result of an exercise of the underwriter's cutback provisions therein, fewer than [***] of the total number of Registrable Securities that Holders have requested to be included in such Registration Statement are actually included.

3. Piggyback Registrations.

- **3.1 Registration of the Company's Securities.** Subject to the terms of this Agreement, if the Company proposes to Register for its own account any of its Equity Securities, or for the account of any holder (other than a Holder) of Equity Securities any of such holder's Equity Securities, in connection with the public offering of such securities (except for Exempt Registrations or a registration relating to a demand pursuant to Section 2.1 or Section 2.2), the Company shall promptly give each Holder written notice of such Registration and, upon the written request of any Holder given within thirty (30) days after delivery of such notice, the Company shall, subject to the provisions of Section 2.4, use its reasonable best efforts to include in such Registration any Registrable Securities thereby requested to be Registered by such Holder. If a Holder decides not to include all or any of its Registrable Securities in such Registration by the Company, such Holder shall nevertheless continue to have the right to include any Registrable Securities in any subsequent Registration Statement or Registration Statements as may be filed by the Company, all upon the terms and conditions set forth herein.
- **3.2 Right to Terminate Registration.** The Company shall have the right to terminate or withdraw any Registration initiated by it under <u>Section 3.1</u> prior to the effectiveness of such Registration, whether or not any Holder has elected to participate therein. The expenses of such withdrawn Registration shall be borne by the Company in accordance with <u>Section 4.3</u>.

3.3 Underwriting Requirements.

In connection with any offering involving an underwriting of the Company's Equity Securities, the Company shall not be required to Register the Registrable Securities of a Holder under this Section 3 unless such Holder's Registrable Securities are included in the underwritten offering and such Holder enters into an underwriting agreement in customary form with the underwriter or underwriters of internationally recognized standing selected by the Company and setting forth such terms for the underwritten offering as have been agreed upon between the Company and the underwriters and then only in such quantity as the underwriters in their sole discretion determine will not jeopardize the success of the offering by the Company. In the event the underwriters advise Holders seeking Registration of Registrable Securities pursuant to this Section 3 in writing that market factors (including the aggregate number of Registrable Securities requested to be Registered, the general condition of the market, and the status of the Persons proposing to sell securities pursuant to the Registration) require a limitation of the number of Registrable Securities to be underwritten, then the Registrable Securities that are included in such offering shall be allocated among the selling Holders in proportion (as nearly as practicable to) the number of Registrable Securities owned by each selling Holder or in such other proportions as shall mutually be agreed to by all such selling Holders; provided, however, that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all other Equity Securities (other than securities to be registered or sold by the Company) are first entirely excluded from the underwriting. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to a Holder to the nearest one hundred (100) shares. Notwithstanding the foregoing, in no event shall the number of Registrable Securities included in the offering be reduced below [***] of the total number of securities included in such offering, unless such offering is the IPO, in which case the selling Holders may be excluded further if the underwriters make the

determination described above and no other shareholder's securities are included in such offering.

- (b) If any Holder disapproves the terms of any underwriting, the Holder may elect to withdraw therefrom by written notice to the Company and the underwriters delivered at least ten days prior to the effective date of the Registration Statement. Any Registrable Securities excluded or withdrawn from the underwritten offering shall be withdrawn from the Registration.
- **3.4 No Limitation.** There shall be no limit on the number of times the Holders may request registration of Registrable Securities under this $\underline{\text{Section 3}}$. Registration pursuant to this $\underline{\text{Section 3}}$ shall not be deemed to be a demand registration as described in $\underline{\text{Section 2}}$.
- **3.5 Exempt Registrations.** The Company shall have no obligation to Register any Registrable Securities under this Section 3 in connection with a Registration by the Company (a) relating solely to the sale of securities to participants in the Incentive Plan, (b) relating to a corporate reorganization or other transaction under Rule 145 of the Securities Act (or comparable provision under the Laws of another jurisdiction, as applicable), or (c) relating to a registration in which the only Ordinary Shares being registered are Ordinary Shares issuable upon conversion of debt securities that are also being registered (collectively, "Exempt Registrations").

4. Registration Procedures.

- **4.1 Registration Procedures and Obligations.** Whenever required under this Agreement to effect the Registration of any Registrable Securities held by the Holders, the Company shall, as expeditiously as reasonably possible:
- (a) prepare and file with the Commission a Registration Statement with respect to those Registrable Securities and use its reasonable best efforts to cause that Registration Statement to become effective, and, upon the request of the Holders holding at least [***] in voting power of the Registrable Securities Registered thereunder, keep the Registration Statement effective until the distribution thereunder has been completed;
- (b) prepare and file with the Commission amendments and supplements to that Registration Statement and the prospectus used in connection with the Registration Statement as may be necessary to comply with the provisions of Applicable Securities Laws with respect to the disposition of all securities covered by the Registration Statement;
- (c) furnish to the Holders the number of copies of a prospectus, including a preliminary prospectus, required by Applicable Securities Laws, and any other documents as they may reasonably request in order to facilitate the disposition of Registrable Securities owned by them;
- (d) use its reasonable best efforts to Register and qualify the securities covered by the Registration Statement under the securities Laws of any jurisdiction, as reasonably requested by the selling Holders, <u>provided</u> that the Company shall not be required to qualify to do business or file a general consent to service of process in any such jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;

- (e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in customary form, with the managing underwriter(s) of the offering;
- (f) promptly notify each Holder of Registrable Securities covered by the Registration Statement at any time when a prospectus relating thereto is required to be delivered under Applicable Securities Laws of (i) the issuance of any stop order by the Commission, or (ii) the happening of any event or the existence of any condition as a result of which any prospectus included in the Registration Statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances under which they were made, or if in the opinion of counsel for the Company it is necessary to supplement or amend such prospectus to comply with law, and at the request of any such Holder promptly prepare and furnish to such Holder a reasonable number of copies of a supplement to or an amendment of such prospectus as may be necessary so that, as thereafter delivered to the purchasers of such securities, such prospectus shall not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading in light of the circumstances under which they were made or such prospectus, as supplemented or amended, shall comply with law;
- (g) furnish, at the request of any Holder requesting Registration of Registrable Securities pursuant to this Agreement, on the date that such Registrable Securities are delivered for sale in connection with a Registration pursuant to this Agreement, (i) an opinion, dated the date of the sale, of the counsel representing the Company for the purposes of the Registration, in form and substance as is customarily given to underwriters in an underwritten public offering, and (ii) comfort letters dated as of (x) the effective date of the registration statement covering such Registrable Securities, and (y) the date of the sale as contemplated in Rule 159 under the Securities Act, from the independent certified public accountants of the Company, in form and substance as is customarily given by independent certified public accountants to underwriters in an underwritten public offering, addressed to the underwriters;
- (h) otherwise comply with all applicable rules and regulations of the Commission to the extent applicable to the applicable registration statement and use its reasonable best efforts to make generally available to its security holders (or otherwise provide in accordance with Section 11(a) of the Securities Act) an earnings statement satisfying the provisions of Section 11(a) of the Securities Act, no later than forty-five (45) days after the end of a twelve (12)-month period (or ninety (90) days, if such period is a fiscal year) beginning with the first month of the Company's first fiscal quarter commencing after the effective date of such registration statement, which statement shall cover such twelve (12)-month period, subject to any proper and necessary extensions;
- (i) provide a transfer agent and registrar for all Registrable Securities Registered pursuant to the Registration Statement and, where applicable, a number assigned by the Committee on Uniform Securities Identification Procedures for all those Registrable Securities, in each case not later than the effective date of the Registration;
- (j) cooperate with each Holder of Registrable Securities covered by the Registration Statement and each underwriter or agent participating in the disposition of such

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- (k) take all reasonable action necessary to list the Registrable Securities on the primary exchange on which the Company's securities are then traded or, in connection with an IPO, the primary exchange on which the Company's securities will be traded;
- (l) notify each selling Holder, promptly after the Company receives notice thereof, of the time when such Registration Statement has been declared effective or a supplement to any prospectus forming a part of such Registration Statement has been filed; and
- (m) after such Registration Statement becomes effective, notify each selling Holder of any request by the Commission that the Company amend or supplement such Registration Statement or prospectus.
- **4.2 Information from Holder.** It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Agreement with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as shall be required to effect the Registration of such Holder's Registrable Securities.
- 4.3 Expenses of Registration. All expenses, other than the underwriting discounts and selling commissions applicable to the sale of Registrable Securities pursuant to this Agreement (which shall be borne by the Holders requesting Registration on a pro rata basis in proportion to their respective numbers of Registrable Securities sold in such Registration), incurred in connection with Registrations, filings or qualifications pursuant to this Agreement, including all Registration, filing and qualification fees, printers' and accounting fees, fees and disbursements of counsel for the Company and reasonable fees and disbursement of one counsel for all selling Holders, not to exceed US\$[***], shall be borne by the Company. The Company shall not, however, be required to pay for any expenses of any Registration proceeding begun pursuant to Section 2.1 or Section 2.2 if the Registration request is subsequently withdrawn at the request of the Holders holding at least [***] of the voting power of the Registrable Securities requested to be Registered by all Holder in such Registration (in which case all participating Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be thereby Registered in the withdrawn Registration) unless the Holders of at least [***] of the voting power of the Registrable Securities then outstanding agree that such registration constitutes the use by the Holders of one demand registration pursuant to Section 2.1 (in which case such registration shall also constitute the use by all Holders of Registrable Securities of one such demand registration); provided, however, that if at the time of such withdrawal, the Holders have learned of a material adverse change in the condition, business or prospects of the Company from that known to the Holders at the time of their request and have withdrawn the request with reasonable promptness following disclosure by the Company of such material adverse change, then the Holders shall not be required to pay any of such expenses and the Company shall pay any and all such expenses.

5. Registration-Related Indemnification.

5.1 Company Indemnity.

- (a) To the maximum extent permitted by Law, the Company will indemnify and hold harmless each selling Holder, such selling Holder's partners, officers, directors, shareholders, members, and legal counsel and accountants, any underwriter (as defined in the Securities Act) and each Person, if any, who controls (as defined in the Securities Act) such selling Holder or underwriter, against any losses, claims, damages or liabilities (joint or several) to which they may become subject under Laws which are applicable to the Company and relate to action or inaction required of the Company in connection with any Registration, qualification, or compliance, insofar as such losses, claims, damages, or liabilities (or actions in respect thereof) arise out of or are based upon any of the following statements, omissions or violations (each a "Violation"): (i) any untrue statement or alleged untrue statement of a material fact contained in such Registration Statement, on the effective date thereof (including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto), (ii) the omission or alleged omission to state in the Registration Statement, on the effective date thereof (including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto), a material fact required to be stated therein or necessary to make the statements therein not misleading, or (iii) any violation or alleged violation by the Company of Applicable Securities Laws, or any rule or regulation promulgated under Applicable Securities Laws. The Company will reimburse, as incurred, each such selling Holder, underwriter or controlling Person for any legal or other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action.
- (b) The indemnity agreement contained in this <u>Section 5.1</u> shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without the consent of the Company (which consent shall not be unreasonably withheld or delayed), nor shall the Company be liable in any such case for any such loss, claim, damage, liability or action to the extent that it arises solely out of or is solely based upon a Violation that occurs in reliance upon and in conformity with written information furnished for use in connection with such Registration by any such selling Holder, such selling Holder's partners, officers, directors, and legal counsel, any underwriter (as defined in the Securities Act) and each Person, if any, who controls (as defined in the Securities Act) such selling Holder or underwriter.

5.2 Holder Indemnity.

(a) To the maximum extent permitted by Law, each selling Holder that has included Registrable Securities in a Registration will, severally and not jointly, indemnify and hold harmless the Company, its directors and officers who have signed the Registration Statement, any other Holder selling securities in connection with such Registration and each Person, if any, who controls (within the meaning of the Securities Act) the Company, such underwriter or other Holder, against any losses, claims, damages or liabilities (joint or several) to which any of the foregoing persons may become subject, under Applicable Securities Laws, or any rule or regulation promulgated under Applicable Securities Laws, insofar as such losses, claims, damages or liabilities (or actions in respect thereto) arise out of or are based upon any Violation, in each case to the extent (and only to the extent) that such Violation occurs solely in reliance upon and in conformity with written information furnished by such selling Holder expressly for use in connection with such Registration; and each such selling Holder will

reimburse, as incurred, any Person intended to be indemnified pursuant to this <u>Section 5.2</u>, for any legal or other expenses reasonably incurred by such Person in connection with investigating or defending any such loss, claim, damage, liability or action. No Holder's liability under this <u>Section 5.2</u> (when combined with any amounts paid by such Holder pursuant to <u>Section 5.4</u>) shall exceed the net proceeds received by such Holder from the offering of securities made in connection with that Registration, except in the case of fraud or willful misconduct by such Holder.

- (b) The indemnity contained in this <u>Section 5.2</u> shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without the consent of the selling Holder (which consent shall not be unreasonably withheld or delayed).
- 5.3 **Notice of Indemnification Claim.** Promptly after receipt by an indemnified party under <u>Section 5.1</u> or Section 5.2 of notice of the commencement of any action (including any governmental action), such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under Section 5.1 or Section 5.2, deliver to the indemnifying party a written notice of the commencement thereof and the indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly noticed, to assume the defense thereof with counsel mutually satisfactory to the indemnifying parties. An indemnified party (together with all other indemnified parties that may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the reasonably incurred fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such proceeding. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such indemnifying party, to the extent so prejudiced, of any liability to the indemnified party under this <u>Section 5</u>, but the omission to deliver written notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 5. No indemnifying party, in the defense of any such claim or litigation, shall, except with the consent of each indemnified party, consent to entry of any judgment or enter into any settlement which does not include as an unconditional term thereof the giving by the claimant or the plaintiff to such indemnified party of a release from all liability in respect to such claim or litigation.
- **5.4 Contribution.** If any indemnification provided for in <u>Section 5.1</u> or <u>Section 5.2</u> is held by a court of competent jurisdiction to be unavailable to an indemnified party with respect to any loss, liability, claim, damage or expense referred to herein, the indemnifying party, in lieu of indemnifying such indemnified party hereunder, shall contribute to the amount paid or payable by such indemnified party as a result of such loss, liability, claim, damage or expense in such proportion as is appropriate to reflect the relative fault of the indemnifying party, on the one hand, and of the indemnified party, on the other, in connection with the statements or omissions that resulted in such loss, liability, claim, damage or expense, as well as any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent

such statement or omission; <u>provided</u>, <u>however</u>, that, in any such case: (a) no Holder will be required to contribute any amount (after combined with any amounts paid by such Holder pursuant to <u>Section 5.2</u>) in excess of the net proceeds to such Holder from the sale of all such Registrable Securities offered and sold by such Holder pursuant to such registration statement, except in the case of fraud or willful misconduct by such Holder; and (b) no person or entity guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person or entity who was not guilty of such fraudulent misrepresentation.

- **5.5 Underwriting Agreement.** To the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with the underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control.
- **5.6 Survival.** Unless superseded by an underwriting agreement entered into in connection with the underwritten public offering, the obligations of the Company and Holders under this <u>Section 5</u> shall survive the completion of any offering of Registrable Securities in a Registration Statement under this Agreement and otherwise shall survive the termination of this Agreement, regardless of the expiration of any statutes of limitation or extensions of such statutes.

6. Additional Registration-Related Undertakings.

- **6.1 Reports under the Exchange Act.** With a view to making available to the Holders the benefits of Rule 144 promulgated under the Securities Act and any comparable provision of any Applicable Securities Laws that may at any time permit a Holder to sell securities of the Company to the public without Registration or pursuant to a Registration on Form F-3 or Form S-3 (or any comparable form in a jurisdiction other than the United States), the Company agrees to:
- (a) make and keep public information available, as those terms are understood and defined in Rule 144 (or comparable provision, if any, under Applicable Securities Laws in any jurisdiction where the Company's securities are listed), at all times following 90 days after the effective date of the first Registration under the Securities Act filed by the Company for an offering of its securities to the general public;
- (b) file with the Commission in a timely manner all reports and other documents required of the Company under all Applicable Securities Laws; and
- (c) at any time following ninety (90) days after the effective date of the first Registration under the Securities Act filed by the Company for an offering of its securities to the general public by the Company, promptly furnish to any Holder holding Registrable Securities, upon request (i) a written statement by the Company that it has complied with the reporting requirements of all Applicable Securities Laws at any time after it has become subject to such reporting requirements or, at any time after so qualified, that it qualifies as a registrant whose securities may be resold pursuant to Form F-3 or Form S-3 (or any form comparable thereto under Applicable Securities Laws of any jurisdiction where the Company's securities are listed), (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents as filed by the Company with the Commission, and (iii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the Commission, that permits the selling of any such securities without Registration or pursuant

to Form F-3 or Form S-3 (or any form comparable thereto under Applicable Securities Laws of any jurisdiction where the Company's Securities are listed).

- **6.2 Limitations on Subsequent Registration Rights.** From and after the Effective Date, the Company shall not, without the written consent of the Requisite Holders, enter into any agreement with any holder or prospective holder of any Equity Securities of the Company that would allow such holder or prospective holder (a) to include such Equity Securities in any Registration filed under Section 2 or Section 3, unless under the terms of such agreement such holder or prospective holder may include such Equity Securities in any such Registration only to the extent that the inclusion of such Equity Securities will not reduce the amount of the Registrable Securities of the Holders that are included, (b) to demand Registration of their Equity Securities, or (c) cause the Company to include such Equity Securities in any Registration filed under Section 2 or Section 3 on a basis *pari passu* with or more favorable to such holder or prospective holder than is provided to the Holders of Registrable Securities.
- "Market Stand-Off" Agreement. Each holder of Registrable Securities agrees, if so required by the managing underwriter(s), that it will not during the period commencing on the date of the final prospectus relating to the Company's IPO and ending on the date specified by the Company and the managing underwriter (such period not to exceed [***] days from the date of such final prospectus, (a) lend, offer, pledge, hypothecate, hedge, sell, make any short sale of, loan, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any Equity Securities of the Company owned immediately prior to the date of the final prospectus relating to the IPO (other than those included in such offering), or (b) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such Equity Securities, whether any such transaction described in clause (a) or (b) above is to be settled by delivery of Equity Securities of the Company or such other securities, in cash or otherwise; <u>provided</u>, <u>however</u>, that the forgoing provisions of this <u>Section 6.3</u> (i) shall apply only to the IPO; (ii) shall not apply to any securities of the Company (x) sold to an underwriter pursuant to any underwriting agreement, (y) acquired by a Holder participating in, whether or not pursuant to an underwriting agreement, a private placement that is concurrent with the IPO or (z) acquired by a Holder in the open market at any time on or after the IPO; (iii) shall not apply to transfer of any shares to any trust for the direct or indirect benefit of the Holder or the immediate family of the Holder, <u>provided</u> that the trustee of the trust agrees to be bound in writing by the restrictions set forth herein, and <u>provided</u> further that any such transfer shall not involve a disposition for value; (iv) shall not be applicable to any Holder unless all directors, officers and all other holders of at least one percent (1%) of the outstanding share capital of the Company (calculated on an as-converted to Ordinary Share basis) must be bound by restrictions at least as restrictive as those applicable to any such Holder pursuant to this <u>Section 6.3</u>; and (v) shall not apply to transfers by the Holder of Registerable Securities to their respective Affiliates so long as the transferees enter into the same lockup agreement. The underwriters in connection with the Company's IPO are intended third party beneficiaries of this Section and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto. Each Holder further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with such Registration that are consistent with this Section 6.3. Any discretionary waiver or termination of the restrictions of any or all of such agreements and similar agreements by the Company or the underwriters shall apply pro rata to all Holders of Registrable Securities that are subject to such agreements, based on the number of shares subject to such agreements and similar agreements. In order to enforce the foregoing

covenant, the Company may place restrictive legends on the certificates and impose stop-transfer instructions with respect to the Registrable Securities of each shareholder (and the shares or securities of every other person subject to the foregoing restriction) until the end of such period.

- **6.4 Termination of Registration Rights.** The registration rights set forth in Section 2 and Section 3 shall terminate on the earlier of (a) the date that is [***] years from the date of closing of an IPO, (b) with respect to any Holder, the date on which such Holder may sell all of such Holder's Registrable Securities under Rule 144 of the Securities Act in any ninety (90)-day period without any limitation, and (c) the closing of a Deemed Liquidation Event, in which the consideration received by such Holders in such Deemed Liquidation Event is in the form of cash and/or publicly traded securities, or if such Holders receive registration rights from the acquiring company or other successor to the Company reasonably comparable to those set forth in this Agreement.
- **6.5 Exercise of Ordinary Share Equivalents.** Notwithstanding anything to the contrary provided in this Agreement, the Company shall have no obligation to Register Registrable Securities which, if constituting Ordinary Share Equivalents, have not been exercised, converted or exchanged, as applicable, for Ordinary Shares as of the effective date of the applicable Registration Statement, but the Company shall cooperate and facilitate any such exercise, conversion or exchange as requested by the applicable Holder.
- **6.6 Intent.** The provisions of Sections 2 through $\underline{6}$ are drafted primarily in contemplation of an offering of securities in the U.S. The parties recognize, however, the possibility that securities may be qualified or registered for offering to the public in a jurisdiction other than the U.S. where registration rights have significance or that the Company might effect an offering in the U.S. in the form of American Depositary Receipts or American Depositary Shares. Accordingly:
- (a) it is their intention that, whenever this Agreement refers to a Law, form, process or institution of the U.S. but the parties wish to effectuate qualification or registration in a different jurisdiction where registration rights have significance, reference in this Agreement to the Laws or institutions of the U.S. shall be read as referring, <u>mutatis mutandis</u>, to the comparable Laws or institutions of the jurisdiction in question; and
- (b) it is agreed that the Company will not undertake any listing of American Depositary Receipts, American Depositary Shares or any other security derivative of the Ordinary Shares unless arrangements have been made reasonably satisfactory to the Requisite Holders to ensure that the spirit and intent of this Agreement will be realized and that the Company is committed to take such actions as are necessary such that the Holders will enjoy rights corresponding to the rights hereunder to sell their Registrable Securities in a public offering in the U.S. as if the Company had listed Ordinary Shares in lieu of such derivative securities.

7. Preemptive Right.

7.1 General. The Company hereby grants to each Major Investor the right of first offer to purchase such Major Investor's Preemptive Pro Rata Share (as defined below) and any oversubscription, as provided below, of all (or any part) of any New Securities (as defined below) that the Company may from time to time issue after the Effective Date (the "Preemptive Right"). Each Major Investor shall be entitled to apportion the right of first offer hereby

granted to it in such proportions as it deems appropriate, among (i) itself and (ii) its Affiliates; provided that each such Affiliate (x) is not a Competitor, unless such Affiliate's purchase of New Securities is otherwise unanimously consented to by the Board and (y) agrees to enter into this Agreement (provided that any Competitor shall not be entitled to any rights as a Major Investor under this Agreement).

- **7.2 Preemptive Pro Rata Share.** An Investor's "Preemptive Pro Rata Share" for purposes of the Preemptive Rights is the ratio of (a) the number of Ordinary Shares issued or issuable upon conversion of Preferred Shares or exercise of the Warrant, if applicable, that has become exercisable pursuant to the terms thereof held by such Major Investor (such Ordinary Shares, the "Major Investor Shares") to (b) the total number of Ordinary Shares on a Fully-Diluted Basis immediately prior to the issuance of New Securities giving rise to the Preemptive Rights.
- **7.3 New Securities.** For purposes hereof, "<u>New Securities</u>" shall mean any Equity Securities of the Company issued after the Effective Date, except for Excluded Securities (as such term is defined in the Memorandum and Articles).

7.4 Procedures.

- (a) <u>First Participation Notice</u>. In the event that the Company proposes to undertake an issuance of New Securities (in a single transaction or a series of related transactions), it shall give to each Major Investor written notice of its intention to issue New Securities (the "<u>First Participation Notice</u>"), describing the amount and type of New Securities, the price and the general terms upon which the Company proposes to issue such New Securities. Each Major Investor shall have twenty (20) Business Days from the date of receipt of any such First Participation Notice to agree in writing to purchase up to such Major Investor's Preemptive Pro Rata Share of such New Securities for the price and upon the terms and conditions specified in the First Participation Notice by giving written notice to the Company and stating therein the quantity of New Securities to be purchased, which shall not exceed such Major Investor's Preemptive Pro Rata Share (such Investor, the "<u>Participating Investor</u>"). If any Major Investor fails to so respond in writing within such twenty (20) Business Day period, then such Major Investor shall forfeit the right hereunder to purchase its Preemptive Pro Rata Share of such New Securities, but shall not be deemed to forfeit any right with respect to any other issuance of New Securities.
- (b) <u>Second Participation Notice; Oversubscription</u>. If any Major Investor fails or declines to exercise its Preemptive Rights in accordance with <u>Section 7.4(a)</u>, the Company shall promptly give written notice (the "<u>Second Participation Notice</u>") to the Participating Investors who exercised in full their Preemptive Rights (the "<u>Oversubscription Participants</u>") in accordance with <u>Section 7.4(a)</u>. Each Oversubscription Participant shall have ten (10) Business Days from the date of the Second Participation Notice (the "<u>Second Participation Period</u>") to notify the Company of its desire to purchase more than its Preemptive Pro Rata Share of the New Securities, stating the number of the additional New Securities it proposes to buy (the "<u>Additional Number</u>"). Such notice may be made by telephone if confirmed in writing within two Business Days. If, as a result thereof, such oversubscription exceeds the total number of the remaining New Securities available for purchase, each Oversubscription Participant will be cut back by the Company with respect to its oversubscription to such number of remaining New Securities equal to the lesser of (i) the Additional Number and (ii) the product obtained by *multiplying* (A) the number of the remaining New Securities available for oversubscription *by* (B) a fraction, the numerator of

which is the number of the Major Investor Shares held by such Oversubscription Participant and the denominator of which is the total number of the Major Investor Shares held by all the Oversubscription Participants.

7.5 Failure to Exercise. Upon the expiration of the Second Participation Period, or in the event no Major Investor exercises the Preemptive Rights within twenty (20) Business Days following the issuance of the First Participation Notice, the Company shall have ninety (90) days thereafter to complete the sale of the New Securities described in the First Participation Notice with respect to which the Preemptive Rights hereunder were not exercised at the same or higher price and upon non-price terms not more favorable to the purchasers thereof than specified in the First Participation Notice. In the event that the Company has not issued and sold such New Securities within such ninety (90) day period, then the Company shall not thereafter issue or sell any New Securities without again first offering such New Securities to the Major Investors pursuant to this Section 7.

8. Information and Inspection Rights.

- **8.1 Delivery of Financial Statements.** The Group Companies shall deliver to each Major Investor the following documents or reports:
- (a) within one hundred twenty (120) days after the end of each fiscal year of the Company starting from the fiscal year ending on December 31, 2022, a consolidated income statement and statement of cash flows for the Company for such fiscal year and a consolidated balance sheet for the Company as of the end of the fiscal year, audited and certified by an internationally reputable firm of independent certified public accountants acceptable to the Board, unless the Board determines not to require such financial statements to be audited for any particular fiscal year, and a management report including a comparison of the financial results of such fiscal year with the corresponding annual budget, all prepared in English and in accordance with the Accounting Standards consistently applied throughout the period;
- (b) within forty-five (45) days of the end of each of the first three fiscal quarters, a consolidated unaudited income statement and statement of cash flows for such quarter and a consolidated balance sheet for the Company as of the end of such quarter, and a comparison of the financial results of such quarter with the corresponding quarterly budget, all prepared in English and in accordance with the Accounting Standards consistently applied throughout the period (except for customary year-end adjustments and except for the absence of notes)
- (c) within forty-five (45) days of the end of each of the first three fiscal quarters, a statement showing the number of shares of each class and series and securities convertible into or exercisable for shares of the Company outstanding at the end of the period, Ordinary Shares issuable upon conversion or exercise of any outstanding securities convertible or exercisable for Ordinary Shares and the exchange ratio or exercise price applicable thereto, and the number of shares of issued options and options not yet issued but reserved for issuance, if any, all in sufficient detail as to permit the Major Investors to calculate their respective percentage equity ownership in the Company;
- (d) an annual budget and strategic plan within thirty (30) days prior to the beginning of each fiscal year, setting forth (i) the projected balance sheets, income statements and statements of cash flows for each month during such fiscal year of each Group Company,

- (ii) projected detailed budgets for each such month, (iii) any dividend or distribution projected to be declared or paid, (iv) the projected incurrence, assumption or refinancing of indebtedness, and (v) all other material matters relating to the operation, development and business of the Group Companies;
 - (e) copies of all documents or other information sent to all other shareholders; and
 - (f) as soon as practicable, any other information reasonably requested by any such Major Investor.
- **8.2 Inspection Rights.** Each Major Investor shall have the right, at its own expenses, to reasonably inspect facilities, properties, records and books of each Group Company at any time during regular working hours on reasonable prior notice to such Group Company and the right to discuss the business, operation and conditions of a Group Company with any Group Company's officers.

9. Election of Directors.

9.1 Board of Directors.

- (a) The Company shall have, and the Parties hereto agree to cause the Company to have, a Board consisting of [***] Directors, comprised of the following:
 - (i) for as long as Chinook, together with its Affiliates, continues to hold at least [***] of Series A Preferred Shares purchased by Chinook under the Purchase Agreement or an equivalent amount of Ordinary Shares issued upon conversion thereof (as adjusted for any share dividends, combinations, reclassifications or splits effected after the Effective Date), [***] designated, appointed, removed, replaced and reappointed by Chinook (the "Chinook [***]"), who shall initially be [***];
 - (ii) for as long as Frazier, together with its Affiliates, continues to hold at least [***] of Series A Preferred Shares purchased by Frazier under the Purchase Agreement or an equivalent amount of Ordinary Shares issued upon conversion thereof (as adjusted for any share dividends, combinations, reclassifications or splits effected after the Effective Date), [***] designated, appointed and removed by Frazier (the "Frazier [***]"), who shall initially be [***];
 - (iii) for as long as Pivotal, together with its Affiliates, continues to hold at least [33%] of Series A Preferred Shares purchased by Pivotal under the Purchase Agreement or an equivalent amount of Ordinary Shares issued upon conversion thereof (as adjusted for any share dividends, combinations, reclassifications or splits effected after the Effective Date), [***] designated, appointed and removed by Pivotal (the "Pivotal [***]" and collectively with the Chinook [***] and the Frazier [***], collectively the "Investor Directors" and each an "Investor Director"), who shall initially be [***];
 - (iv) one (1) Director designated, appointed and removed by the Requisite Holders, who shall be the then-current chief executive officer of the Company (the "<u>CEO Director</u>"), initially vacant; and

- (v) one (1) Director designated, appointed and removed by the Requisite Holders, who shall not be an Affiliate with, and shall be acceptable to, the Company and each Lead Investor, initially vacant.
- (b) Upon approval by the Board, including the Investor Directors, each other Group Company shall, and the Parties hereto shall cause each Group Company to, (i) have a board of directors or similar governing body (the "Subsidiary Board"), (ii) the authorized size of each Subsidiary Board at all times be the same authorized size as the Board, and (iii) the composition of each Subsidiary Board to at all times consist of the same persons as Directors as those then on the Board.
- **9.2 Vote to Increase Authorized Ordinary Shares.** Each Shareholder agrees to vote or cause to be voted all Shares owned by such Shareholder, or over which such Shareholder has voting control, from time to time and at all times, in whatever manner as shall be necessary to increase the number of authorized Ordinary Shares from time to time to ensure that there will be sufficient Ordinary Shares available for conversion of all of the Preferred Shares outstanding at any given time.

9.3 Voting Agreements.

- (a) With respect to each election of Directors, each holder of voting securities of the Company shall vote at each meeting of shareholders of the Company, or in lieu of any such meeting shall give such holder's written consent with respect to, as the case may be, all of the voting securities of the Company now or hereafter directly or indirectly owned (of record or beneficially) by such holder, or over which such holder has voting control, from time to time and at all times as may be necessary (i) to keep the authorized size of the Board at [***] Directors, (ii) to cause the election or re-election as members of the Board, and during such period to continue in office, each of the individuals designated or appointed pursuant to Section 9.1.
- (b) Any Director designated or appointed pursuant to Section 9.1 may be removed from the Board, either for or without cause, only upon the vote or written consent of the Person or group of Persons then entitled to designate or appoint such Director pursuant to Section 9.1, and the Parties agree not to seek, vote for or otherwise effect the removal of any such Director without such vote or written consent. Any Person or group of Persons then entitled to designate or appoint any individual to be elected as a Director shall have the exclusive right at any time or from time to time to remove any such Director occupying such position and to fill any vacancy caused by the death, disability, retirement, resignation or removal of any Director occupying such position or any other vacancy therein, and each other Party agrees to cooperate with such Person or group of Persons in connection with the exercise of such right. Each holder of voting securities of the Company agrees to always vote at a meeting of the members of the Company, or in lieu of any such meeting shall give such holder's written consent with respect to, as the case may be, all of the voting securities of the Company now or hereafter directly or indirectly owned (of record or beneficially) by such holder, or over which such holder has voting control in support of the foregoing.
- (c) The Company and each other Group Company shall take such action, and each other Party agrees to take such action, as is necessary to cause the election or appointment to the Board and each Subsidiary Board of each Director designated or appointed to serve on the Board pursuant to <u>Section 9.1</u>. Upon a removal or replacement of such Director

from the Board or any Subsidiary Board in accordance with <u>Section 9.3(b)</u>, the Company and each other Group Company agrees to take such action, and each other Party agrees to take such action, as is necessary to cause the removal of such Director from the Board and such Subsidiary Board.

- (d) No Shareholder, nor any Affiliate of any Shareholder, shall have any liability as a result of designating a person for election as a director for any act or omission by such designated person in his or her capacity as a director of the Company, nor shall any shareholder have any liability as a result of voting for any such designee in accordance with the provisions of this Agreement.
- Board Meetings; Quorum. The Board and each Subsidiary Board shall hold no less than one (1) board meeting during each fiscal quarter unless otherwise agreed upon by a vote of the majority of the Directors (which must include the approval of each Investor Director). A meeting of the Board and each Subsidiary Board shall only proceed where there are present (whether in person or by means of a conference telephone or any other equipment which allows all participants in the meeting to speak to and hear each other simultaneously) a majority of all Directors of such Group Company then in office (provided that such majority includes each Investor Director), and the Parties shall cause the foregoing to be the quorum requirements for the Board and each Subsidiary Board. Notwithstanding the foregoing, if written notice of the board meeting has been duly delivered to all members of the Board or the applicable Subsidiary Board five (5) Business Days prior to the scheduled meeting in accordance with the notice procedures under the Charter Documents of the applicable Group Company, and the number of Directors or directors required to be present under this <u>Section 9.4</u> for such meeting to proceed is not present within one (1) hour from the time appointed for the meeting solely because of the absence of an Investor Director, each holder of voting securities of the Company, or the applicable Group Company, as the case may be, shall procure that the Directors or directors present at the meeting shall adjourn the meeting to the same day one (1) week later, at the same time and place or to such other day, time or place as such Directors may determine, with written notice delivered to all Directors two (2) Business Days prior to the adjourned meeting in accordance with the notice procedures under the Charter Documents of the applicable Group Company. If at the adjourned meeting, the number of Directors required to be present under this <u>Section 9.4</u> for such meeting to proceed is not present within one (1) hour from the time appointed for the meeting solely because of the absence of any Investor Director, then the presence of such Investor Director shall not be required at such adjourned meeting solely for purpose of determining if a quorum has been established.
- 9.5 Observers. For as long as Chinook, together with its Affiliates, continues to hold at least [***] of Series A Preferred Shares purchased by Chinook under the Purchase Agreement or an equivalent amount of Ordinary Shares issued upon conversion thereof (as adjusted for any share dividends, combinations, reclassifications or splits effected after the Effective Date), Chinook shall be entitled to appoint [***] (the "Chinook [***]") to attend all meetings of the Board and all committees of the Board, in a nonvoting observer capacity. For so long as Frazier, together with its Affiliates, continues to hold at least [***] of Series A Preferred Shares purchased by Frazier under the Purchase Agreement or an equivalent amount of Ordinary Shares issued upon conversion thereof (as adjusted for any share dividends, combinations, reclassifications or splits effected after the Effective Date), Frazier shall be entitled to appoint [***] (the "Frazier [***]") to attend all meetings of the Board and all committees of the Board, in a nonvoting observer capacity. For as long as Pivotal, together with its Affiliates, continues to hold at least [***] of Series A Preferred Shares purchased by

Pivotal under the Purchase Agreement or an equivalent amount of Ordinary Shares issued upon conversion thereof (as adjusted for any share dividends, combinations, reclassifications or splits effected after the Effective Date), Pivotal shall be entitled to appoint [***] (the "Pivotal [***]") to attend all meetings of the Board and all committees of the Board, in a nonvoting observer capacity. For as long as Samsara and Versant, together with their respective Affiliates, continue to hold at least [***] of the aggregate number of Series A Preferred Shares purchased by Samsara and Versant under the Purchase Agreement or an equivalent amount of Ordinary Shares issued upon conversion thereof (as adjusted for any share dividends, combinations, reclassifications or splits effected after the Effective Date), Samsara and Versant shall be entitled to appoint, jointly and upon their mutual consent, [***] (the "Joint [***]," and collectively with the Chinook [***], the Frazier [***] and the Pivotal [***], collectively the "Observers" and each an "Observer") to attend all meetings of the Board and all committees of the Board, in a nonvoting observer capacity. The Company shall give each Observer copies of all notices, minutes, consents, and other materials that the Company provides to the Company's directors at the same time and in the same manner as provided to such directors. Each Observer shall agree to hold in confidence and trust all information so provided and may be excluded from that portion of a meeting of the Board or a subcommittee thereof to the extent that (a) the Board has reasonably determined in good faith that such Observer's presence at such meeting or portion thereof would reasonably be expected to result in the disclosure of trade secrets or would be a conflict of interest, (b) the Board has reasonably determined in good faith that such Observer is a Competitor of the Company; provided, however, that such Observer shall not be deemed to be a Competitor solely because such representative is either a member or observer of the board of directors of a company that is a Competitor or (c) counsel to the Company has determined that such Observer's presence at such meeting or portion thereof would result in the loss of the Company's attorney-client privilege; provided that to the extent practical such Observer shall be notified in writing by the Company at least forty-eight (48) hours prior to the meeting of the exclusion and grounds on which the exclusion is based and provided further that the Company shall in good faith endeavor to ensure that meetings of the Board or committees thereof are conducted in such a manner as to minimize those portions during which such Observer shall be excluded, with a view to allowing such Observer to attend and observe such meetings to the maximum extent possible. Each Observer shall be entitled to be reimbursed for all reasonable out-of-pocket expenses incurred in connection with attending board or committee meetings.

- **9.6 Expenses.** The Company will promptly pay or reimburse each non-employee Director and each non-employee director of any Subsidiary Board for all reasonable out-of-pocket expenses incurred in connection with attending board or committee meetings and otherwise performing their duties as directors and committee members.
- **9.7 Alternates.** Subject to applicable Law, each Director shall be entitled to appoint an alternate to serve at any Board or Subsidiary Board meeting, and such alternate shall be permitted to attend all Board or Subsidiary Board meetings and vote on behalf of the director for whom she or he is serving as an alternate.
- **9.8 Board Committees.** If and to the extent the Board or any Subsidiary Board establishes a committee or subcommittee thereof, each Investor Director shall have the right to be a member of such committee.
- **9.9 D&O Insurance.** The Company shall, within thirty (30) days after the Effective Date, purchase and thereafter maintain, directors' and officers' insurance on commercially reasonable and customary terms (including the coverage amount) acceptable to

the Lead Investors, in relation to any person who is or was a Director or an officer of the Company, or who at the request of the Company is or was serving as a director or an officer of, or in any other capacity is or was acting for, another company or a partnership, joint venture, trust or other enterprise, against any liability asserted against the person and incurred by the person in that capacity, except to the extent otherwise agreed to in writing by the Lead Investors. To the maximum extent permitted by the Law of the jurisdiction in which the Company is organized, the Company shall indemnify and hold harmless each of its Directors and shall comply with the terms of the Indemnification Agreements, and at the request of any Director who is not a party to an Indemnification Agreement, shall enter into an indemnification agreement with such Director in a similar form to the Indemnification Agreements.

9.10 Executive Officers. The Board will appoint, remove and determine the compensation for the chief executive officer and chief medical officer of the Group Company, by the affirmative votes of a simple majority of the Directors, excluding the CEO Director with respect to his or her appointment, removal or compensation approval. The chief executive officer shall appoint, remove and determine the compensation for the other senior executives reporting to him or her, with consultation with and advice of the Board and its consent in the case of other C-suite executive, and shall be in charge of executing the day-to-day management of the Company and implementing the budget and operation plan.

Restriction on Transfers; Rights of First Refusal and Co-Sale Rights.

10.1 Restriction on Transfers.

10.

- (a) **Restricted Holders.** No Ordinary Shareholder (each a "<u>Restricted Holder</u>"), regardless of such Restricted Holder's employment status with the Company, shall directly or indirectly sell, assign, transfer, pledge, hypothecate, or otherwise encumber or dispose of in any way or otherwise grant any interest or right with respect to ("<u>Transfer</u>") all or any part of any interest (direct or indirect) in any Equity Securities of the Company now or hereafter owned or held by such Restricted Holder prior to a Qualified IPO, without the prior written consent of the Requisite Holders.
- (b) **Investors.** For the avoidance of doubt, the Investors may freely Transfer any Equity Securities of the Company now or hereafter owned or held by them without limitation; <u>provided</u> that (i) such Transfer is effected in compliance with all applicable Laws and (ii) the transferee shall execute and deliver an Adoption Agreement in substantially the form attached hereto as <u>Schedule III</u> and such other documents and take such other actions as may be necessary for the transferee to join in and be bound by the terms of this Agreement as an "Investor" (if not already a Party hereto) and a "Shareholder" upon and after such Transfer. The Company will update its Register of Members upon the consummation of any such permitted Transfer.
- (c) **Prohibited Transfers Void.** Any Transfer of Equity Securities of the Company not made in compliance with this Agreement shall be null and void as against the Company, shall not be recorded on the books of the Company and shall not be recognized by the Company or any other Party.
- (d) **No Indirect Transfers.** Each of the Restricted Holders agrees not to circumvent or otherwise avoid the transfer restrictions or intent thereof set forth in this Agreement, whether by holding the Equity Securities of the Company indirectly through

another Person (including any holding vehicle of any Restricted Holder) or by causing or effecting, directly or indirectly, the Transfer or issuance of any Equity Securities by any such Person (including any holding vehicle of any Restricted Holder), or otherwise. Each of the Restricted Holders further agrees that, so long as such Restricted Holder is bound by this Agreement, the Transfer, sale or issuance of any Equity Securities of any holding vehicle of any Restricted Holder without the prior written consent of the Requisite Holders shall be prohibited, and each such Restricted Holder agree not to make, cause or permit any Transfer, sale or issuance of any Equity Securities of any holding vehicle of any Restricted Holder without the prior written consent of the Requisite Holders. Any purported Transfer, sale or issuance of any Equity Securities of any holding vehicle in contravention of this Agreement shall be void and ineffective for any and all purposes and shall not confer on any transferee or purported transferee any rights whatsoever, and no Party (including any Restricted Holder) shall recognize any such Transfer, sale or issuance.

- (e) **Performance.** Each Restricted Holder irrevocably agrees to cause and guarantee the performance by or any holding vehicle of any Restricted Holder of all of their respective covenants and obligations under this Agreement.
- (f) **Cumulative Restrictions.** For purposes of clarity, the restrictions on transfer set forth in this Agreement on a Party are cumulative with, and in addition to, the restrictions set forth in each other agreement imposing restrictions on transfer by such Person of Equity Securities of the Company (collectively, the "Other Restriction Agreements"), if any, and not in lieu thereof.
- **Exempt Transactions.** Regardless of anything else contained herein, this Section 10 shall not apply with respect to (i) any sale of Ordinary Shares made pursuant to Section 11, (ii) in the case of a Restricted Holder that is an entity, upon a transfer by such Restricted Holder to its stockholders, members, partners or other equity holders for no consideration, (iii) to a repurchase of Equity Securities from a Restricted Holder by the Company at a price no greater than that originally paid by such Restricted Holder for such Equity Securities and pursuant to an agreement containing vesting and/or repurchase provisions approved by the Board, or (iv) the case of a Restricted Holder that is a natural person, any Transfer of any Equity Securities of the Company now or hereafter held by a Restricted Holder for no consideration to such Restricted Holder's parents, children (natural or adopted), spouse (including any life partner or similar statutorily-recognized domestic partner), any direct lineal descendant of such Restricted Holder or his/her spouse (including any life partner or similar statutorily-recognized domestic partner), or to a trustee, executor, or other fiduciary for the benefit of such Restricted Holder's parents, children, spouse for bona fide estate planning purposes (each such transferee, a "Permitted Transferee", and collectively, the "Permitted Transferees"); provided that (x) such Transfer is effected in compliance with all applicable Laws, (y) respecting any transfer pursuant to clause (iv) above, the Restricted Holder has provided the Requisite Holders reasonable evidence of the bona fide estate planning purposes for such Transfer, and (z) each such Permitted Transferee, as a condition precedent and prior to the completion of the Transfer, shall have executed and delivered an Adoption Agreement in substantially the form attached hereto as Schedule III and such other documents in form and substance reasonably satisfactory to the Requisite Holders and take such other actions as may be necessary for the transferee to join in and be bound by the terms of this Agreement and the applicable Other Restriction Agreements as a Restricted Holder, with respect to the transferred Equity Securities; provided, further, that the Transferor shall remain liable for any breach by

such Permitted Transferee of any provision under this Agreement and the applicable Other Restriction Agreements

- (h) **Exempted Offerings**. Notwithstanding the foregoing or anything to the contrary herein, the provisions of this <u>Section 10</u> shall not apply to the sale of any Equity Securities (a) to the public in a Qualified IPO; or (b) pursuant to a Deemed Liquidation Event.
- (i) **Prohibited Transferees**. Notwithstanding the foregoing, no Restricted Holder shall transfer any Equity Securities to (a) any entity which, in the determination of the Board, is a Competitor; or (b) any customer, distributor or supplier of the Company, if the Board should determine that such transfer would result in such customer, distributor or supplier receiving information that would place the Company at a competitive disadvantage with respect to such customer, distributor or supplier.

10.2 Rights of First Refusal.

- (a) **Transfer Notice.** To the extent the applicable consent of the Requisite Holders is given pursuant to <u>Section 10.1</u>, if any Restricted Holder (a "<u>Transferor</u>") proposes to Transfer any Equity Securities of the Company or any interest therein to one or more third parties, then the Transferor shall give the Company and each Investor written notice of the Transferor's intention to make the Transfer (the "<u>Transfer Notice</u>") not later than forty-five (45) days prior to the consummation of the proposed Transfer, which shall include (i) a description of the Equity Securities to be transferred (the "<u>Offered Shares</u>"), (ii) the identity and address of the prospective transferee (the "<u>Transferee</u>") and (iii) the consideration and the material terms and conditions upon which the proposed Transfer is to be made. The Transfer Notice shall certify that the Transfer has received a definitive offer from the prospective transferee and in good faith believes a binding agreement for the Transfer is obtainable on the terms set forth in the Transfer Notice. The Transfer Notice shall also include a copy of any written proposal, term sheet or letter of intent or other agreement relating to the proposed Transfer.
- (b) **Option of Company.** To exercise its Right of First Refusal under this <u>Section 10</u>, the Company must deliver a written notice to the Transferor and the Investors within fifteen (15) days after delivery of the Transfer Notice specifying the number of Offered Shares to be purchased by the Company (the "<u>Company Notice</u>"). If the Company does not provide the Company Notice exercising its right of first refusal with respect to all Offered Shares, the Company must deliver a written notice to the Transferor and to each Investor to that effect no later than fifteen (15) days after the Transferor delivers the Transfer Notice to the Company. The Investors shall then have a secondary right of first refusal to purchase the Offered Shares pursuant to <u>Section 10.2(c)</u> below.

(c) **Option of Investors.**

(i) Each such Investor shall have an option for a period of twenty (20) Business Days following receipt of the Company Notice (the "Option Period") to elect to purchase all or any portion of its respective ROFR Pro Rata Share (as defined below) of the Offered Shares at the same price and subject to the same terms and conditions as described in the Transfer Notice, by notifying the Transferor in writing before expiration of the Option Period as to the number of such Offered Shares that it wishes to purchase.

- (ii) For the purposes of this <u>Section 10.2(b)</u>, an Investor's "<u>ROFR Pro Rata Share</u>" of the Offered Shares shall be equal to (A) the total number of the Offered Shares (not subscribed for by the Company pursuant to its primary right of first refusal), *multiplied* by (B) a fraction, the numerator of which shall be the aggregate number of Ordinary Shares issued or issuable upon conversion of Preferred Shares or exercise of the Warrant, if applicable, that has become exercisable pursuant to the terms thereof held by such Investor on the date of the Transfer Notice and the denominator of which shall be the total number of Ordinary Shares issued or issuable upon conversion of Preferred Shares or exercise of the Warrant, if applicable, that has become exercisable pursuant to the terms thereof held by all Investors on such date.
- (iii) If any Investor fails to exercise its right to purchase its full ROFR Pro Rata Share of the Offered Shares, the Transferor shall deliver written notice thereof (the "Second Notice"), within five days after the expiration of the Option Period, to each Investor that elected to purchase its entire ROFR Pro Rata Share of the Offered Shares (an "Exercising Shareholder"). The Exercising Shareholders shall have a right of re-allotment, and may exercise an additional right to purchase such unpurchased Offered Shares by notifying the Transferor and the Company in writing within ten Business Days after receipt of the Second Notice; provided, however, that if the Exercising Shareholders desire to purchase in aggregate more than the number of such unpurchased Offered Shares, then such unpurchased Offered Shares shall be allocated to the extent necessary among the Exercising Shareholders in accordance with their relative ROFR Pro Rata Shares (provided that, for purposes of this Section 10.2(c)(iii), the reference to "Investors" in the denominator contained in such definition shall be replaced with a reference to "Exercising Shareholders").
- (iv) Subject to applicable securities Laws, each Investor shall be entitled to apportion Offered Shares to be purchased among its Affiliates, <u>provided</u> that such Investor notifies the Company and the Transferor in writing.
- (d) **Procedure.** If any Investor gives the Transferor notice that it desires to purchase Offered Shares, and, as the case may be, any re-allotment, then payment for the Offered Shares to be purchased shall be made by check (if agreeable to the Transferor), or by wire transfer in immediately available funds of the appropriate currency, against delivery of such Offered Shares to be purchased, at a place agreed to by the Transferor and all the Exercising Shareholders (if they are purchasers) and at the time of the scheduled closing therefor, but if they cannot agree, then at the principal executive offices of the Company on the thirtieth (30th) day after the Company's receipt of the Transfer Notice, unless such notice contemplated a later closing date with the prospective Transferee or unless the value of the purchase price has not yet been established pursuant to Section 10.2(e), in which case the closing shall be on such later date or as provided in Section 10.2(e). The Company will update its Register of Members upon the consummation of any such Transfer.

(e) Valuation of Property.

(i) If the purchase price specified in the Transfer Notice will be payable in property, services or other non-cash consideration, the Investors, as applicable, shall have the right to pay the purchase price in the form of cash equal in amount to the fair market value of such property, services or non-cash consideration as determined in good faith by the Board.

- (ii) If the Transferor and the Exercising Shareholders cannot agree on such cash value within the Option Period, the valuation shall be made by an appraiser of internationally recognized standing jointly selected by agreement of such groups or, if they cannot agree on an appraiser within the Option Period, each such group shall select an appraiser of internationally recognized standing and such appraisers shall designate another appraiser of internationally recognized standing, whose appraisal shall be determinative of such value.
- (iii) The cost of such appraisal shall be shared equally by the Transferor, on the one hand, and the purchasers pro rata based on the number of Offered Shares such purchaser is purchasing, on the other hand.
- (iv) If the value of the purchase price offered by the prospective transferee is not determined within thirty (30) days following the receipt of the Transfer Notice from the Transferor, the closing of the purchase of Offered Shares by the Exercising Shareholders shall be held on or prior to the fifth (5th) Business Day after such valuation shall have been made pursuant to this <u>Section 10.2(e)</u>.

10.3 Right of Co-Sale.

- (a) To the extent the Investors do not exercise their respective rights of first refusal as to all of the Offered Shares proposed to be sold by the Transferor to the Transferee identified in the Transfer Notice, the Transferor shall give notice thereof to each Investor not exercising any right of first refusal pursuant to Section 10.2 (the "Co-Sale Notice") (specifying in such Co-Sale Notice the number of remaining Offered Shares as well as the number of Shares that such Shareholder may participate with), and each such Investor shall have the right to participate in such sale, to the Transferee identified in the Transfer Notice, of the remaining Offered Shares not purchased pursuant to Section 10.2, on the same terms and conditions as specified in the Transfer Notice (but in no event less favorable to the Transferor) by notifying the Transferor in writing within ten (10) Business Days following the date of the Co-Sale Notice (each such electing Investor, a "Selling Shareholder"). Such Selling Shareholder wishes to sell under its right to participate. To the extent one or more Investors exercise such right of participation in accordance with the terms and conditions set forth below, the number of Offered Shares that the Transferor may sell in the Transfer to the third party transferee identified in the Transfer Notice shall be correspondingly reduced.
- (b) The total number of Equity Securities that each Selling Shareholder may elect to sell shall be equal to the product of (i) the aggregate number of the remaining Offered Shares being transferred to the third party transferee identified in the Transfer Notice after giving effect to the exercise of all rights of first refusal pursuant to Section 10.2, multiplied by (ii) a fraction, the numerator of which is the number of Ordinary Shares issued or issuable upon conversion of Preferred Shares or exercise of the Warrant, if applicable, that has become exercisable pursuant to the terms thereof held by such Selling Ordinary Shares issued or issuable upon conversion of Preferred Shares or exercise of the Warrant, if applicable, that has become exercisable pursuant to the terms thereof) held by the Transferor and all Investors entitled to exercise their co-sale right hereunder.
- (c) Each Selling Shareholder shall effect its participation in the sale by promptly delivering to the Transferor for transfer to the Transferee, before the applicable

closing, one or more certificates, properly endorsed for transfer, which represent the type and number of Equity Securities which such Selling Shareholder elects to sell; <u>provided</u>, <u>however</u>, that if the Transferee objects to the delivery of Ordinary Share Equivalents in lieu of Ordinary Shares, such Selling Shareholder shall only deliver Ordinary Shares (and therefore shall convert any such Ordinary Share Equivalents into Ordinary Shares) and certificates corresponding to such Ordinary Shares, and the Company shall effect any such conversion concurrent with the actual transfer of such shares to the purchaser and contingent on such transfer.

- (d) The share certificate or certificates that a Selling Shareholder delivers to the Transferor pursuant to this Section 10.3 shall be transferred to the prospective purchaser in consummation of the sale of the Equity Securities pursuant to the terms and conditions specified in the Transfer Notice, and the Transferor shall concurrently therewith remit to such Selling Shareholder that portion of the sale proceeds to which such Selling Shareholder is entitled by reason of its participation in such sale. The Company will update its Register of Members upon the consummation of any such Transfer.
- (e) To the extent that any Transferee prohibits the participation by a Selling Shareholder exercising its co-sale rights hereunder in a proposed Transfer or otherwise refuses to purchase shares or other securities from a Selling Shareholder exercising its co-sale rights hereunder, the Transferor shall not sell to such prospective purchaser any Equity Securities unless and until, simultaneously with such sale, the Transferor shall purchase from such Selling Shareholder such shares or other securities that such Selling Shareholder would otherwise be entitled to sell to the prospective purchaser pursuant to its co-sale rights for the same consideration and on the same terms and conditions as the proposed transfer described in the Transfer Notice.

10.4 Non-Exercise of Rights.

- (a) If the Investors do not elect to purchase all of the Offered Shares in accordance with Section 10.2, then, subject to the right of the Investors to exercise their rights to participate in the sale of Offered Shares within the time periods specified in Section 10.3, the Transferor shall have a period of sixty (60) days from the expiration of the Option Period in which to sell the remaining Offered Shares to the Transferee identified in the Transfer Notice upon terms and conditions (including the purchase price) no more favorable to the purchaser than those specified in the Transfer Notice, so long as any such sale is effected in accordance with all applicable Laws. The Parties agree that each such transferee, prior to and as a condition to the consummation of any sale, shall execute and deliver to the Parties documents and other instruments assuming the obligations of such Transferor, and the Transfer shall not be effective and shall not be recognized by any Party until such documents and instruments are so executed and delivered.
- (b) In the event the Transferor does not consummate the sale of such Offered Shares to the third party transferee identified in the Transfer Notice within the sixty (60)-day period, the rights of the Investors under <u>Section 10.2</u> and <u>Section 10.3</u> shall be re-invoked and shall be applicable to each subsequent disposition of such Offered Shares by the Transferor until such rights lapse in accordance with the terms of this Agreement.
- (c) The exercise or non-exercise of the rights of the Investors under this <u>Section 10</u> to purchase Equity Securities from a Transferor or participate in the sale of Equity Securities by a Transferor shall not adversely affect their rights to make subsequent purchases

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- (d) No Equity Securities shall be transferred by the Transferor or any Selling Shareholder pursuant to Section 10.3 if such Transfer, in a single transaction or a series of related transactions, will result in the change of the Control over the Company to be acquired by any Exercising Shareholder or Transferee unless such Transferee offers in writing to purchase all of the issued and outstanding Equity Securities of the Company, in which even the aggregate consideration payable by such Transferee shall be distributed pursuant to Article 3.2 of the Memorandum and Articles.
- **10.5 Prohibited Transfers.** In the event the Transferor should sell any Equity Securities in contravention of the co-sale rights of the Investors under Section 10.3 (a "Prohibited Transfer"), the Investors, in addition to such other remedies as may be available at law, in equity or hereunder, shall have the put option provided below, and such Transferor shall be bound by the applicable provisions of such option.
- (a) **Put Option.** In the event of a Prohibited Transfer, each Investor shall have the right to sell to the Transferor the type and number of Equity Securities equal to the number of Equity Securities such Investor would have been entitled to transfer to the third-party transferee under <u>Section 10.3</u> had the Prohibited Transfer been effected pursuant to and in compliance with the terms hereof. Such sale shall be made on the following terms and conditions.
 - (i) The price per share at which the shares are to be sold to the Transferor shall be equal to the price per share paid by the third-party transferee to the Transferor in the Prohibited Transfer. The Transferor shall also reimburse each Investor for any and all reasonable fees and expense, including legal fees and expenses, incurred pursuant to the exercise or the attempted exercise of such Investor's rights under this <u>Section 10</u>.
 - (ii) Within ninety (90) days after the later of the dates on which an Investor (x) received notice of the Prohibited Transfer or (y) otherwise becomes aware of the Prohibited Transfer, such Investor shall, if exercising the option created hereby, deliver to the Transferor an instrument of transfer and either the certificate or certificates representing shares to be sold under this Section 10.5 by such Investor, each certificate to be properly endorsed for transfer, or an affidavit of lost certificate. The Transferor shall, upon receipt of the foregoing, pay the aggregate purchase price therefor and the amount of reimbursable fees and expenses, in cash by wire transfer of immediately available funds or by other means acceptable to such Investor. The Company will concurrently therewith record such transfer on its books and update its Register of Members and will promptly thereafter and in any event within five days reissue certificates, as applicable, to the Transferor and the Investor reflecting the new securities held by them giving effect to such transfer.
- (b) **Voidability of Prohibited Transfer.** Notwithstanding anything to the contrary contained herein and the rights afforded to the Investor in this <u>Section 10.5</u>, any attempt by a Transferor to transfer Equity Securities in violation of this <u>Section 10</u> shall be void, and the Company agrees it will not effect such a transfer nor will it treat any alleged transferee as the holder of such shares without the written consent of the Requisite Holders.

11. Drag-Along Rights.

- **11.1 Drag-Along Obligations.** If the Requisite Holders (collectively, the "<u>Drag Holders</u>") and the Board approve a Deemed Liquidation Event or Share Sale, whether structured as a merger, reorganization, asset sale, share sale, sale of control of the Company or otherwise (collectively, the "<u>Approved Sale</u>"), to any Person that is not a Drag Holder or an Affiliate of any Drag Holder, then at the request of the Drag Holders, the Company shall promptly notify each other Shareholder in writing of such approval and the material terms and conditions of such proposed Approved Sale, whereupon each such Shareholder shall, in accordance with instructions received from the Company at the direction of the Drag Holders:
- (a) if such transaction requires shareholder approval, with respect to all Shares that such Shareholder owns or over which such Shareholder otherwise exercises voting power, to vote (in person, by proxy or by action by written consent, as applicable) all Shares in favor of, and adopt, such Approved Sale (together with any related amendment or restatement to the Memorandum and Articles required to implement such Approved Sale) and to vote in opposition to any and all other proposals that could reasonably be expected to delay or impair the ability of the Company to consummate such Approved Sale;
- (b) if such transaction is a Share Sale, to sell the same proportion of capital shares of the Company beneficially held by such Shareholder as is being sold by the Drag Holders to the Person to whom the Drag Holders propose to sell their Shares, and, except as permitted in <u>Section 11.2</u>, on the same terms and conditions as the other Shareholders of the Company;
- (c) to execute and deliver all related documentation and take such other action in support of the Approved Sale as shall reasonably be requested by the Company or the Drag Holders in order to carry out the terms and provision of this <u>Section 11.1</u>, including executing and delivering instruments of conveyance and transfer, and any purchase agreement, merger agreement, any associated indemnity agreement, or escrow agreement, any associated voting, support, or joinder agreement, consent, waiver, governmental filing, share certificates duly endorsed for transfer (free and clear of impermissible liens, claims and encumbrances), and any similar or related documents;
- (d) not to deposit, and to cause their Affiliates not to deposit, except as provided in the Articles, any Shares owned by such party or Affiliate in a voting trust or subject any Shares to any arrangement or agreement with respect to the voting of such Shares, unless specifically requested to do so by the acquirer in connection with the Approved Sale;
- (e) to refrain from (i) exercising any dissenters' rights or rights of appraisal under applicable Law at any time with respect to such Approved Sale, or (ii) asserting any claim or commencing any suit (A) challenging the Approved Sale or this Agreement or (B) alleging a breach of any fiduciary duty of the Drag Holders or any Affiliate or Associate thereof (including aiding and abetting breach of fiduciary duty) in connection with the evaluation, negotiation or entry into the Approved Sale, or the consummation of the transactions contemplated thereby;
- (f) if the consideration to be paid in exchange for the Shares pursuant to this <u>Section 11.1</u> includes any securities and due receipt thereof by any Shareholder would require

under applicable Law (x) the registration or qualification of such securities or of any person as a broker or dealer or agent with respect to such securities; or (y) the provision to any Shareholder of any information other than such information as a prudent issuer would generally furnish in an offering made solely to "accredited investors" as defined in Regulation D promulgated under the Securities Act, the Company may cause to be paid to any such Shareholder in lieu thereof, against surrender of the Shares which would have otherwise been sold by such Shareholder, an amount in cash equal to the fair value (as determined in good faith by the Board) of the securities which such Shareholder would otherwise receive as of the date of the issuance of such securities in exchange for the Shares; and

- (g) in the event that the Drag Holders, in connection with such Approved Sale, appoint a shareholder representative (the "Shareholder Representative") with respect to matters affecting the Shareholders under the applicable definitive transaction agreements following consummation of such Approved Sale, (i) to consent to (A) the appointment of such Shareholder Representative, (B) the establishment of any applicable escrow, expense or similar fund in connection with any indemnification or similar obligations, and (C) the payment of such Shareholder's pro rata portion (from the applicable escrow or expense fund or otherwise) of any and all reasonable fees and expenses to such Shareholder Representative in connection with such Shareholder Representative's services and duties in connection with such Approved Sale and its related service as the representative of the Shareholders, and (ii) not to assert any claim or commence any suit against the Shareholder Representative, within the scope of the Shareholder Representative's authority, in connection with its service as the Shareholder Representative, absent fraud, bad faith, gross negligence or willful misconduct.
- **11.2** Notwithstanding anything to the contrary set forth herein, a Shareholder will not be required to comply with <u>Section 11.1</u> in connection with any proposed Approved Sale, unless:
- (a) any representations and warranties to be made by such Shareholder in connection with such Approved Sale are limited to representations and warranties related to authority, ownership and the ability to convey title to such Shares, including representations and warranties that (i) the Shareholder holds all right, title and interest in and to the Shares such Shareholder purports to hold, free and clear of all liens and encumbrances, (ii) the obligations of the Shareholder in connection with the transaction have been duly authorized, if applicable, (iii) the documents to be entered into by the Shareholder have been duly executed by the Shareholder and delivered to the acquirer and are enforceable (subject to customary limitations) against the Shareholder in accordance with their respective terms, and (iv) neither the execution and delivery of documents to be entered into by the Shareholder in connection with the transaction, nor the performance of the Shareholder's obligations thereunder, will cause a breach or violation of the terms of any agreement to which the Shareholder is a party, or any law or judgment, order or decree of any court or governmental agency that applies to the Shareholder;
- (b) such Shareholder is not required to agree (unless such Shareholder is a Company officer or employee) to any covenant not to compete or covenant not to solicit customers, employees or suppliers of any party to such Approved Sale or any release of claims other than a release in customary form of claims arising solely in such Shareholder's capacity as a shareholder of the Company;

- (c) such Shareholder and its Affiliates are not required to amend, extend or terminate any contractual or other relationship with the Company, the acquirer or their respective Affiliates, except that the Shareholder may be required to agree to terminate the investment-related documents between or among such Shareholder, the Company and/or other shareholders of the Company;
- (d) the Shareholder is not liable for the breach of any representation, warranty or covenant made by any other Person in connection with such Approved Sale, other than the Company (except to the extent that funds may be paid out of an escrow established to cover breach of representations, warranties and covenants of the Company as well as breach by any shareholder of any of identical representations, warranties and covenants provided by all shareholders);
- (e) liability shall be limited to such Shareholder's applicable share (determined based on the respective proceeds payable to each Shareholder in connection with such Approved Sale in accordance with the provisions of the Memorandum and Articles) of a negotiated aggregate indemnification amount that applies equally to all Shareholders but that in no event exceeds the amount of consideration otherwise payable to such Shareholder in connection with such Approved Sale, except with respect to claims related to fraud by such Shareholder, the liability for which need not be limited as to such Shareholder;
- upon the consummation of such Approved Sale, (i) each holder of each class or series of the (f) capital shares of the Company will receive the same form of consideration for their shares of such class or series as is received by other holders in respect of their shares of such same class or series of stock, and if any holders of any capital shares of the Company are given a choice as to the form of consideration to be received as a result of such Approved Sale, all holders of such capital shares will be given the same option, (ii) each holder of a series of Preferred Shares will receive the same amount of consideration per share of such series of Preferred Shares as is received by other holders in respect of their shares of such same series, (iii) each holder of Ordinary Shares will receive the same amount of consideration per share of Ordinary Shares as is received by other holders in respect of their shares of Ordinary Shares, and (iv) unless waived pursuant to the terms of the Memorandum and Articles and as may be required by law, the aggregate consideration receivable by all holders of the Preferred Shares and Ordinary Shares shall be allocated among the holders of Preferred Shares and Ordinary Shares on the basis of the relative liquidation preferences to which the holders of each respective series of Preferred Shares and the holders of Ordinary Shares are entitled in a Deemed Liquidation Event (assuming for this purpose that such Approved Sale is a Deemed Liquidation Event) in accordance with the Memorandum and Articles in effect immediately prior to such Approved Sale; provided, however, that, notwithstanding the foregoing provisions of this <u>Section 11.2(f)</u>, if the consideration to be paid in exchange for the Shares held by any Shareholder pursuant to this Section 11.2(f) includes any securities and due receipt thereof by any Shareholder would require under applicable law (x) the registration or qualification of such securities or of any person as a broker or dealer or agent with respect to such securities; or (y) the provision to any Shareholder of any information other than such information as a prudent issuer would generally furnish in an offering made solely to "accredited investors" as defined in Regulation D promulgated under the Securities Act, the Company may cause to be paid to any such Shareholder in lieu thereof, against surrender of the Shares held by the Shareholder, which would have otherwise been sold by such Shareholder, an amount in cash equal to the fair value (as determined in good faith by the Board) of the securities which such Shareholder

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- (g) subject to <u>Section 11.2(f)</u>, requiring the same form of consideration to be available to the holders of any single class or series of capital shares, if any holders of any capital shares of the Company are given an option as to the form and amount of consideration to be received as a result of such Approved Sale, all holders of such capital shares will be given the same option; <u>provided</u>, <u>however</u>, that nothing in this <u>Section 11.2(g)</u> shall entitle any holder to receive any form of consideration that such holder would be ineligible to receive as a result of such holder's failure to satisfy any condition, requirement or limitation that is generally applicable to the Shareholders
- 11.3 Restrictions on Sales of Control of the Company. No Shareholder shall be a party to any Share Sale unless (a) all Preferred Shareholders are allowed to participate in such transaction(s) and (b) the consideration received pursuant to such transaction is allocated among the parties thereto in the manner specified in the Memorandum and Articles as in effect immediately prior to such Share Sale (as if such transaction(s) were a Deemed Liquidation Event), unless the Requisite Holders elect to allocate the consideration differently by written notice given to the Company at least ten (10) days prior to the effective date of any such transaction or series of related transactions.

12. Legend.

12.1 Each existing or replacement certificate for Equity Securities of the Company now owned or hereafter acquired by a Party and their permitted transferees shall bear the following legend:

"THE SALE, PLEDGE, HYPOTHECATION, ASSIGNMENT OR TRANSFER OF THESE SECURITIES IS SUBJECT TO THE TERMS AND CONDITIONS OF A SHAREHOLDERS AGREEMENT (AS AMENDED FROM TIME TO TIME) BY AND BETWEEN THE SHAREHOLDER, THE COMPANY AND CERTAIN OTHER PARTIES THERETO. COPIES OF SUCH AGREEMENT MAY BE OBTAINED UPON WRITTEN REQUEST TO THE COMPANY."

12.2 The Company may annotate its Register of Members with an appropriate, corresponding legend. At such time as Equity Securities are no longer subject to this Agreement, the Company shall, at the request of the holder of such Equity Securities, issue replacement certificates for such Equity Securities without such legend. In order to ensure compliance with the terms of this Agreement, the Company may issue appropriate "stop transfer" instructions to its transfer agent, if any, and, if the Company acts as transfer agent for its own securities, it may make appropriate notations to the same effect in its own records.

13. Additional Covenants.

- **13.1 Anti-corruption, Anti-sanction and Anti-money Laundering Undertakings.** Promptly following the Closing, each Group Company shall:
- (a) maintain an anti-corruption compliance program reasonably designed to prevent the violation of applicable Anti-Corruption Laws, including a code of conduct of the Group Companies (including a written travel and entertainment policy). The anti-corruption

compliance program shall include (i) written anti-corruption and anti-bribery policies and procedures that are reasonably designed to ensure compliance with applicable Laws, (ii) routine and periodic compliance trainings for the employees conducted by the Company or by a third party, (iii) the maintenance of internal controls sufficient to prevent, detect and deter violations of applicable Anti-Corruption Laws, (iv) risk-based diligence on relevant third parties and, where appropriate, compliance terms in third party contracts, (v) measures reasonably designed to ensure that any health care professionals, Public Officials, consultants or other relevant third parties retained by any Group Company are paid fair market value, and mitigate any improper conflict of interest or corruption risks associated therewith, (vi) measures reasonably designed to mitigate anti-corruption risks associated with product donations or other charitable donations, (vii) measures reasonably designed to mitigate anti-corruption risks associated with the provision of gifts, meals, entertainment, travel or lodging to third parties, (viii) adequate resources and employees expertise dedicated to ethics and anticorruption compliance and (ix) periodic internal audits or reviews to assess the compliance program's effectiveness;

- (b) comply in all material respects with all Anti-Corruption Laws; <u>provided</u> that without limiting the generality of the foregoing, each of the Group Companies shall not violate, and shall use reasonable best efforts to prevent any of the Group Companies or any of its Representatives, acting for or on behalf of the foregoing (the "<u>Group Affiliates</u>") from violating, any Anti-Corruption Laws;
- (c) maintain systems of internal controls (including, but not limited to, accounting systems, purchasing systems and billing systems) that are reasonably designed to ensure compliance with Anti-Corruption Laws;
- (d) not directly or indirectly use the proceeds of this transaction, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person for the purpose of (i) funding or facilitating any activities or business of or with any person towards any sales or operations in any Sanctioned Country or (ii) funding any operations or financing any investments in, or make any payments to, any person targeted by or subject to any Sanctions; and
- (e) operate at all times in compliance with applicable anti-money laundering statutes of all applicable jurisdictions, including Chinese and U.S. anti-money laundering laws, the rule and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental or regulatory agency.
- **13.2 Incentive Plan.** Unless otherwise approved by the Board, all shares, options or other securities or awards granted or issued under the Incentive Plan shall vest for a period of four years, with the first twenty-five percent (25%) of such shares or shares underlying the options or other securities or awards to vest as of the first anniversary of the vesting commencement date and the remaining to vest in twelve (12) equal installments over the next twelve (12) quarters, subject generally to the recipient continuing to be an employee of, or otherwise provide services to, a Group Company.
- 13.3 Employee Matters. Unless otherwise approved by the Board, the each Group Company will cause (i) each Person now or hereafter employed by it or by any other Group Company (or engaged by a Group Company as a consultant/independent contractor) with access to confidential information and/or trade secrets to enter into a nondisclosure, proprietary rights assignment and non-solicitation agreement. In addition, the Company shall not amend, modify, terminate, waive, or otherwise alter, in whole or in part, any of the above-referenced

agreements or any restricted stock agreement between the Company and any employee, without the consent of the Board.

13.4 No Avoidance; Voting Trust. The Company will not, by any voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be performed hereunder by the Company, and the Company will at all times in good faith assist and take action as appropriate in the carrying out of all of the provisions of this Agreement. Each holder of Shares agrees that it shall not enter into any other agreements or arrangements of any kind with respect to the voting of any Shares or deposit any Shares in a voting trust or other similar arrangement.

13.5 United States Tax Matters.

- (a) None of the Group Companies will take any action inconsistent with its treatment of the Company as a corporation for U.S. federal income tax purposes or elect to be treated as an entity other than a corporation for U.S. federal income tax purposes.
- (b) The Company shall use, and shall cause each of its Subsidiaries to use, its best efforts to arrange its management and business activities in such a way that the Company and each of its Subsidiaries are not treated as residents for tax purposes, or is otherwise subject to income tax in, a jurisdiction other than the jurisdiction in which they have been organized.
- The Company shall use its best effort to avoid future status of the Company or any of its (c) Subsidiaries as a PFIC. Within 45 days from the end of each taxable year of the Company, the Company shall determine, in consultation with a reputable accounting firm, whether the Company or any of its Subsidiaries was a PFIC in such taxable year (including whether any exception to PFIC status may apply). If the Company determines that the Company or any of its Subsidiaries was a PFIC in such taxable year (or if a Governmental Authority or an Investor informs the Company that it has so determined), it shall, within 60 days from the end of such taxable year, provide the following information to each holder of Preferred Shares that is a United States Person ("Direct U.S. Investor") and each United States Person that holds either direct or indirect interest in such holder ("Indirect U.S. Investor") (hereinafter, collectively referred to as a "PFIC Shareholder"): (i) all information reasonably available to the Company to permit such PFIC Shareholder to (1) accurately prepare its U.S. tax returns and comply with any other reporting requirements, if any, arising from its investment in the Company and relating to the Company or any of its Subsidiaries' classification as a PFIC and (2) make any election (including, without limitation, a "qualified electing fund" election under Section 1295 of the Code), with respect to the Company (or any of its Subsidiaries); and (ii) a completed "PFIC Annual Information Statement" as described under Treasury Regulation Section 1.1295-1(g). The Company shall be required to provide the information described above to an Indirect U.S. Investor only if the relevant holder of Preferred Share requests in writing that the Company provide such information to such Indirect U.S. Investor.
- (d) The Company shall use its best efforts to avoid future status of the Company or any of its Subsidiaries as a CFC. Upon written request of a holder of Preferred Shares from time to time, the Company will promptly provide in writing such information concerning its shareholders and the direct and indirect interest holders in each shareholder sufficient for such holder of Preferred Shares to determine whether the Company is a CFC. In the event that the Company does not have in its possession all the information necessary for

the holder of Preferred Shares to make such determination, the Company shall promptly procure such information from its shareholders. The Company shall, upon written request of a holder of Preferred Shares, furnish on a timely basis all information requested by such holder to satisfy its (or any Indirect U.S. Investor's) U.S. federal income tax return filing requirements, if any, arising from its investment in the Company and relating to the Company or any of its Subsidiaries' classification as a CFC. The Company and each of its Subsidiaries shall use their commercially reasonable best efforts to avoid generating for any taxable year in which the Company or any of its Subsidiaries is a CFC, income that would be includible in the income of such holder of Preferred Shares (or any Indirect U.S. Investor) pursuant to Section 951 of the Code.

- (e) The Company shall comply and shall cause each of its Subsidiaries to comply with all record-keeping, reporting, and other requirements that a holder of Preferred Shares inform the Company are necessary to enable such holder to comply with any applicable U.S. tax rules. The Company shall also provide each holder of Preferred Shares with any information reasonably requested by such holder of Preferred Shares to enable such holder to comply with any applicable U.S. tax rules.
- (f) The cost incurred by the Company in providing the information that it is required to provide, or is required to cause to be provided, and the cost incurred by the Company in taking the action, or causing the action to be taken, as described in this <u>Section 13.5</u> shall be borne by the Company.

13.6 Confidentiality.

- (a) The terms and conditions of the Transaction Documents and all exhibits, restatements and amendments hereto and thereto (collectively, the "Confidential Information"), including their existence, shall be considered confidential information and shall not be disclosed by any of the Parties to any other Person except as permitted in accordance with the provisions set forth below.
 - (i) <u>Press Release</u>. None of the Parties shall issue a press release or make any public announcement or other public disclosure with respect to any of the transactions contemplated herein and therein without obtaining the prior written consent of the Company and the Requisite Holders, or use the name of any other Party or any of its Affiliates without obtaining in each instance the prior written consent of such other Party, in each instance such consent not to be unreasonably withheld.
 - (ii) <u>Permitted Disclosure</u>. Notwithstanding the foregoing, each Party may disclose Confidential Information or permit the disclosure of Confidential Information (A) to its Representatives on a need-to-know basis for the performance of its obligations in connection herewith so long as such Party advises each Person to whom any Confidential Information is so disclosed as to the confidential nature thereof and such Person is subject to appropriate nondisclosure obligations, (B) in the case of the Investors, to its auditors, counsel, professional advisors, directors, officers, employees, fund manager, shareholders, partners and Affiliates, and (C) to its current or bona fide prospective investors, investment bankers and any Person otherwise providing debt or equity financing to such Party so long as the Party advises each Person to whom any Confidential Information is so disclosed as to the confidential nature thereof and such Person is subject to appropriate nondisclosure obligations.

- (iii) <u>Legally Compelled Disclosure</u>. If any Party is requested or becomes legally compelled (including pursuant to any applicable tax, securities or other Laws and regulations of any jurisdiction, or by subpoena or any requirement by any Governmental Authority) to disclose the existence or content of any of the Confidential Information in contravention of the provisions of this <u>Section 13.6</u>, such Party shall, to the extent legally permissible, promptly provide the other Parties with written notice of that fact so that such other Parties may seek a protective order, confidential treatment or other appropriate remedy and in any event shall furnish only that portion of the information that is legally required and shall exercise reasonable efforts to obtain reliable assurance that confidential treatment will be accorded such information.
- (iv) Other Exceptions. The confidentiality obligations of the Parties set out in this Section 13.6 shall not apply to (A) information which was in the public domain or otherwise known to the relevant Party before it was furnished to it by another Party hereto or, after it was furnished to that Party, entered the public domain otherwise than as a result of a breach by that Party of this Section 13.6, (B) is or has been independently developed or conceived by a Party without use of the confidential information of any other Party, or (C) is or has been made known or disclosed to a Party by another Person without a breach of any obligation of confidentiality such Person may have to the subject Party.
- (b) The provisions of this <u>Section 13.6</u> shall supersede and replace the provisions of any separate nondisclosure agreement executed by any of the Parties with respect to the transactions contemplated hereby, including any term sheet, letter of intent, memorandum of understanding or other similar agreement entered into by the Company and any Investors in respect of the transactions contemplated hereby.
- (c) Each Party agrees to use, and to use commercially reasonable efforts to ensure that its authorized representatives use, the same degree of care as such recipient uses to protect its own confidential information to keep confidential any information furnished to it which the Company identifies in writing as being proprietary, confidential or like trade secrets except such information pursuant to this <u>Section 13.6</u>.
- 13.7 Right to Conduct Activities. The Company hereby agrees and acknowledges that each of Frazier, Pivotal, Samsara and Versant (together with its respective Affiliates) is a professional investment fund or company, and as such reviews the business plans and related proprietary information of many enterprises and invests capital in numerous portfolio companies, some of which may be deemed competitive directly or indirectly with the Group Companies' businesses as currently conducted or as currently propose to be conducted. Nothing in this Agreement shall preclude or in any way restrict Frazier, Pivotal, Samsara, Versant or any of its respective Affiliates from evaluating or purchasing securities, including publicly traded securities, of a particular enterprise, or investing or participating in any particular enterprise whether or not such enterprise has products or services which compete with those of the Group Companies. The Company hereby agrees that, to the extent permitted under applicable Law, none of Frazier, Pivotal, Samsara, Versant or any of its respective Affiliates shall be liable to any Group Company for any claim arising out of, or based upon, (a) the investment by Frazier, Pivotal, Samsara, Versant or any of its respective Affiliates in any entity competitive with the Company, or (b) actions taken by any partner, officer, employee or other representative of Frazier, Pivotal, Samsara, Versant or any of its respective Affiliates to assist any such competitive company, whether or not such action was taken as a member of the board of directors of such competitive company or otherwise, and whether or not such

action has a detrimental effect on any Group Company; <u>provided, however</u>, that the foregoing shall not relieve (i) Frazier, Pivotal, Samsara, Versant or any of its respective Affiliates from liability associated with the unauthorized disclosure of any Group Company's confidential information obtained pursuant to this Agreement, or (ii) any director or officer of the Company from any liability associated with his or her fiduciary duties to the Company.

Share, neither such Shareholder nor any of its Representatives (collectively, a "Restricted Party") will, directly or indirectly, solicit the services of or employ, as employee, consultant or otherwise, the [***] (each, a "Covered Employee"); provided, however, that the foregoing shall not preclude any Restricted Party from (a) conducting any general solicitation for employees or public advertising of employment opportunities (including through the use of employment agencies) not specifically directed at any Covered Employee or hiring or engaging any Covered Employee as a result of such general solicitation or (b) soliciting or hiring or engaging any Covered Employee who has been terminated without cause by any Group Company at least [***] prior to commencement of any solicitation by the Restricted Party; provided, further, that none of the current and future portfolio companies of any Restricted Party shall be restricted with respect to any Covered Employee by this Section 13.8 so long as such portfolio company does not solicit for employment or other engagement the applicable Covered Employee at the direction of or with encouragement by, or on the basis of information with respect to the applicable Covered Employee obtained from, such Restricted Party.

14. Miscellaneous.

- **14.1 Termination**. This Agreement shall terminate upon mutual consent of the Parties hereto. The provisions of Sections 7, 8, 9, 10, 11 and 13 (other than Sections 13.6 through 13.8) shall terminate upon the earlier to occur of (a) immediately prior to the consummation of the Qualified IPO and (b) the consummation of a Deemed Liquidation Event and completion of full payment and/or distribution of the proceeds, assets or funds to the shareholders of the Company in accordance with the Memorandum and Articles Association. If this Agreement terminates, the Parties shall be released from their obligations under this Agreement, except in respect of any obligation stated, explicitly or otherwise, to continue to exist after the termination of this Agreement (including those under Sections 2 through 6, Section 12, Sections 13.6 through 13.8 and Section 14). If any Party breaches this Agreement before the termination of this Agreement, it shall not be released from its obligations arising from such breach on termination.
- **14.2 Further Assurances.** Upon the terms and subject to the conditions herein, each of the Parties hereto agrees to use its reasonable best efforts to take or cause to be taken all action, to do or cause to be done, to execute such further instruments, and to assist and cooperate with the other Parties hereto in doing, all things necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated by this Agreement.
- **14.3 Assignments and Transfers; No Third Party Beneficiaries.** Except as otherwise provided herein, this Agreement and the rights and obligations of the Parties hereunder shall inure to the benefit of, and be binding upon, their respective successors, permitted assigns and legal representatives, but shall not otherwise be for the benefit of any third party. The rights of any Investor hereunder (including registration rights) are assignable (together with the related obligations) in connection with the transfer of Equity Securities of

the Company held by such Investor but only to the extent of such transfer. This Agreement and the rights and obligations of each other Party hereunder shall not otherwise be assigned without the mutual written consent of the other Parties except as expressly provided herein.

- **14.4 Ordinary Shareholders.** In the event that after the Effective Date, the Company issues Ordinary Shares to any Person, including Ordinary Shares issued upon exercise of options to purchase Ordinary Shares, following which such Person holds Shares constituting 1% or more of Ordinary Shares on a Fully-Diluted Basis, the Company shall, as a condition to such issuance, cause such employee or consultant to execute an Adoption Agreement in the form attached hereto as <u>Schedule III</u>, agreeing to be bound by and subject to the terms of this Agreement as a Party, an "Ordinary Shareholder" and a "Shareholder," and such person shall thereby be bound by, and subject to, all the terms and provisions of this Agreement applicable to an "Ordinary Shareholder" and "Shareholder."
- **14.5 Governing Law.** This Agreement shall be governed by and construed under the Laws of New York, without regard to principles of conflict of laws thereunder.

14.6 Dispute Resolution.

- (a) Any dispute, controversy, or claim arising out of, relating to, or in connection with this Agreement, including with respect to the formation, applicability, breach, termination, validity or enforceability thereof (a "<u>Dispute</u>"), shall be finally resolved by binding arbitration administered in accordance with the Rules of Conciliation and Arbitration of the International Chamber of Commerce (the "<u>ICC Rules</u>") then in effect. Judgment on the arbitration award may be entered in any court having jurisdiction thereof. Notwithstanding the foregoing, in all events, the provisions contained herein shall govern over any conflicting rules which may now or hereafter be contained in the ICC Rules. Arbitration proceedings shall be held in New York, and the language of the arbitration proceedings shall be English.
- (b) The arbitration shall be conducted by a panel of three arbitrators, knowledgeable in the subject matter that is in dispute. Each Party shall name one arbitrator. The chairman shall be selected by mutual nomination by the coarbitrators within thirty (30) days after confirmation or appointment of the last of the co-arbitrators to be confirmed or appointed, or, failing such mutual nomination, shall be selected according to the ICC Rules. No arbitrator shall be or have been an Affiliate, employee, consultant, officer, director or stockholder of either Party or of an Affiliate of either Party, or have a conflict of interest under applicable rules of ethics.
- (c) Either Party may apply to the arbitrator for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award.
- (d) The decision by the arbitrators will be binding and conclusive upon the Parties, their successors and permitted assigns and the Parties will comply with such decision in good faith. The Parties expressly exclude any and all rights to appeal, set aside or otherwise challenge an award by the arbitrators, insofar as such exclusion can validly be made. The arbitrator shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and

attorneys' fees and an equal share of the arbitrator's fees and any administrative fees of arbitration.

- (e) All aspects of the arbitration shall be treated as confidential. Except to the extent necessary to confirm an award or as may be required by Law or the rules of any stock exchange, neither Party nor its representatives nor a witness nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. At the request of either Party, the arbitrators shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable statute of limitations.
- 14.7 Notices. Any notice required or permitted pursuant to this Agreement shall be given in writing and shall be given either personally or by sending it by next-day or second-day courier service, fax, electronic mail or similar means to the address of the relevant Party as shown on such Party's signature page hereto (or at such other address as such Party may designate by fifteen (15) days' advance written notice to the other Parties given in accordance with this Section 14.7). Where a notice is sent by next-day or second-day courier service, service of the notice shall be deemed to be effected by properly addressing, pre-paying and sending by next-day or second-day service through an internationally-recognized courier a letter containing the notice, with a written confirmation of delivery, and to have been effected at the earlier of (a) delivery (or when delivery is refused) and (b) expiration of two (2) Business Days after the letter containing the same is sent as aforesaid. Where a notice is sent by fax or electronic mail, service of the notice shall be deemed to be effected by properly addressing, and sending such notice through a transmitting organization, with a written confirmation of delivery, and to have been effected on the day the same is sent as aforesaid, if such day is a Business Day and if sent during normal business hours of the recipient, otherwise the next Business Day. Notwithstanding the foregoing, to the extent a "with a copy to" address is designated, notice must also be given to such address in the manner above for such notice, request, consent or other communication hereunder to be effective.
- Party hereto will be considered to be cumulative with and in addition to any other rights, powers and remedies which such Party may have at Law or in equity in the event of the breach of any of the terms of this Agreement. The exercise or partial exercise of any right, power or remedy will neither constitute the exclusive election thereof nor the waiver of any other right, power or remedy available to such Party. Without limiting the foregoing, the Parties hereto acknowledge and agree irreparable harm may occur for which money damages would not be an adequate remedy in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the Parties shall be entitled to injunction to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement.
- **14.9 Severability.** In case any provision of this Agreement shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby. If, however, any provision of this Agreement shall be invalid, illegal, or unenforceable under any such applicable Law in any jurisdiction, it shall, as to such jurisdiction, be deemed modified to conform to the minimum requirements of such Law, or, if for any reason it is not deemed so modified, it shall be invalid, illegal, or

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unenforceable only to the extent of such invalidity, illegality, or limitation on enforceability without affecting the remaining provisions of this Agreement, or the validity, legality, or enforceability of such provision in any other jurisdiction.

Amendments and Waivers. Any provision in this Agreement may be amended and the observance thereof may be waived (either generally or in a particular instance and either retroactively or prospectively), only by the written consent of the Company and the Requisite Holders; provided, however, that (a) any provision that specifically and expressly gives a right to a named Investor shall not be amended or waived without the prior written consent of such named Investor: (b) without limiting the generality of the foregoing clause (a), the definition of "Competitor" in Section 1.1, Section 9.1(a)(i), the first sentence of Section 9.5 and this clause (b) shall not be amended or waived without the prior written consent of Chinook for as long as Chinook, together with its Affiliates, continues to hold at least [***] of Series A Preferred Shares purchased by Chinook under the Purchase Agreement or an equivalent amount of Ordinary Shares issued upon conversion thereof (as adjusted for any share dividends, combinations, reclassifications or splits effected after the Effective Date); (c) without limiting the generality of the foregoing clause (a), the definition of "Competitor" in Section 1.1, Section 9.1(a)(ii), the second sentence of Section 9.5 and this clause (c) shall not be amended or waived without the prior written consent of Frazier for as long as Frazier, together with its Affiliates, continues to hold at least [***] of Series A Preferred Shares purchased by Frazier under the Purchase Agreement or an equivalent amount of Ordinary Shares issued upon conversion thereof (as adjusted for any share dividends, combinations, reclassifications or splits effected after the Effective Date); (d) without limiting the generality of the foregoing clause (a), the definition of "Competitor" in Section 1.1, Section 9.1(a)(iii), the third sentence of Section 9.5 and this clause (d) shall not be amended or waived without the prior written consent of Pivotal for as long as Pivotal, together with its Affiliates, continues to hold at least [***] of Series A Preferred Shares purchased by Pivotal under the Purchase Agreement or an equivalent amount of Ordinary Shares issued upon conversion thereof (as adjusted for any share dividends, combinations, reclassifications or splits effected after the Effective Date); and (e) without limiting the generality of the foregoing clause (a), the definition of "Competitor" in Section 1.1, the fourth sentence of Section 9.5 and this clause (e) shall not be amended or waived without the prior written consent of Samsara and Versant for as long as Samsara and Versant, together with their respective Affiliates, continue to hold at least [***] of the aggregate number of Series A Preferred Shares purchased by Samsara and Versant under the Purchase Agreement or an equivalent amount of Ordinary Shares issued upon conversion thereof (as adjusted for any share dividends, combinations, reclassifications or splits effected after the Effective Date). Notwithstanding the foregoing, any Party hereunder may waive any of its rights hereunder without obtaining the consent of any other Party. Notwithstanding anything to the contrary contained herein, (i) this Agreement may not be amended and the observance of any term hereof may not be waived if such amendment or waiver by its terms treats an Investor adversely and in a manner materially different and disproportionate from the other Investors without the written consent of such adversely affected Investor, and (ii) Schedules I and II attached hereto may be amended by the Company from time to time in accordance with the Purchase Agreement to add information regarding additional Investor or pursuant to Section 14.3 or 14.4 to add information about Ordinary Shareholder or permitted transferees without the consent of the other Parties. Any amendment or waiver effected in accordance with this Section 14.10 shall be binding upon all the Parties. The Company shall give prompt written notice of any amendment or modification hereof or waiver hereunder to any Party that did not consent in writing to such amendment, modification or waiver.

- **14.11 No Waiver.** Failure to insist upon strict compliance with any of the terms, covenants, or conditions hereof will not be deemed a waiver of such term, covenant, or condition, nor will any waiver or relinquishment of, or failure to insist upon strict compliance with, any right, power or remedy hereunder at any one or more times be deemed a waiver or relinquishment of such right, power or remedy at any other time or times.
- **14.12 Delays or Omissions.** No delay or omission to exercise any right, power or remedy accruing to any Party under this Agreement, upon any breach or default of any other Party under this Agreement, shall impair any such right, power or remedy of such non-breaching or non-defaulting Party nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of or in any similar breach or default thereafter occurring; nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character on the part of any Party of any breach or default under this Agreement, or any waiver on the part of any Party of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing.
- **14.13 No Presumption.** The Parties acknowledge that any applicable Law that would require interpretation of any claimed ambiguities in this Agreement against the Party that drafted it has no application and is expressly waived. If any claim is made by a Party relating to any conflict, omission or ambiguity in the provisions of this Agreement, no presumption or burden of proof or persuasion will be implied because this Agreement was prepared by or at the request of any Party or its counsel.
- **14.14 Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile and e-mailed copies of signatures shall be deemed to be originals for purposes of the effectiveness of this Agreement.
- **14.15 Entire Agreement.** This Agreement (including the Exhibits and Schedules hereto), the Charter Documents and the Purchase Agreement constitute the full and entire understanding and agreement among the Parties with regard to the subjects hereof, and supersede all other agreements between or among any of the Parties with respect to the subject matter hereof.
- 14.16 Control. In the event of any conflict or inconsistency between any of the terms of this Agreement and any of the terms of any of the Charter Documents for any of the Group Companies, or in the event of any dispute related to any such Charter Document, the terms of this Agreement shall prevail in all respects, the Parties shall give full effect to and act in accordance with the provisions of this Agreement over the provisions of the Charter Documents, and the Parties hereto shall exercise all voting and other rights and powers (including to procure any required alteration to such Charter Documents to resolve such conflict or inconsistency) to make the provisions of this Agreement effective, and not to take any actions that impair any provisions in this Agreement.
- **14.17 Aggregation of Shares.** All Shares held or acquired by any Affiliates shall be aggregated together for the purpose of determining the availability of any rights of any Investor under this Agreement.
- **14.18 Adjustments for Share Splits, Etc.** Wherever in this Agreement there is a reference to a specific number of Shares of the Company, then, upon the occurrence of any

subdivision, combination or share dividend of the relevant class or series of the Shares, the specific number of shares so referenced in this Agreement shall automatically be proportionally adjusted, as appropriate, to reflect the effect on the outstanding shares of such class or series of Shares by such subdivision, combination or share dividend.

- **14.19 Grant of Proxy.** Upon the failure of any Shareholder to vote the Equity Securities of the Company held thereby or to implement the provisions hereof, such Shareholder hereby grants to a Person designated by the Company a proxy coupled with an interest in all Equity Securities of the Company held by such Shareholder, which proxy shall be irrevocable until this Agreement terminates pursuant to its terms or this <u>Section 14.19</u> is amended to remove such grant of proxy in accordance with <u>Section 14.10</u>, to vote all such Equity Securities to implement the provisions of and to achieve the purposes of this Agreement.
- **14.20 Independent Nature of Investors' Obligations and Rights.** The obligations and liabilities (including for all claims, losses, costs or damages, including attorneys' and accountants' fees and expenses and costs of any nature whatsoever) of each Investor under this Agreement are several and not joint, and no Investor is responsible in any way for the performance or conduct of the other parties in connection with the transactions contemplated hereby. Nothing contained herein and no action taken by any Investor pursuant hereto or thereto, shall be or shall be deemed to constitute a partnership, association, joint venture, or joint group with respect to the other Investors. Each Investor agrees that no other party has acted as an agent for such Investor in connection with the transactions contemplated hereby.

[Signature Pages Follow]

COMPANY

SanReno Therapeutics Holdings Limited

By: /s/ Jing Qian

Name: Jing Qian Title: Director

Address:

Suite 2503, 25F, Tower 2, Century Link, 1196 Century Avenue, Shanghai 200122, People's Republic of China

HK SUBSIDIARY

SanReno Therapeutics (Hong Kong) Limited

By: /s/ Jing Qian

Name: Jing Qian Title: Director

Address:

Suite 2503, 25F, Tower 2, Century Link, 1196 Century Avenue, Shanghai 200122, People's Republic of China

INVESTOR:

Chinook Therapeutics, Inc.

By: /s/ Eric Dobmeier

Name: Eric Dobmeier

Title: Chief Executive Officer

Address: 400 Fairview Avenue North

9th Floor

Seattle, WA 98109 Seattle, WA 98109

INVESTOR:

Frazier Life Sciences X, L.P.

By: FHMLS X, L.P.

Its general partner

By: FHMLS X, L.L.C.

Its general partner

By: <u>/s/ Patrick Heron</u>

Name: Patrick Heron Title: Managing Director

Address for Notice:

Frazier Life Sciences X, L.P. Attn: Patrick Heron 70 Willow Rd, Suite 200 Menlo Park, CA 94025

With a copy to:

Frazier Life Sciences X, L.P. Attn: Chief Financial Officer Two Union Square

601 Union St., Suite 3200

Seattle, WA 98101

INVESTOR:

Greatest Guide Limited

By: /s/ Jing Qian

Name: Jing Qian Title: Director

Address:

Suite 2503, 25F, Tower 2, Century Link, 1196 Century Avenue, Shanghai 200122, People's Republic of China

INVESTOR:

Versant Vantage II, L.P.

By:

Versant Vantage II GP, L.P. Versant Vantage II GP-GP, LLC By:

Its: General Partner

By: /s/ Robin Praeger

Name: Robin Praeger Title: Managing Director

Address:

One Sansome Street, Suite 3630 San Francisco, CA 94104

INVESTOR:

Samsara BioCapital, L.P.

By: Samsara BioCapital GP, LLC,

General Partner

By: /s/ Srinivas Akkaraju

Name: Srinivas Akkaraju, MD, PhD

Title: Managing Member

Address: 628 Middlefield Road

Palo Alto, CA 94301

Email:[***]

SCHEDULE I

LIST OF INVESTORS

- 1. Chinook Therapeutics, Inc.
- 2. Frazier Life Sciences X, L.P.
- 3. Greatest Guide Limited
- 4. Versant Vantage II, L.P.
- 5. Samsara BioCapital, L.P.

[SCHEDULE I]

Shareholders Agreement

SCHEDULE II

ORDINARY SHAREHOLDERS

[SCHEDULE I]

Shareholders Agreement

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SCHEDULE III

ADOPTION AGREEMENT

	ADOFTION AGREEMENT		
(the " Holder ") pursamong the Compa hereafter. Capitaliz	option Agreement (" Adoption Agreement ") is executed on		
1.1 reasons (Check the	Acknowledgement . Holder acknowledges that Holder is acquiring certain Shares for one of the following correct box):		
	As a transferee of Shares from a party in such party's capacity as an "Investor" bound by the Agreement, and after such transfer, Holder shall be considered an "Investor" and a "Shareholder" for all purposes of the Agreement.		
	As a transferee of Shares from a party in such party's capacity as an "Ordinary Shareholder" bound by the Agreement, and after such transfer, Holder shall be considered an "Ordinary Shareholder" and a "Shareholder" for all purposes of the Agreement.		
	As a new Investor, in which case Holder will be an "Investor" and a "Shareholder" for all purposes of the Agreement.		
	In accordance with <u>Section 14.4</u> of the Agreement, as a new party who is not a new Investor, in which case Holder will be an "Ordinary Shareholder," "Shareholder" for all purposes of the Agreement.		
	Agreement . Holder hereby (a) agrees that the Shares and any other shares of capital stock or securities reement to be bound thereby, shall be bound by and subject to the terms of the Agreement and (b) adopts the same force and effect as if Holder were originally a party thereto.		
1.3 facsimile number li	Notice . Any notice required or permitted by the Agreement shall be given to Holder at the address or sted below Holder's signature hereto.		
HOLDER:	ACCEPTED AND AGREED:		
By: Name and	Title of Signatory SanReno Therapeutics Holdings Limited		
Address:	By:		
	Title:		
Facsimile Number:	,		

[SCHEDULE I]

Shareholders Agreement

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CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO CHINOOK THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

LICENSE AGREEMENT

This License Agreement (the "Agreement") is entered into on November 24, 2021 (the "Execution Date"), by and between Chinook Therapeutics, Inc., a Delaware corporation with a place of business at 400 Fairview Ave North, 9th Floor, Seattle, WA 98109 ("Chinook" or "Licensor"), and SanReno Therapeutics (Hong Kong) Limited, a limited company organized under the laws of Hong Kong ("Licensee") and wholly owned subsidiary of SanReno Therapeutics Holdings Limited. Licensor and Licensee are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

Recitals

Whereas, SanReno Therapeutics Holdings Limited, Chinook and a few additional Persons have entered into a Series A Preferred Share Purchase Agreement (the "Purchase Agreement") and a Shareholders Agreement, each of even date herewith; and

WHEREAS, Licensee wishes to obtain from Licensor, and Licensor is willing to grant to Licensee, an exclusive license to research, develop, manufacture and commercialize such Licensed Product in the Territory, all on the terms and conditions set forth herein.

Now Therefore, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, Licensee and Licensor hereby agree as follows:

ARTICLE 1 DEFINITIONS

Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized, shall have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

- **1.1 "AbbVie Agreement"** means the License Agreement dated December 16, 2019, executed by and between AbbVie Ireland Unlimited Company and Chinook, as amended from time to time.
- **1.2** "**Accounting Standards**" means, with respect to a Person, generally accepted accounting principles ("**GAAP**") as practiced in the United States, IFRS, or other applicable international standards followed by such Person.
- **1.3** "**Affiliate**" means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party at the time at which the determination of affiliation is being made, but only for the period of time that such Person meets the definition of Affiliate hereunder. For the purpose of this definition, "control" (including, with correlative meaning, the

terms "controlled by" and "under the common control"), means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such Person, whether by the ownership of at least fifty percent (50%) of the voting stock or other ownership interest of such Person, the power to elect or appoint at least fifty percent (50%) of the members of the governing body of such Person through ownership of the outstanding voting securities, by contract or otherwise. For the purposes of this Agreement, (a) Licensor and Licensee shall not be considered Affiliates of each other, and (b) neither Frazier Life Sciences X, L.P. nor Pivotal bioVenture Partners China USD Fund I, L.P., individually or collectively, shall be considered Affiliates of Licensee (nor of SanReno Therapeutics Holdings Limited).

- **1.4** "ATRASENTAN" means the small molecule inhibitor of the endothelin A receptor antagonist set forth in **Schedule 1.4** (ATRASENTAN), including any metabolic precursors. prodrugs, isomers (chiral and otherwise), metabolites, hydrates, anhydrides, solvates, salt forms, free acids or bases, esters, amides, ethers, complexes, conjugates or polymorphs thereof.
- **1.5** "ATRASENTAN Licensed Product" means any pharmaceutical product that contains ATRASENTAN as an active pharmaceutical ingredient (whether alone as the sole active pharmaceutical ingredient or as a combination with other active pharmaceutical ingredient(s)), in any formulation or dosage form and for any mode of administration.
- 1.6 "ATRASENTAN Regulatory Exclusivity" means with respect to an ATRASENTAN Licensed Product in a jurisdiction in the Territory, the rights (other than the Patent Rights) granted by the applicable Regulatory Authority in connection with the MAA approval of the ATRASENTAN Licensed Product, providing the ATRASENTAN Licensed Product: (i) a period of marketing exclusivity, during which the Regulatory Authority will refrain from approving an MAA submitted by a Third Party seeking to market a generic product of the ATRASENTAN Licensed Product, or (ii) a period of data exclusivity, during which a Third Party seeking to market a generic product of the ATRASENTAN Licensed Product is precluded from either referencing or relying upon, without an express right of reference from the dossier holder, the clinical dossier of the ATRASENTAN Licensed Product or relying on previous Regulatory Authority findings of safety or effectiveness with respect to the ATRASENTAN Licensed Product to support the submission, review or approval of an MAA before the Regulatory Authority.
- 1.7 "ATRASENTAN Royalty Term" means, with respect to an ATRASENTAN Licensed Product and each jurisdiction in the Territory, the period beginning on the date of the First Commercial Sale of such ATRASENTAN Licensed Product in such jurisdiction, and ending on the latest to occur of (a) the expiration of the last-to-expire Licensed Patent that includes a Valid Claim that Covers such ATRASENTAN Licensed Product or the Exploitation thereof in such jurisdiction; (b) the [***] of the ATRASENTAN Licensed Product in such jurisdiction, or (c) the expiration of ATRASENTAN Regulatory Exclusivity for the ATRASENTAN Licensed Product in such jurisdiction.
- **1.8** "Background IP" means any Patent Rights, Know-How, and other IP rights that (a) a Party Controls prior to the Effective Date of this Agreement, (b) a Party makes or develops independently and outside the scope of this Agreement, or (c) a Party acquires after the Effective Date outside the performance of the activities under this Agreement.

- **1.9** "BION-1301" means the humanized IgG4 monoclonal antibody set forth in **Schedule 1.9** (BION-1301), together with all derivatives of the foregoing.
- **1.10** "BION-1301 Clinical Trial" means the Clinical Trial sponsored by Licensor entitled "Safety and Tolerability of BION-1301 in Healthy Volunteers and Adults with IgA Nephropathy (IgAN)" (NCT03945318; Licensor internal reference ADU-CL-19).
- **1.11** "BION-1301 Licensed Product" means any pharmaceutical product that contains BION-1301 as an active pharmaceutical ingredient (whether alone as the sole active pharmaceutical ingredient or as a combination with other active pharmaceutical ingredient(s)), in any formulation or dosage form and for any mode of administration.
- **1.12** "Business Day" means a day other than Saturday, Sunday or any other day on which banking institutions in the United States or in the Territory are required by Law to close.
- **1.13** "Calendar Quarter" means each successive period of three (3) months ending on March 31, June 30, September 30 and December 31 of each Calendar Year; provided that the first Calendar Quarter for the first Calendar Year extends from the Effective Date to the end of the then-current Calendar Quarter and the last Calendar Quarter extends from the first day of such Calendar Quarter until the effective date of the termination or expiration of this Agreement.
- **1.14** "Calendar Year" means each successive period of twelve (12) months commencing on January 1 and ending on December 31; provided that the first Calendar Year under this Agreement will be the period beginning on the Effective Date and ending on the end of the Calendar Year in which the Effective Date is encompassed and the last Calendar Year of the Term will be the period beginning on January 1 and ending on the effective date of expiration or termination of this Agreement.
- **1.15** "Change of Control" means, with respect to any Person, a transaction or a series of related transactions involving (a) a consolidation or merger of such Person which results in the shareholders of such Person immediately prior to the transaction owning less than a majority of the equity or voting power of the surviving entity, (b) the sale, transfer, exclusive license, lease or other disposition of all or substantially all of such Person's assets taken as a whole together with any assets of its subsidiaries, or (c) any sale, transfer or other disposition of all or substantially all of such Person's equity or any other transaction which results in the shareholders of such Person immediately prior to the transaction owning less than a majority of the equity or voting power of the surviving entity; provided that in no event shall a Change of Control be deemed to include (i) any transaction effected solely for the purpose of changing, directly or indirectly, the form of organization or the organizational structure of such Person or its subsidiaries, or (ii) any transaction principally for bona fide equity financing purposes in which cash is received by such Person or any successor or indebtedness of such Person is cancelled or converted or a combination thereof occurs.
- **1.16** "Chasin Agreement" means the Materials Commercial License Agreement date January 7, 2016, executed by and between Lawrence Chasin, Gail Urlaub Chasin and Aduro Biotech, Inc., as amended from time to time.

- **1.17 "Claims"** means all Third Party charges, complaints, demands, claims, actions, proceedings, hearing and investigations.
- **1.18** "Clinical Trial" means a study in humans to obtain information regarding a product, including information relating to the safety, tolerability, pharmacological activity, pharmacokinetics, dose ranging or efficacy of such product.
- **1.19** "CMC ICOS Agreement" means the CHEF1 License Agreement dated December 31, 2015, executed by and between CMC ICOS Biologics, Inc. and Aduro Biotech Europe BV, as amended from time to time.
- **1.20** "Commercialize" or "Commercialization" means all activities directed to marketing, distributing, detailing, offering for sale or selling the Licensed Product (as well as importing and exporting activities in connection therewith), including all medical affairs activities, activities directed to obtaining pricing and reimbursement approvals for the Licensed Product.
- 1.21 "Commercially Reasonable Efforts" means with respect to a Party, those efforts and resources consistent with those typically applied by a biopharmaceutical or biotechnology company of comparable size and resources to such Party and its Affiliates to a product that is at a similar stage of development or commercialization and has similar market potential, taking into account efficacy, safety, patent and regulatory exclusivity, anticipated or approved labeling, present and future market potential, competitive conditions, the profitability of the product in light of pricing and reimbursement issues, and all other relevant factors [***]. Commercially Reasonable Efforts shall be determined on a market-by-market and indication-by-indication basis, and it is anticipated that the level of efforts required may be different for different markets and indications and may change over time, reflecting changes in the status of the Licensed Product and markets involved.
- **1.22** "Confidential Information" of a Party means all non-public or proprietary information (including Know-How and unpublished patent applications) and data of such Party that is: (a) disclosed by or on behalf of such Party or any of its Affiliates or otherwise made available to the other Party, any of its Affiliates, or any of their respective employees, agents or contractors pursuant to or in connection with this Agreement; or (b) that is expressly deemed pursuant to the terms and conditions of this Agreement to be Confidential Information, whether or not disclosed by or on behalf of a Party or any of its Affiliates to the other Party, any of its Affiliates or any of their respective employees, agents or contractors, in each case ((a) or (b)), without regard as to whether any of the foregoing is marked "confidential" or "proprietary," or in oral, written, graphic or electronic form. The terms and conditions of this Agreement are the Confidential Information of both Parties.
- 1.23 "Control" or "Controlled" means, with respect to any Know-How, Patent Rights or other IP, that a Party owns such Know-How, Patent Rights or other IP, or otherwise has the legal authority or right (whether by license or otherwise) to grant a license, sublicense, access or other right (as applicable) under such Know-How, Patent Rights, or other IP to the other Party on the terms and conditions set forth herein, in each case without (a) breaching the terms of any agreement with a Third Party and (b) paying any consideration to any Third Party, except for that which a Party in-licenses and under which the other Party elects to take a sublicense and agrees to

make the associated payments, which will be considered under the Control of such Party. Notwithstanding the foregoing, no Know-How, Patent Rights or other IP will be "Controlled" by a Party hereunder if such Know-How, Patent Rights or other IP are owned or in-licensed by a Third Party that becomes an Affiliate of such Party after the Effective Date as a result of a Change of Control of such Party, but solely to the extent such Know-How, Patent Rights or other IP were owned or in-licensed by such Third Party prior to the consummation of such Change of Control or were developed by such Third Party without referencing or using any Know-How, Patent Rights or other IP or Confidential Information of the other Party after the consummation of such Change of Control.

- **1.24** "Cover," "Covering" and "Covered" means, with respect to a Patent Right and a Licensed Compound or Licensed Product, or a particular method of making or using of such Licensed Compound or Licensed Product, or an Invention, that, in the absence of ownership of or a license under such Patent Right, the making, use and sale of such Licensed Compound or Licensed Product, or the practice of such method to make or use such Licensed Compound or Licensed Product, or the practice of such Invention (as applicable) would infringe a Valid Claim of such Patent Right (or in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).
- **1.25** "**Data Lock**" means, with respect to a Phase I Clinical Trial being conducted by or on behalf of any Party or any of its Affiliates for a ROFN Asset, [***].
 - **1.26** "**Data Package**" means, with respect to a ROFN Asset, the following, to the extent available: [***].
- **1.27** "**Develop"** or "**Development**" means all development activities necessary or useful to obtain or maintain Regulatory Approval for the Licensed Product, including all research, non-clinical studies and clinical trials of the Licensed Product, preclinical and clinical drug development activities and manufacture process development, distribution of Licensed Product for use in clinical trials (including placebos and comparators), statistical analyses, and the preparation and submission of Regulatory Materials for, and all regulatory affairs related to the Licensed Product.
 - **1.28 "Dollar"** means U.S. dollars, and "\$" shall be interpreted accordingly.
 - **1.29** "Effective Date" means the Closing Date (as defined in the Purchase Agreement).
 - **1.30 "Exploit"** or **"Exploitation"** means to Develop, use, Manufacture, register or Commercialize.
- **1.31 "FDA"** means the United States Food and Drug Administration or any successor agency in the U.S. with responsibilities comparable to those of the United States Food and Drug Administration.
- **1.32** "FFDCA" means the U.S. Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.), and any regulations promulgated thereunder.

- **1.33 "Field"** means all therapeutic, prophylactic and diagnostic uses in or for humans or animals.
- **1.34** "**First Commercial Sale**" means the first sale of a Licensed Product by Licensee, its Affiliates or sublicensees to an unrelated Third Party in the Territory after the MAA approval of the Licensed Product has been granted in the Territory. For clarity, First Commercial Sale does not include the supply or transfer of Licensed Product to an Affiliate or sublicensee or for clinical trials, compassionate use or sales made on a named-patient basis.
- **1.35** "**Good Clinical Practice**" or "**GCP**" means the current standards for clinical trials for pharmaceuticals, as set forth in 21 C.F.R. Parts 50, 56, and 312 and applicable equivalent Laws in other jurisdictions to the extent no less stringent.
- **1.36 "Good Laboratory Practice"** or **"GLP"** means the current standards for laboratory activities for pharmaceuticals, as set forth in 21 C.F.R. Part 58 and applicable equivalent Laws in other jurisdictions to the extent no less stringent.
- **1.37 "Good Manufacturing Practice"** or "**GMP"** means the current quality assurance standards, as set forth in 21 C.F.R. Parts 210 and 211 and applicable equivalent Laws in other jurisdictions to the extent no less stringent.
- **1.38** "Government Authority" means any federal, state, national, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).
- **1.39** "**IFRS**" means the International Financial Reporting Standards, as promulgated by the International Standards Accounting Board.
- **1.40** "**IND**" means any investigational new drug application (as defined in the FFDCA and in 21 C.F.R. Part 312 or foreign equivalent), clinical trial application, clinical trial exemption or similar or equivalent application filed with the applicable Regulatory Authority for approval to conduct clinical testing of a Licensed Product in humans.
- **1.41** "**Intellectual Property**" or "**IP**" means any and all intellectual property rights (whether registered or unregistered) in Know-How, rights to Inventions, Patent Rights, trademarks and copyrights.
- **1.42** "**Invention**" means any data, results, discovery, finding, process, improvement, method, composition of matter, article of manufacture, patentable or otherwise, that is invented, reduced to practice, or otherwise generated by either Party exercising its rights or carrying out its obligations under this Agreement, whether directly or via its Affiliates, agents, contractors or sublicensees, including all rights, title and interest in and to the IP rights therein.
- **1.43** "**Know-How**" means any proprietary information, including discoveries, improvements, modifications, processes, methods, protocols, formulas, data, inventions, know-how and trade secrets, patentable or otherwise, but excluding any Patent Rights.

- **1.44 "Knowledge"** means, with respect to a Party, such Party's actual knowledge without further inquiry.
- **1.45** "**Law**" means any federal, state, local, regional, provincial, foreign or multinational law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation, or any order by any Government Authority that may be in effect from time to time with respect to the validity or enforceability of this Agreement or activities under this Agreement.
- **1.46 "Licensed Compound"** means either or both of ATRASENTAN and BION-1301, as the context may require.
- **1.47** "**Licensed Know-How**" means all Know-How that (a) is Controlled by Licensor or its Affiliates as of the Effective Date or at any time during the Term and (b) is necessary or reasonably useful for the Exploitation of the Licensed Compound or the Licensed Product, including all applicable Regulatory Materials and raw data in support of Regulatory Approvals for such Licensed Product in the Field in the Territory.
- **1.48** "Licensed Patents" means all Patent Rights that (a) are Controlled by Licensor or its Affiliates as of the Effective Date or at any time during the Term and (b) Cover the Licensed Compound or the Licensed Product (including composition of matter, methods of making and using) or are necessary or reasonably useful for the Exploitation of the Licensed Compound or Licensed Product. Licensed Patents existing as of the Effective Date are set forth in **Schedule 1.48** (Licensed Patents).
- **1.49** "**Licensed Product**" means either or both of ATRASENTAN Licensed Product and the BION-1301 Licensed Product, as the context may require.
 - **1.50** "Licensed Technology" means the Licensed Patents and Licensed Know-How.
- **1.51** "**Licensee Know-How**" means all Know-How in Inventions that (a) is Controlled by Licensee or its Affiliates as of the Effective Date or at any time during the Term and (b) is necessary or reasonably useful for the Exploitation of the Licensed Compound and Licensed Product.
- **1.52** "**Licensee Patents**" means all Patent Rights in Inventions that (a) are Controlled by Licensee or its Affiliates and (b) Cover the Licensed Compound or Licensed Product (including composition of matter, methods of making and using) or are necessary or reasonably useful for the Exploitation of the Licensed Compound or Licensed Product.
 - **1.53** "Licensee Technology" means the Licensee Know-How and Licensee Patents.
- **1.54** "**Losses**" means any and all damages awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses and expenses (including, but not limited to, court costs, interest and reasonable fees of attorneys, accountants and other experts) that are required to be paid to a Third Party with respect to a Claim.
- **1.55** "MAA" or "Marketing Authorization Application" means an application to the appropriate Regulatory Authority for approval to commercially sell a Licensed Product in a

particular jurisdiction and all amendments and supplements thereto, including New Drug Application ("**NDA**") and Biologic License Application ("**BLA**") and equivalent foreign applications, but excluding applications for pricing and reimbursement approval.

- **1.56** "Manufacture" or "Manufacturing" means any activities directed to making, having made, producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a drug or biologic product or compound, or any raw materials thereof, directly or through one or more Third Parties, whether for Development or Commercialization.
- **1.57** "**Manufacturing Cost**" means, with respect to the Licensed Compound and Licensed Product supplied by one Party to the other Party hereunder:
- (a) if the Licensed Compound or Licensed Product is manufactured by such Party's Third Party contract manufacturers, the actual amounts paid by or on behalf of such Party to such contract manufacturers for manufacturing, processing, testing, filling, finishing, packaging and labeling such Licensed Compound or Licensed Product, including any amounts charged by such contract manufacturers (or out of pocket costs incurred by a Party) for the supply of raw materials, precursors or other ingredients that are used in the manufacture of Licensed Compound or Licensed Product (to the extent such amounts are not included in the purchase price paid by such Party to the contract manufacturers for such Licensed Compound or Licensed Product); or
- (b) if the Licensed Compound or Licensed Product (or any precursor or intermediate thereof) is manufactured by such Party itself or its Affiliates, such Party's actual, fully burdened cost of manufacturing, processing, testing, filling, finishing, packaging and labeling the Licensed Compound or Licensed Product, including raw materials, direct labor and benefits, and the proportionate share of indirect manufacturing costs that are reasonably allocable to the manufacture of the Licensed Compound or Licensed Product, and all other reasonable and customary manufacturing-related costs for such Licensed Product (or the Licensed Compound contained therein). For clarity, the fully-burdened cost referenced under this subsection (b) shall be (i) calculated in accordance with such Party's Accounting Standards consistently applied; (ii) calculated on a theoretical full-capacity basis with the percentage allocable to Manufacturing Cost representing the number of units or runs of the Licensed Compound or Licensed Product produced or performed as a percentage of the total number of units or runs, including those of other Licensed Product, that could be manufactured in such facility during a calendar year; and (iii) shall not include any corporate or administrative overhead, or depreciation of fixed assets.
- **1.58** "Net Sales" means, with respect to an ATRASENTAN Licensed Product for any period, the total amount billed or invoiced on sales of such ATRASENTAN Licensed Product during such period by Licensee, its Affiliates, or sublicensees in the Territory to Third Parties

(including wholesalers or distributors), less (without duplication) the following normal and customary deductions:

- (a) trade, cash and quantity discounts;
- **(b)** price reductions or rebates, retroactive or otherwise, imposed by, negotiated with or otherwise paid to governmental authorities, their agencies and purchasers and reimbursers (including Medicare and Medicaid);
- (c) Taxes, duties or other governmental charges (including Taxes on sales (such as sales, value added, or use Taxes) to the extent added to the sale price and set forth separately as such in the total amount invoiced) relating to the sale of such ATRASENTAN Licensed Product, as adjusted for reimbursement, rebates and refunds of or on such Taxes, duties or governmental charges from any Third Party, including pharmaceutical excise Taxes;
- **(d)** amounts repaid or credited by reason of rejections, defects, recalls or returns, or because of retroactive price reductions, including rebates or wholesaler charge backs, or for uncollectible amounts;
- **(e)** freight, insurance, and other transportation charges to the extent added to the sale price and set forth separately as such in the total amount invoiced; and
- **(f)** the portion of administrative fees paid during the relevant time period to group purchasing organizations or pharmaceutical benefit managers relating to such ATRASENTAN Licensed Product.

Net Sales shall not include transfers or dispositions for charitable, pre-clinical, clinical, regulatory, or governmental purposes (other than sales that are paid or reimbursed by government payors). Net sales shall not include sales between or among Licensee, its Affiliates, or sublicensees. Any rebates, chargebacks and other deductions will be fairly and equitably allocated to the ATRASENTAN Licensed Product and other products of Licensee and its Affiliates and sublicensees such that an ATRASENTAN Licensed Product does not bear a disproportionate portion of any such deductions. For purposes of calculating the Net Sales of any ATRASENTAN Licensed Product sold for consideration other than for cash in any jurisdiction, the price for such ATRASENTAN Licensed Product will equal the average price of such ATRASENTAN Licensed Product that are sold for cash in such jurisdiction during the prior Calendar Year (or, if none, the average price of such ATRASENTAN Licensed Product that are sold for cash in the Territory during the applicable calendar quarter) in similar quantities.

If an ATRASENTAN Licensed Product is sold in the form of a combination in either a single finished product or multiple finished products at a single price containing both an ATRASENTAN Licensed Product and one or more other active ingredients that are not ATRASENTAN or ATRASENTAN Licensed Product (a "Combination Product"), the Net Sales of such ATRASENTAN Licensed Product, for the purpose of calculating any royalty owed under this Agreement based on sales of such ATRASENTAN Licensed Product, shall be determined as follows: first, Licensee shall determine the actual Net Sales of such Combination Product (using the above provisions) and then such amount shall be multiplied by the fraction A/(A+B), where A is the sales-volume-weighted average sale price in a particular jurisdiction of the ATRASENTAN

Licensed Product as the only active ingredient in the previous calendar year when sold separately, and B is the sales volume-weighted average sale price in that country in the previous calendar year of any other active ingredient(s) in the Combination Product sold separately. If any other active ingredient(s) in the Combination Product is not sold separately, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product by a fraction A/C where A is the sales-volume-weighted average sale price in a particular country of such ATRASENTAN Licensed Product in the previous calendar year when sold separately, and C is the sales volume-weighted average sale price in that country in the previous year of the Combination Product. If such ATRASENTAN Licensed Product is not sold separately, the adjustment to Net Sales shall be determined by the Parties in good faith to reasonably reflect the fair market value of the contribution of the ATRASENTAN Licensed Product to the total fair market value of such Combination Product.

Subject to the above, Net Sales shall be calculated in accordance with the standard internal policies and procedures of Licensee, its Affiliates, or sublicensees, which must be in accordance with Licensee's Accounting Standards.

- **1.59** "NMPA" means National Medicine Licensed Product Administration of China (formerly known as the China Food and Drug Administration), or its successor.
- **1.60 "Patent Rights"** means all patents and patent applications (which for the purpose of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, reissues, additions, renewals, revalidations, extensions, registrations, pediatric exclusivity periods and supplemental protection certificates and the like of any such patents and patent applications, and any and all foreign equivalents of the foregoing.
- **1.61 "Person"** means any individual, partnership, limited liability company, firm, corporation, association, trust, unincorporated organization or other entity.
- **1.62 "Phase I Clinical Trial"** means a human Clinical Trial of a product, the principal purpose of which is a determination of initial tolerance or safety of such product in healthy volunteers or the target patient population, as described in 21 CFR 312.21(a) (as amended or any replacement thereof), or a similar clinical trial prescribed by the Regulatory Authority in a country other than the United States.
- 1.63 "Pivotal Clinical Trial" means a human Clinical Trial of a Licensed Product on a sufficient number of subjects that, prior to commencement of such Clinical Trial: (a) is designed to establish that such Licensed Product has an acceptable safety and efficacy profile for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such Licensed Product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of such Licensed Product, or a similar clinical study prescribed by the applicable Regulatory Authority; or (b) is a registration trial sufficient for filing a Marketing Authorization Application for such Licensed Product, as evidenced by: (i) an agreement with or statement from the applicable Regulatory Authority on a special protocol assessment or its equivalent; or (ii) other guidance or minutes issued by the applicable Regulatory Authority for such registration trial. For clarity, a Clinical Trial that is accepted by a Regulatory Authority as a

registrational trial to support Regulatory Approval after the commencement of such Clinical Trial shall also be deemed a Pivotal Clinical Trial.

- **1.64** "**Regulatory Approval**" means all approvals granted by any Regulatory Authority, department, bureau, commission, council or other Governmental Authority, which are necessary or useful for and specifically related to the Development, Manufacture or Commercialization of the Licensed Compound or Licensed Product in any country, region or jurisdiction for any indication.
- **1.65** "**Regulatory Authority**" means any applicable regulatory agency, ministry, department or other Government Authority (and any successor thereto) responsible for granting Regulatory Approvals for the Licensed Product.
- **1.66** "**Regulatory Material**" means any regulatory application, submission, notification, communication, correspondence, registration and other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Exploit the Licensed Product in a particular country, region or jurisdiction. For clarity, Regulatory Materials include IND, MAAs and Regulatory Approvals and all supporting documents submitted to or received from an applicable Regulatory Authority relating to any of the applications or Regulatory Approvals.
- 1.67 "Right of Cross-Reference" means, with regard to a Party, an authorization that permits the other Party (or an applicable Regulatory Authority in a country or region in such other Party's territory) to rely on the relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Materials (and any data contained therein) filed or otherwise Controlled by such Party or its Affiliates for the Licensed Product, as necessary for such other Party, its Affiliates or its or their licensees, to conduct a clinical trial, to support an MAA, to support a label expansion, or to support a further indication for such Licensed Product in such country or region or as otherwise expressly permitted or required under this Agreement to enable a Party, its Affiliates or its or their licensees, to exercise its rights or perform its obligations hereunder. To the extent permitted by applicable Laws, a Party may provide a Right of Cross-Reference to the other Party without the disclosure of underlying Confidential Information to the other Party by disclosing such Confidential Information directly to the relevant Regulatory Authority.
- **1.68 "Tax"** means any taxes, levies, duties, charges, or assessments of any nature imposed by any Government Authority.
- **1.69** "**Territory**" means (a) Greater China, including mainland China, Hong Kong, Macau and Taiwan, and (b) Singapore. For clarity, each of mainland China, Hong Kong, Macau and Taiwan, and Singapore shall be deemed a separate jurisdiction for the purpose of this Agreement.
- **1.70** "TI Pharma Agreement" means the Patent Purchase Agreement dated January 30, 2012, executed by and between BioNovion B.V., BioNovion Holding B.V., Stichting Het Nederlands Kanker Instituut, Academisch Medisch Centrum, Universitair Medisch Centrum Groningen, Rijksuniversiteit Groningen, VU Medisch Centrum, Stichting Top Institute Pharma and Pepscan Presto B.V., as amended from time to time.

- **1.71 "Third Party"** means any Person other than a Party or an Affiliate of a Party.
- **1.72** "Valid Claim" means (a) a claim of any issued and unexpired patent whose validity, enforceability, or patentability has not been affected by any of the following: (i) irretrievable lapse, abandonment, revocation, dedication to the public, or disclaimer; or (ii) a holding, finding, or decision of invalidity, revocation, or non-patentability by a court, governmental agency, national or regional patent office, or other appropriate body that has competent jurisdiction, such holding, finding, or decision being final and unappealable or unappealed within the time allowed for appeal, or (b) a claim in a pending patent application which was filed and is being prosecuted in good faith, and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application, for up to [***] from its filing date.
 - **1.73 "United States"** or **"U.S."** means the United States of America and its territories and possessions.
- **1.74 "Upstream Agreements"** means the AbbVie Agreement, the Chasin Agreement, the TI Pharma Agreement, and the CMC ICOS Agreement.
 - **1.75 Interpretation.** In this Agreement, unless otherwise specified:
- (a) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation"; and "for example", "e.g.," and "such as" shall be descriptive and not limiting;
- **(b)** words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;
 - (c) the word "or" is used in the inclusive sense typically associated with the phrase "and/or;"
- **(d)** words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear;
 - (e) a number of days without using a term otherwise defined herein, refers to calendar days;
- (f) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein);
- **(g)** any reference to any Law herein will be construed as referring to such Law and any rules or regulations promulgated thereunder as from time to time enacted, repealed or amended;

- **(h)** any reference herein to any Person will be construed to include the Person's successors and assigns to the extent not prohibited by this Agreement;
- (i) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein shall be interpreted in a correlative manner; and
- **(j)** the Exhibits and other attachments form part of the operative provision of this Agreement and references to this Agreement shall include references to the Exhibits and attachments.

1.76 Additional Definitions. The following table identifies the location of definitions set forth in various Sections of the Agreement:

Defined Terms	Section
Acquired Party	2.4(a)
Agreement	Preamble
Articles	8.2(c)
Bankruptcy Code	6.7
BION-1301 Approval Milestone	5.1(a)
Candidate	2.5(a)
Chinook	Preamble
Chinook Acquired ROFN Asset	2.5(a)
Chinook Developed ROFN Asset	2.5(a)
Chinook ROFN	2.5(a)
Chinook ROFN Asset	2.5(a)
Chinook ROFN Expiration Date	2.5(c)
Chinook ROFN Negotiation Period	2.5(b)
Chinook ROFN Notice	2.5(b)
Chinook ROFN Period	2.5(b)
Chinook ROFN Review Period	2.5(b)
Chinook Transaction	2.5(a)
Combination Product	1.58(f)
Competing Asset	2.4
Contract Manufacturing Organization or CMO	4.3(b)
Deficient Site	4.4(d)(ii)
Dispute	11.8(a)
Excluded Claim	11.8(f)
Execution Date	Preamble
Executive Officers	3.4
Global Development Plan	4.4(b)(ii)
Global Study	4.4(c)
[***]	[***]
[***]	[***]
Global Study Participation Option	4.4(c)
ICC Rules	11.8(a)
Indemnified Party	10.3

Indemnifying Party 10.3 10.3 11.5 10.3 11.5 10.3 11.5 10.3 12.5 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3 10.3		
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Territory-Specific Development Plan 4.4(b)(i)	Territory Infringement	6.4(a)
	Territory-Specific Development Plan	4.4(b)(i)

ARTICLE 2 LICENSE

- **2.1 License to Licensee**. Subject to the terms and conditions of this Agreement, Licensor (on behalf of itself and its Affiliates) hereby grants Licensee:
- (a) an exclusive (even as to Licensor and its Affiliates, subject to Section 2.2), non-transferable (except as provided in Section 11.2), sublicensable (solely as permitted under Section 2.3), fully paid-up and royalty free (except with respect to the ATRASENTAN Licensed Product as set forth in Section 5.2) license under the Licensed Technology to Exploit the Licensed Product in the Field solely in the Territory; and
- **(b)** a non-exclusive, non-transferable (except as provided in Section 11.2), sublicensable (solely as permitted under Section 2.3), and royalty-free license under the Licensed Technology to Manufacture the Licensed Compound and the Licensed Product outside the Territory solely for supply to Licensee, its Affiliates or sublicensees for Development and Commercialization of the Licensed Product in the Territory, provided that Licensee will not practice under the license granted under this Section 2.1(b) unless and until Licensor provides its prior written consent, such consent not to be unreasonably withheld or delayed.

2.2 Licensor Retained Rights; License to Licensor.

- (a) Notwithstanding the grant in Section 2.1, Licensor retains the right under the Licensed Technology, and Licensee hereby grants Licensor the right under the Licensee Technology, in each case, with the right to grant sublicenses (through multiple tiers), to Develop, Manufacture and have Manufactured Licensed Compounds and Licensed Products anywhere in the world (including clinical Development activities in the Territory) for obtaining Regulatory Approval of Licensed Products in any indications outside the Territory, provided that with respect to any clinical Development activities in the Territory, [***].
- **(b)** Subject to the terms and conditions of this Agreement, Licensee (on behalf of itself and its Affiliates) hereby grants Licensor an exclusive (even as to Licensee but subject to Licensee's exercise of its rights under Section 2.1(b)), royalty-free, fully paid-up, perpetual, sublicensable (through multiple tiers) license under the Licensee Technology to Exploit the Licensed Product solely outside the Territory.
- **2.3 Sublicenses.** Licensee shall have the right to grant sublicenses (through multiple tiers) to its Affiliates and Third Parties under its license in Section 2.1, provided that, Licensee shall not grant such sublicenses to any Third Party without the prior written consent of Licensor (except as may be necessary in connection with the engagement of a Third Party contract services provider to Develop, Manufacture and/or Commercialize the Licensed Products on Licensee's behalf, solely in the Territory), such consent not to be unreasonably withheld or delayed. Each sublicense shall include the following obligations: (a) a requirement that the sublicensee comply with all applicable terms of this Agreement, (b) if such sublicense contains a right to Commercialize Licensed Products, such sublicense will also contain the following provisions: (i) a requirement that the sublicensee submit applicable sales or other reports to Licensee to the extent

necessary or relevant to the reports required to be made or records required to be maintained under this Agreement, and (ii) a requirement that such sublicensee submit to the audit requirement set forth in Section 5.7, and (c) provisions whereby Licensee obtains (i) assignment and transfer of ownership and possession of, or a right to reference all Regulatory Materials and Regulatory Approvals Controlled by such sublicensee that relate to any Licensed Product (which assignment or right of reference may also be provided directly to Licensee), and (ii) ownership of, or a fully sublicensable (through multiple tiers) license under and to, any Know-How and Patent Rights that are developed by or on behalf of the sublicensee in the performance of such agreement and are reasonably necessary or useful to the Development, Manufacture or Commercialization of Licensed Products (which license shall be exclusive with respect to the right to practice such Know-How and Patent Rights outside the Territory). Licensee shall remain primarily responsible for the acts, errors or omissions, breach, or performance of the obligations hereunder by each of its sublicensees. Licensee shall provide Licensor with a copy of any sublicense agreement it enters into, within thirty (30) days after the execution thereof, provided that such copy may be subject to redaction as Licensee reasonably believes appropriate to protect confidential business information, including financial provisions and other sensitive information as applicable.

- **2.4 Non-Compete.** During the Term, neither Licensee nor any of its Affiliates shall, directly or indirectly, Develop, Manufacture, or Commercialize, or enter into any collaboration or license agreement with, or otherwise authorize or grant any right to, any Third Party in connection with the Development, Manufacture or Commercialization of, any compound or product (other than the Licensed Compound or Licensed Product) having [***] (a "**Competing Asset**"), unless such Competing Asset is an in-licensed Chinook ROFN Asset that is licensed pursuant to Section 2.5(a). Notwithstanding the foregoing, on a Licensed Product-by-Licensed Product basis, if Chinook in-licenses or acquires (other than through a Change of Control) a Competing Asset of such Licensed Product from a Third Party or internally develops a Competing Asset of such Licensed Product to the stage of triggering notice to Licensee of the Chinook ROFN and Chinook ROFN Review Period under Section 2.5(b), and Licensee exercises its rights under the Chinook ROFN Notice but the Parties fail to mutually agree on the terms of a Chinook Transaction with respect to such Competing Asset prior to the expiration of the Chinook Negotiation Period, under Section 2.5(b), then this Section 2.4 [***].
- **(a) Business Combinations.** Neither Licensee nor its Affiliates shall be in breach of the restrictions set forth in this Section 2.4 if Licensee or such Affiliate undergoes a Change of Control with a Third Party (together with such Third Party and its Affiliates following the closing of the applicable Change of Control transaction, the "**Acquired Party**") that is (either directly or through an Affiliate, or in collaboration with or license to or from a Third Party) Developing, Manufacturing or Commercializing one or more Competing Assets at the closing of the Change of Control transaction, and such Acquired Party may continue to Develop, Manufacture or Commercialize such Competing Assets as long as: (i) no Licensed Technology is used by or on behalf of such Acquired Party or its Affiliates in connection with any subsequent Development, Manufacture or Commercialization of such Competing Assets, and (ii) such Acquired Party institutes commercially reasonable technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (i) are met, including by creating "firewalls" between the personnel working on Developing such Competing Assets and the personnel teams charged with working on Development of the Licensed Product.

2.5 Chinook ROFN.

- (a) <u>ROFN</u>. Beginning on the Effective Date and until the Chinook ROFN Expiration Date, with respect to [***] (a "Candidate") and that is (i) researched, discovered, developed, or conceived of by Licensor or its Affiliates (each a "Chinook Developed ROFN Asset") or (ii) in-licensed or acquired by Licensor or its Affiliates from a Third Party (other than a license or acquisition under terms that would be breached by Licensor's entering into a license agreement with Licensee in the Territory with respect to such asset) (each a "Chinook Acquired ROFN Asset" and together with any Chinook Developed ROFN Asset, each such Candidate, a "Chinook ROFN Asset"), Licensee shall have an exclusive right of first negotiation (the "Chinook ROFN") to enter into a license agreement [***] to Develop, Manufacture and Commercialize such Chinook ROFN Asset in the Field in the Territory (a "Chinook Transaction").
 - **(b)** ROFN Exercise. Within [***] following:
 - (i) [***], or
 - (ii) [***]

in each case in any jurisdiction, Chinook shall provide a written notice to Licensee thereof and shall provide to Licensee a Data Package for such Chinook ROFN Asset. If Licensee intends to exercise the Chinook ROFN to negotiate for a Chinook Transaction with respect to such Chinook ROFN Asset, then within [***] after receiving the Data Package (the "Chinook ROFN Review Period"), Licensee shall provide written notice to Chinook of Licensee's intention (the "Chinook ROFN Notice"). Upon receipt of the Chinook ROFN Notice, Licensee and Chinook shall, in good faith, negotiate exclusively for a Chinook Transaction with respect to the applicable Chinook ROFN Asset for a period of [***] (the "Chinook ROFN Negotiation Period"); together with the Chinook ROFN Review Period, the "Chinook ROFN Period"). During the Chinook ROFN Period, Licensee may reasonably request Chinook to clarify any information contained in the Data Package, or supplement the Data Package with additional information, data or results. Within five (5) Business Days of receiving such request, Chinook shall provide such clarification and shall provide such additional information, data or results to the extent then in existence and available to Chinook.

(c) Expiration. On a Chinook ROFN Asset-by-Chinook ROFN Asset basis, Licensee's Chinook ROFN shall expire, and Sections 2.5(a) through 2.5(d) shall no longer apply with respect to such Chinook ROFN Asset, upon the earlier of (i) if Licensee does not provide the Chinook ROFN Notice to Chinook within the Chinook ROFN Review Period, the expiration of the Chinook ROFN Review Period; and (ii) if Licensee and Chinook do not consummate or agree to consummate a Chinook Transaction with respect to such Chinook ROFN Asset within the Chinook ROFN Negotiation Period, the expiration of the Chinook ROFN Negotiation Period (the "Chinook ROFN Expiration Date"). Section 2.5(a) through 2.5(d) shall no longer apply with respect to any Chinook ROFN Asset upon the earlier of (1) the effective date of a [***], or (2) the date on which Chinook no longer owns at least [***].

Limitations. Notwithstanding the foregoing, the obligations set forth in this Section 2.5 will not restrict Chinook or its Affiliates from entering into (i) any agreement between Chinook or its Affiliates and any academic, government, or not-for-profit Third Party, (ii) any agreement between Chinook or its Affiliates and any contract research organization, contract manufacturing organization, or other Third Party under which such Third Party performs contract services on behalf of Chinook or its Affiliates that would grant such Third Party any license relating to the Chinook ROFN Assets in all or any portion of the Territory for the purpose of providing such services; and (iii) any license or collaboration with a Third Party for global rights (including the Territory) to Develop, Manufacture or Commercialize a Chinook ROFN Asset in which the Phase I Clinical Trial Database Lock for such asset has not yet occurred, provided that, such Third Party agrees to be subject to the Chinook ROFN set forth in Section 2.5 herein, including Licensee's right to exercise the Chinook ROFN to enter into a license agreement [***] under which such Third Party grants to Licensee or an Affiliate designated by Licensee an exclusive sublicense under Patent Rights and Know-How Controlled by Licensor or its Affiliates to Develop, Manufacture and Commercialize such Chinook ROFN Asset in the Field in the Territory.

2.6 Licensee ROFN.

- (a) <u>ROFN</u>. Beginning on the Effective Date and until the Licensee ROFN Expiration Date, with respect to any Candidate that is (i) researched, discovered, developed, or conceived of by Licensee or its Affiliates (each a "Licensee Developed ROFN Asset") or(ii) in-licensed or acquired by Licensee or its Affiliates from a Third Party (other than a license or acquisition under terms that would be breached by Licensee's entering into such license agreement with Chinook for such asset) (each a "Licensee Acquired ROFN Asset and together with any Licensee Developed ROFN Asset, each such Candidate, a "Licensee ROFN Asset"), Chinook shall have an exclusive right of first negotiation (the "Licensee ROFN") to enter into a license agreement [***] to Develop, Manufacture and Commercialize such Licensee ROFN Asset in the Field outside the Territory (a "Licensee Transaction").
- (b) ROFN Exercise. Within [***] following (i) [***], or (ii) [***], in each case in any jurisdiction, Licensee shall provide a written notice to Chinook thereof and shall provide to Chinook a Data Package for such Licensee ROFN Asset. If Chinook intends to exercise the Licensee ROFN to negotiate for a Licensee Transaction with respect to such Licensee ROFN Asset, then within [***] after receiving the Data Package (the "Licensee ROFN Review Period"), Chinook shall provide written notice to Licensee of Chinook's intention (the "Licensee ROFN Notice"). Upon receipt of the Licensee ROFN Notice, Chinook and Licensee shall, in good faith, negotiate exclusively for a Licensee Transaction with respect to the applicable Licensee ROFN Asset for a period of [***] (the "Licensee ROFN Negotiation Period"); together with the Chinook ROFN Review Period, the "Licensee ROFN Period"). During the Licensee ROFN Period, Chinook may reasonably request Licensee to clarify any information contained in the Data Package, or supplement the Data Package with additional information, data or results. Within five (5) Business Days of receiving such request, Licensee shall provide such clarification and shall provide such additional information, data or results to the extent then in existence and available to Licensee.

- (c) Expiration. On a Licensee ROFN Asset-by-Licensee ROFN Asset basis, Chinook's Licensee ROFN shall expire, and Sections 2.6(a) through 2.6(d) shall no longer apply with respect to such Licensee ROFN Asset, upon the earlier of (i) if Chinook does not provide the Licensee ROFN Notice to Licensee within the Licensee ROFN Review Period, the expiration of the Licensee ROFN Review Period; and (ii) if Chinook and Licensee do not consummate or agree to consummate a Licensee Transaction with respect to such Licensee ROFN Asset within the Licensee ROFN Negotiation Period, the expiration of the Licensee ROFN Negotiation Period (the "Licensee ROFN Expiration Date"). Section 2.6(a) through 2.6(d) shall no longer apply with respect to any Licensee ROFN Asset upon the earlier of (a) the effective date of a [***], or (b) the date on which Chinook no longer owns at least [***]).
- (d) <u>Limitations.</u> Notwithstanding the foregoing, the obligations set forth in this Section 2.6 will not restrict Licensee or its Affiliates from entering into (i) any agreement between Licensee or its Affiliates and any academic, government, or not-for-profit Third Party, and (ii) any agreement between Licensee or its Affiliates and any contract research organization, contract manufacturing organization, or other Third Party under which such Third Party performs contract services on behalf of Licensee or its Affiliates that would grant such Third Party any license relating to the Licensee ROFN Assets in all or any portion of the Territory for the purpose of providing such services; and (iii) any license or collaboration with a Third Party for global rights (including the Territory) to Develop, Manufacture or Commercialize a Licensee ROFN Asset in which the Phase I Clinical Trial Database Lock for such asset has not yet occurred, provided that, such Third Party agrees to be subject to the Licensee ROFN set forth in Section 2.6 herein, including Chinook's right to exercise the Licensee ROFN to enter into a license agreement [***] under which such Third Party grants to Chinook or an Affiliate designated by Chinook an exclusive sublicense under Patent Rights and Know-How Controlled by Licensee or its Affiliates to Develop, Manufacture and Commercialize such Licensee ROFN Asset.
- **2.7 Reservation of Rights**. No rights, other than those expressly set forth in this Agreement, are granted to either Party under this Agreement, and no additional rights will be deemed granted to either Party by implication, estoppel, or otherwise, with respect to any intellectual property rights. Neither Party nor any of its Affiliates will use or practice any Know-How or Patent Rights licensed or provided to such Party or any of its Affiliates outside the scope of or otherwise not in compliance with the rights and licenses granted to such Party and its Affiliates under this Agreement.
 - 2.8 Upstream Agreements. [***].

ARTICLE 3 GOVERNANCE

- **3.1 Joint Steering Committee.** Within sixty (60) days after the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or the "**JSC**"), composed of [***] representatives of each Party, to oversee and coordinate the Parties' activities in the Territory under this Agreement. The JSC shall in particular:
- (a) provide a forum for and facilitate communications between the Parties with respect to reviewing the research, Development, Manufacture and Commercialization of the Licensed Product in the Territory;
- **(b)** review and approve the Territory-Specific Development Plan and coordinate the clinical Development of the Licensed Product in the Field in the Territory through the Territory-Specific Development Plan;
- (c) review and discuss updates to the Global Development Plan solely as they relate to clinical Development of the Licensed Product in the Field being conducted in the Territory;
- **(d)** provide guidance for and resolve high level conflict during the Development of the Licensed Compound and Licensed Product;
 - (e) coordinate and oversee the technology transfer to be conducted under Section 4.3;
- **(f)** establish joint subcommittees as it deems necessary or advisable for the Development, Manufacture and Commercialization of the Licensed Compound and Licensed Product in the Territory; and
- **(g)** perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or allocated to it by the Parties in writing.
- 3.2 Limitations of JSC Authority. The JSC shall only have the powers expressly assigned to it in this Article 3 and elsewhere in this Agreement and shall not have the authority to: (a) modify or amend the terms and conditions of this Agreement; (b) waive or determine either Party's compliance with the terms and conditions of under this Agreement; (c) decide any such issue in a manner that would conflict with the express terms and conditions of this Agreement; (d) make any decision that, under the terms of this Agreement, requires Licensor's or Licensee's consent, approval or agreement or the consent, approval or agreement of both Parties; or (e) require Licensor or Licensee to conduct any activities outside the scope of this Agreement.

3.3 JSC Membership and Meetings.

(a) Within thirty (30) days following the Effective Date, each Party shall designate its initial members to serve on the JSC. Each JSC member shall have the requisite experience and seniority to enable such representative to make decisions on behalf of the Party who appointed such member with respect to the issues falling within the jurisdiction of the JSC.

Neither Party shall appoint any member to the JSC that is not an employee of such Party or one of its Affiliates without the prior written consent of the other Party. Each Party may replace its representatives on the JSC on written notice to the other Party. Each Party shall appoint one (1) of its representatives on the JSC to act as a co-chairperson of the JSC. The co-chairpersons shall jointly prepare and circulate agendas prior to a JSC meeting and reasonably detailed minutes for each JSC meeting. The Alliance Managers will work with the chairpersons to prepare and circulate agendas and to ensure the preparation and approval of minutes. Such minutes shall provide a description, in reasonable detail, of the discussions at the meeting, a list of material actions and decisions made by the JSC, a list of ongoing action items and a list of material issues not resolved by the JSC. The Parties shall approve in writing the minutes of each meeting promptly, but in no event later than the next meeting of the JSC, provided that, if the Parties cannot agree as to the content of the minutes by the time of the next JSC meeting, such minutes shall be finalized to reflect any areas of disagreement. No fewer than five (5) Business Days prior to each meeting, and in any event as soon as reasonably practicable, each Party shall use reasonable efforts to disclose to the other Party any proposed agenda items together with all appropriate information with respect to such proposed agenda items.

- (b) The JSC shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than once every three (3) months until the MAA approval is obtained with respect to a Licensed Product from the NMPA, and then twice yearly in respect of such Licensed Product thereafter. A Party may request a special meeting upon five (5) Business Days' prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting. The other Party will use reasonable efforts to comply with such request but such other Party will not be in breach of this Agreement in the event that it is unable to comply with such request but is using reasonable efforts to conduct a JSC meeting as promptly as practicable. Meetings of the JSC may be held in person, by audio or video teleconference. In person JSC meetings shall be held at locations selected alternatively by the Parties, and such selecting Party shall be responsible for meeting logistics. Each Party shall be responsible for all of its own expenses of participating in the JSC. No action taken at any meeting of the JSC shall be effective unless at least one (1) representative from each Party is participating.
- (c) Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend the JSC meetings in a non-voting capacity; provided that such participants shall be bound by confidentiality and non-use obligations consistent with the terms of this Agreement and that each Party shall provide prior written notice to the other Party if it has invited any Third Party (including any consultant) to attend such a meeting; provided further that any JSC meeting that includes attendees of either Party who are not JSC members may, at the request of any JSC member, include a closed session consisting of only JSC members.
- **3.4 Decision-Making.** All decisions of the JSC shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC that is within its authority, the representatives of the Parties cannot reach unanimous agreement as to such matter within [***] after such matter was brought to the JSC for resolution, such disagreement shall be referred to the Chief Executive Officer of Licensor and the Chief Executive Officer of Licensee,

or his or her designated direct report (the "Executive Officers"), for resolution. If the Executive Officers do not resolve such matter within [***] after such matter has been referred to them, then: Licensee shall have the final decision making authority with respect to [***]; provided that neither Party shall exercise its final decision-making authority to [***].

ARTICLE 4 DEVELOPMENT AND COMMERCIALIZATION

- **4.1 General.** Subject to the terms and conditions of this Agreement, Licensee shall be solely responsible for the Development, Manufacture and Commercialization of the Licensed Product in the Field in the Territory pursuant to the Territory-Specific Development Plan agreed to by the JSC, at Licensee's own cost and expense, in a good scientific manner and in compliance with applicable Law.
- **4.2 Diligence.** Licensee (either by itself or through its Affiliates and sublicensees) shall use Commercially Reasonable Efforts to obtain MAA approval in the Field in the Territory for one ATRASENTAN Licensed Product and for one BION-1301 Licensed Product.

4.3 Technology Transfer.

- (a) IND Filing Transfer. Within [***] after the Effective Date, Licensor shall transfer to Licensee all Licensed Know-How described on Schedule 4.3(a) (Licensed Know-How). During the Term, following the initial transfer of Licensed Know-How, upon Licensee's request, Licensor shall disclose or make available to Licensee any additional Licensed Know-How requested by Licensee that was not previously provided to Licensee and that is required or reasonably useful to Develop or Commercialize the Licensed Product according to the Territory-Specific Development Plan. Upon Licensee's request [***], Licensor shall assign to Licensee any IND filing for the ATRASENTAN Product already entered, and all Regulatory Materials Controlled by Licensor or its Affiliates in the Territory related to the Licensed Compound or Licensed Product. Licensor shall execute such documents as Licensee reasonably requests to confirm such assignment(s) and hereby authorizes Licensee to submit such confirmation documents on Licensor's behalf to applicable Regulatory Authorities in the Territory or, if directed in writing by Licensee, Licensor shall submit such documents to applicable Regulatory Authorities in the Territory. Licensee shall be responsible for the costs of the transfers and assignments described in this Section 4.3(a).
- Manufacturing Technology Transfer. Licensor acknowledges and agrees to the importance of Manufacturing Licensed Product in mainland China to enable Licensee to achieve its Development and regulatory strategy, and to maximize commercial success, which success inures to the direct and indirect benefit of Licensor. Upon receiving a notice and request from Licensee, the Parties shall discuss in good faith through the JSC and agree to a technology transfer plan (the "Technology Transfer Plan"), under which Licensor shall, enable Licensee, Licensee's mainland China-based manufacturer, or other Third Party designee of Licensee (each such manufacturer or designee, a "Contract Manufacturing Organization" or "CMO") with all Licensed Technology necessary or reasonably useful to Manufacture the Licensed Compound and/or the Licensed Product for Exploitation in the Territory at a mutually-agreed upon time, and

at no cost to Licensee other than any amounts charged by Licensee's CMO. Such CMO must be approved by Licensor (such approval not to be unreasonably withheld or delayed). Licensee would enter into a manufacturing agreement with such CMO for the supply of the Licensed Compound and/or Licensed Product to Licensee for Exploitation in the Territory. Notwithstanding the foregoing, Licensor and Licensee agree that the Technology Transfer Plan shall be agreed and the Technology Transfer Plan activities shall be completed no later than filing of an MAA for the Licensed Product in the Territory.

(c) Ongoing Transfer. If any additional Licensed Know-How existing as of the Effective Date, or subject to Licensee's exercise of its options in Section 4.4(c), that is generated following the Effective Date, comes into Licensor's Control during the Term of this Agreement (including any data resulting from the Development of the Licensed Compound and Licensed Product outside the Territory), Licensor shall promptly notify Licensee in writing and provide copies thereof to Licensee's designee). Licensor shall provide all such documents in the English language. Upon Licensee's request, Licensor shall also provide Licensee with reasonable technical assistance, in connection with the practice of the Licensed Technology in the Development and of the Licensed Compound and Licensed Product in the Territory, including reasonable access to Licensor's, its Affiliates' and contractors' (including contract manufacturer's) technical personnel involved in the research, Development of the Licensed Compound and Licensed Product [***].

4.4 Development.

(a) General; Territory and Global Clinical Trials. Licensee (either by itself or through its Affiliates and sublicensees) shall be responsible for the Development of the Licensed Product in the Field in the Territory, including all preclinical studies and all clinical trials of the Licensed Product in the Field that are conducted by or on behalf of Licensee in the Territory, at [***], in accordance with the Territory-Specific Development Plan. Through the JSC, Licensor may review and provide input on the Territory-Specific Development Plan and Development of the Licensed Product in the Field in the Territory, including all clinical trial protocols and amendments. [***]. The JSC shall also generally discuss the design and conduct of Global Studies of the Licensed Product in the Territory designed to support Regulatory Approvals outside the Territory and, upon mutual agreement of the Parties, pursuant to Section 4.4(c), Licensee may participate in such Global Studies that are to be conducted at clinical sites in the Territory.

(b) Development Plans.

(i) Territory-Specific Development Plan. Except for the activities allocated to Licensee under a Global Development Plan, all Development of Licensed Products in the Field for use in the Territory will be conducted pursuant to a written a development and regulatory plan (the "Territory-Specific Development Plan"). The Territory-Specific Development Plan shall be approved by the JSC and will contain in reasonable detail (i) all major Development activities for the Licensed Products (including all non-clinical studies, pre-clinical studies and Clinical Trials to be conducted in the Territory and the trial design thereof) to be conducted in furtherance of obtaining Regulatory Approval of Licensed Products in the Territory (and not outside of the Territory) and (ii) the estimated timelines for achieving such activities. Licensee will update the Territory-Specific Development Plan regularly as appropriate to track

activity thereunder (but in no event less than once per Calendar Year), and either Party may propose modifications to the Territory-Specific Development Plan at any time, subject in each case to approval by the JSC pursuant to Section 3.3. Once approved by the JSC (subject Section 3.4 with respect to final decision-making), each update to the Territory-Specific Development Plan will become effective and supersede the then-current Territory-Specific Development Plan. In the event of any proposed change to the Territory-Specific Development Plan as a result of any interaction with any Regulatory Authority, the JSC will meet as promptly as practicable to review and discuss any such proposed changes and determine an appropriate revision (if any) to the Territory-Specific Development Plan.

- (ii) Global Development Plan. Licensor's global Development of the Licensed Products inside and outside of the Territory will be conducted pursuant to a written global development plan (the "Global Development Plan"). The Global Development Plan will include an outline of all major Development activities, including Global Studies, for the Licensed Product to be conducted throughout the world by Licensor. From time to time, Licensor may make and implement updates to the then-current Global Development Plan for the Licensed Products. To the extent such amendments relate to activities to be conducted by Licensee in the Territory, Licensor will submit such proposed updates to the JSC for review and discussion of such activities.
- Clinical Trial Participation Rights. With respect to ongoing Clinical Trials and in the event Licensor decides, in the exercise of reasonable judgement, that it is necessary to conduct a Pivotal Clinical Trial in the Territory after the Effective Date in order to support filing a Marketing Authorization Application for a Licensed Product in the Field outside the Territory (each, a "Global Study"), Licensee will have the option to participate in such Global Study and include Clinical Trial sites in the Territory, subject to Licensee's agreement to the study design and study protocol for such Global Study ("Global Study Participation Option"). In the event the Licensee elects to participate in such Global Study, such activities will be included in the Territory-Specific Development Plan and Licensee will support Licensor for such Global Study as set forth in the Global Development Plan, including being responsible for (i) [***] and (ii) a [***]. In addition, Licensee will have the option to participate in other Clinical Trials conducted by Licensor in the Territory and such activities including share of costs and expenses shall be determined by the JSC in a similar manner as for a Global Study as described above. However, Licensor shall not (and shall not allow any of its Affiliates or other licensees to) conduct any clinical trial in the Territory if Licensee reasonably believes that such trials present an unreasonable medical or safety risk to the trial subjects.
- **(i)** If Licensee did not elect or elected not to participate in a Global Study prior to initiation of such Global Study, Licensee [***].

(d) Clinical Trial Audit Rights.

(i) Upon reasonable notification by Licensor and at Licensor's cost and expense, and based on an audit scope agreed upon by the Parties, Licensor or its representatives may conduct an audit, to the extent permitted under Licensee's applicable agreements, of Licensee's sublicensees, subcontractors and all Pivotal Clinical Trial Global Study sites (or any other Clinical Trial site in the Territory that Licensor reasonably believes presents an unreasonable medical or safety risk to the trial subjects, provided there has been a prior review and good faith

discussion of the perceived medical or safety risks through the JSC) engaged by Licensee or its Affiliates or sublicensees to perform Licensee's obligations under any Global Development Plan to ensure that the applicable Clinical Trials are conducted in compliance with the Global Development Plan, GCP, and applicable Law and meet Licensor's Clinical Trial standards provided by Licensor from time to time during the Term. Licensee will obtain such audit rights from its sublicensees, subcontractors and Clinical Trial sites engaged by Licensee or its Affiliates and sublicensees to enable Licensor to audit such Persons in accordance with this Section 4.4(d), provided that if Licensee is unable to obtain such audit rights, Licensee will obtain the right to conduct substantially equivalent audits itself and, upon the reasonable request of Licensor, exercise such audit right on Licensor's behalf and provide the results of the audit to Licensor within [***] after becoming available. No later than thirty (30) days after preparing or receiving the audit report, Licensor will provide Licensee with a written summary of Licensor's findings of any deficiencies or other areas of remediation that Licensor reasonably identifies during any such audit. Licensee will remediate any material deficiencies identified in an audit report (whether the audit is conducted by Licensor or Licensee) within [***]. Without limiting the foregoing, Licensee will have the right to be present at any such audit conducted by Licensor pursuant to this Section 4.4(d) of any sublicensees, subcontractors, or Clinical Trial sites.

- (ii) If either Party reasonably determines that any deficiencies with respect to a Clinical Trial site identified pursuant to Section 4.4(d) (each, a "**Deficient Site**") may cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from the conduct of any such Clinical Trial at such Deficient Site, or if the any such deficiencies are not remediated within the time period for remediation specified in Section 4.4(d)(i), then such Party will notify the other Party of such Deficient Site and the Parties will discuss, attempt to agree upon, and implement a remediation plan for such Deficient Site. If the Parties do not agree to such a remediation plan for a Deficient Site that is participating in a Clinical Trial, then [***].
- (iii) Licensee will provide Licensor with copies of all quality oversight or audit reports prepared in connection with any audit that Licensee or its Affiliates or sublicensees conduct of any sublicensee, subcontractor, or Clinical Trial site pursuant to Section 4.4(d) that Licensee or its Affiliates or sublicensees have engaged or are evaluating to potentially engage to fulfill Licensee's obligations under a Global Development Plan no later than [***] after receiving or preparing any such report (as applicable), to the extent permitted under the applicable agreement and subject to redaction as Licensee reasonably believes appropriate to protect confidential business information and other sensitive information as applicable. If Licensor believes in good faith that any such quality oversight or audit report may be necessary in connection with obtaining, supporting, or maintaining one or more Regulatory Approvals for a Licensed Product or for other communications with Regulatory Authorities outside of the Territory, then upon Licensor's request, Licensee will provide a certified translation thereof at Licensor's sole cost and expense.
- **(e) Compliance**. Licensee will conduct, and will ensure that all of its Affiliates, sublicensees, and other Third Party subcontractors conduct Development of the Licensed Product in the Field in the Territory in compliance with applicable Laws.
- **(f) Records.** Each Party shall prepare and maintain, and shall cause its Affiliates and Third Party subcontractors to prepare and maintain, complete and accurate written records, accounts, notes, reports and data with respect to the Development of the Licensed

Compound and Licensed Product, in sufficient detail and in good scientific manner appropriate for Patent Rights and regulatory purposes and in conformity with applicable Law and such Party's standard practices, which records shall reflect all work done and results achieved in connection with the Development of the Licensed Compound and Licensed Product. Each Party shall retain, and cause its Affiliates and Third Party subcontractors to retain, such records for at least five (5) years from the completion of the applicable activities or such longer period as may be required by applicable Law.

4.5 Regulatory.

- (a) Subject to and upon completion of the IND transfer and manufacturing technology transfer described in Sections 4.3(a) and 4.3(b), Licensee (either by itself or through its Affiliates and sublicensees) shall apply for and maintain, at its own cost and expense, all Regulatory Approvals of the Licensed Product in the Field in the Territory. Licensee shall be responsible for the preparation of all Regulatory Materials and all communications and interactions with Regulatory Authorities with respect to the Licensed Product in the Field in the Territory, both prior to and subsequent to Regulatory Approval; provided that Licensee shall provide copies of such Regulatory Materials and communications and interactions to Licensor (together with English translations of any material communications and filings with Regulatory Authorities); provided further that Licensee shall endeavor to provide draft copies [***] in advance to permit Licensor's review and comment (with an reasonably expected ten (10) day turnaround from Licensor) prior to the submission of such proposed communications and filings and Licensor shall have the right to review and comment on all material regulatory communications and Licensee shall consider in good faith any such comments provided in a timely manner; provided further that Licensor shall have the right to review and comment on all Marketing Authorization Applications (including any material supplements and amendments thereto) for a Licensed Product prior to submission to the Regulatory Authority. Licensee or its designee shall file all required regulatory dossiers to obtain (and maintain) Regulatory Approval of the Licensed Product in the Field in the Territory, and shall be the holder of such Regulatory Approvals in the Territory.
- (b) Licensee shall provide Licensor with reasonable advance notice of all scheduled material meetings, conferences and discussions between such Party and any Regulatory Authorities in the Territory pertaining to the Licensed Product. To the extent permitted under applicable Laws, Licensee shall invite Licensor to participate in such meetings, conferences and discussions, and Licensor shall participate at Licensor's sole discretion. In addition, in the event that either Party is notified of any material regulatory or other inquiries or inspections that relate to any Clinical Trial, Development, Manufacture, or Commercialization for a Licensed Compound or Licensed Product, each such Party shall promptly notify the other Party of such inquiries or inspection. To the extent permitted under applicable Laws, Licensee shall invite Licensor to be present and participate in such inquiries or inspections in the Territory.
- **(c)** Prior to Licensee becoming the holder of the MAA (or otherwise assuming control of the Regulatory Approval process for the Licensed Product), Licensor shall maintain, at its own cost and expense, all Regulatory Approvals of the Licensed Product in the Field in the Territory, and the terms and conditions of this Section 4.5 shall apply *mutatis mutandis* to Licensor as if it were Licensee, and to Licensee as if it were Licensor.

- Data Sharing. Each Party shall keep the other Party reasonably informed on the Development of the 4.6 Licensed Compound and Licensed Product in the Territory (in the case of Licensee) or outside the Territory (in the case of Licensor), and the Parties shall discuss the progress and results of the Development of the Licensed Compound and Licensed Product at each regularly scheduled JSC meeting. Each Party shall promptly provide the other Party with electronic copies (unless otherwise required by applicable Law) of all data and results generated from pre-clinical studies and chemistry, manufacturing, and controls activities in the Territory (in the case of Licensee) or outside the Territory (in the case of Licenser) for the Licensed Compound and Licensed Product that fall within the definition of Licensed Know-How and Licensee Know-How with respect to Licensor and Licensee, respectively. Each Party also shall provide the other Party with copies of all clinical reports generated in every clinical trial of the Licensed Product conducted by or on behalf of such Party, its Affiliates, licensees or sublicensees within [***]. Upon reasonable request, each Party shall also provide the other Party with reasonable access to the underlying data and supporting documentation for such clinical reports. Disclosures hereunder shall be treated as disclosures of Confidential Information and subject to the use and disclosure restrictions (and exceptions and authorizations) set forth in Article 7. Further, each Party shall have the right to use and reference such data and results provided by the other Party, without additional consideration, for the purpose of obtaining and maintaining Regulatory Approval of the Licensed Product in the Field in its territory. [***].
- 4.7 Cross Reference. Each Party shall also keep the other Party reasonably informed on the regulatory matters relating to the Licensed Product in its territory and shall provide the other Party with copies of all Regulatory Materials for the Licensed Product submitted to or received from Regulatory Authorities in its territory within [***] after submission or receipt, except that [***]. Each Party hereby grants to the other Party, its Affiliates and (sub)licensees access to, and a Right of Cross-Reference to, all Regulatory Materials filed by or on behalf of such Party (including its Affiliates, licensees and sublicensees) for the Licensed Product in its respective territory and all data generated by or on behalf of such Party (including its Affiliates, licensees and sublicensees) relating to the Licensed Product, including clinical and preclinical data and safety data contained in or referenced in any Regulatory Materials, for the sole purpose of, and to the extent reasonably useful or necessary for, seeking, obtaining and maintaining Regulatory Approvals of the Licensed Product in the Field in such other Party's territory, except that [***].
- 4.8 Pharmacovigilance. Licensor shall establish, hold, and maintain the global safety database for the Licensed Products with respect to information on adverse events concerning the Licensed Products throughout the world, as and to the extent required by applicable Laws. Promptly following the Effective Date, but in no event later than six (6) months thereafter, Licensor and Licensee shall develop and agree to the worldwide safety and pharmacovigilance procedures for the Parties with respect to the Licensed Product, such as safety data sharing and exchange, adverse events reporting and prescription events monitoring, in a written pharmacovigilance agreement (the "Pharmacovigilance Agreement"). Such agreement shall describe the coordination of collection, investigation, reporting, and exchange of information concerning adverse events or any other safety problem of any significance, and Licensed Product quality and Licensed Product complaints involving adverse events, sufficient to permit each Party, its Affiliates, licensees or sublicensees to comply with its legal obligations with respect thereto. The Pharmacovigilance Agreement shall be promptly updated if required by changes in legal requirements. Each Party hereby agrees to comply with its respective obligations under the

Pharmacovigilance Agreement and to cause its Affiliates, licensees and sublicensees to comply with such obligations.

4.9 Manufacture and Supply.

- (a) Until the technology transfer described in Section 4.3 is complete and Licensee is able to establish and commence Manufacturing of the Licensed Product in the Territory, Licensor shall supply to Licensee the Licensed Compound and Licensed Product for pre-clinical and clinical use at [***] of Licensor's Manufacturing Cost; provided that Licensee shall be responsible for [***]. All Licensed Compound and Licensed Product supplied by Licensor shall comply with applicable specifications, shall be Manufactured in compliance with all applicable Laws (including GMP), and shall be accompanied by certificate of analysis and certificate of compliance in accordance with a clinical supply agreement to be entered into by the Parties within a reasonable time period after the Effective Date, which shall include mutually acceptable, customary supply terms consistent with clinical supply agreements between collaboration partners, including manufacturing audit rights and quantity forecast estimates. Licensee further is entitled to audit Licensor's financial records related to its Manufacturing Cost similar to the audit right set forth in Section 5.7.
- (b) After the technology transfer described in Section 4.3 is complete and Licensee is able to establish and commence Manufacturing of the Licensed Product in the Territory, the Parties may discuss and agree, through the JSC, for Licensee to supply to Licensor the Licensed Compound and Licensed Product Manufactured by or on behalf of Licensee for preclinical, clinical or Commercialization use outside the Territory at [***] of Licensee's Manufacturing Cost; provided that Licensor shall be responsible for [***]. To the extent any Licensed Compound or Licensed Product supplied by Licensee will be used for Commercialization of the Licensed Product in the United States, Licensee shall require that its CMO supply Licensed Compound and Licensed Product that meet all the technical specifications identical to those in the U.S., if the Licensed Product manufactured by such CMO are to be sold in the U.S. Licensor is further entitled to audit Licensee's financial records related to its Manufacturing Cost similar to the audit right set forth in Section 5.7.
- (c) In the event that a Party provides the other Party with clinical or commercial supplies of Licensed Compound or Licensed Product pursuant to this Agreement, such receiving Party shall have the right to engage a Third Party auditor reasonably acceptable for the other Party to conduct an audit of the manufacturing sites where such supplies are Manufactured by or on behalf of such audited Party or its Third Party subcontractor or sublicensee, and subject to the terms of any agreement between such audited Party and the applicable Third Party subcontractor or sublicensee. Such audited Party shall facilitate the accommodation of such request with its Third Party subcontractor or sublicensee.
- **4.10 Commercialization.** Licensee (either by itself or through its Affiliates and sublicensees) shall be responsible for all aspects of the Commercialization of the Licensed Product in the Field in the Territory, [***], including: (a) developing and executing a commercial launch and pre-launch plan; (b) negotiating with applicable Governmental Authorities regarding the price and reimbursement status of the Licensed Product; (c) marketing and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing,

invoicing and collection, inventory and receivables; (f) providing patient support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures to applicable Laws relating to the marketing, detailing and promotion of the Licensed Product in the Territory. Licensee will provide Licensor with written notice of the First Commercial Sale of each Licensed Product in the Field in the Territory as soon as reasonably practicable after such event; provided, however, that, Licensee will inform Licensor of such event prior to public disclosure of such event by Licensee.

- **4.11 Commercialization Plan.** All Commercialization of the Licensed Product in the Territory will be conducted pursuant to a Commercialization Plan. No later than [***] prior to the anticipated First Commercial Sale of a Licensed Product in the Territory, Licensee will prepare a draft of a commercial plan for the Commercialization of the Licensed Product in the Field in the Territory, including details with respect to (a) Commercialization timelines, sales force and physician education activities, (b) market development activities including disease awareness campaigns and physician education campaigns, and (c) commercial preparedness and launch readiness (the "Commercialization Plan"). Such draft Commercialization Plan and any material changes to the Commercialization Plan as a result of any interaction with any Regulatory Authority, will be submitted to the JSC for review and discussion.
- **4.12 Diversion**. Subject to applicable Law, each Party hereby covenants and agrees that (a) it and its Affiliates will not, and it will contractually obligate (and use Commercially Reasonable Efforts to enforce such contractual obligation) its licensees, Sublicensees and contractors not to, directly or indirectly, actively promote, market, distribute, import, sell or have sold any Licensed Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like, in the other Party's territory, and (b) neither Party will engage, nor permit its Affiliates, Sublicensees or contractors to engage, in any advertising or promotional activities relating to any Licensed Product for use directed primarily to customers or other buyers or users of such product located in any country, region or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country, region or jurisdiction in the other Party's territory.
- **4.13 Remedial Actions.** Each Party will notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Licensed Product may be subject to any recall, corrective action or other regulatory action with respect to such Licensed Product taken by virtue of applicable Law (a "**Remedial Action**"). The Parties will assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Licensee shall have sole discretion with respect to any matters relating to any Remedial Action for the Licensed Product in the Field in the Territory. In the event that Licensee determines that any Remedial Action with respect to the Licensed Product should be commenced in the Field in the Territory, or if Remedial Action is required by any Regulatory Authority having jurisdiction over the matter, Licensee will control and coordinate all efforts necessary to conduct such Remedial Action in the Field in the Territory. Without limiting either Party's obligations under Article 10, Licensee shall be responsible for the costs, or share of costs, of any Remedial Action for the Licensed Product in the Territory.

ARTICLE 5 Payments

5.1 BION-1301 Milestone Payment.

- (a) Milestone Event. Subject to the remainder of this Section 5.1, Licensee shall pay to Licensor a one-time, non-refundable development milestone payment of Twenty Five Million Dollars (\$25,000,000) upon the first MAA approval for a BION-1301 Licensed Product by the NMPA (the "BION-1301 Approval Milestone"). The BION-1301 Approval Milestone shall be due and payable (i) irrespective of whether such milestone event is achieved by Licensee, its Affiliates or sublicensee and (ii) only if the milestone event is achieved in mainland China. The BION-1301 Approval Milestone is payable only once, regardless of how many times such milestone event is achieved and/or the number of BION-1301 Licensed Products that achieve such milestone event.
- **(b) Payment**. Licensee shall pay to Licensor the milestone payment pursuant to Section 5.1(a) within thirty (30) days after the first achievement of the BION-1301 Approval Milestone.

5.2 ATRASENTAN Royalty Payments.

- **(a) Royalty Rate.** Subject to the remainder of this Section 5.2 and Section 5.3, Licensee shall make quarterly royalty payments to Licensor on the aggregate annual Net Sales of the ATRASENTAN Licensed Product sold in the Territory during the applicable ATRASENTAN Royalty Term, calculated at [***] solely of the portion of aggregated annual Net Sales of the ATRASENTAN Licensed Product sold in the Territory in the applicable Calendar Year that [***]. To be clear, [***]. For illustration, (i) if the aggregate annual Net Sales of the ATRASENTAN Licensed Product sold in the Territory in a Calendar Year are [***], and (ii) if the aggregate annual Net Sales of the ATRASENTAN Licensed Product sold in the Territory in a Calendar Year are [***] is due to Licensor for such Calendar Year.
- **(b) Royalty Conditions.** The royalties under this Section 5.2 shall be subject to the following conditions:
- (i) only one (1) royalty shall be due with respect to each unit of ATRASENTAN Licensed Product, without regard to whether there is more than one Valid Claim of a Licensed Patent Covering such ATRASENTAN Licensed Product;
- (ii) no royalties shall be due upon the sale or other transfer of any ATRASENTAN Licensed Product if (a) such ATRASENTAN Licensed Product is sold as a Combination Product together with any other active pharmaceutical ingredient, and (b) no Valid Claim of any Licensed Patent would Cover such ATRASENTAN Licensed Product if such ATRASENTAN Licensed Product were not sold as a Combination Product together with such other active pharmaceutical ingredient, as applicable;
- (iii) no royalties shall be due upon the sale or other transfer of the ATRASENTAN Licensed Product among Licensee, its Affiliates and sublicensees, but in such

cases the royalty shall be due and calculated upon Licensee's, its Affiliate's or sublicensee's Net Sales of ATRASENTAN Licensed Product to the first independent Third Party; and

- **(iv)** the Net Sales of ATRASENTAN Licensed Product sold in a jurisdiction of the Territory after the expiration of the ATRASENTAN Royalty Term in such jurisdiction shall not be included in the calculation of annual Net Sales to determine the applicable royalty payment.
- (c) Report and Payment. Within thirty (30) days after the end of each Calendar Quarter, commencing with the First Commercial Sale of an ATRASENTAN Licensed Product in the Territory, Licensee shall provide Licensor with a royalty report that contains the following information for the applicable calendar quarter, on an ATRASENTAN Licensed Product-by-ATRASENTAN Licensed Product and jurisdiction-by-jurisdiction basis: (i) the amount of gross sales of the ATRASENTAN Licensed Product, (ii) a calculation of Net Sales of the ATRASENTAN Licensed Product, (iii) a calculation of the royalty payment due on such Net Sales [***] (iv) the exchange rate for such jurisdiction, and (v) the amount of Taxes, if any, withheld to comply with applicable Laws. Licensor shall determine the royalty rates and royalty amounts applicable to Licensee's Net Sales in the Territory [***] within five (5) days of receiving Licensee's royalty report hereunder, and in any event no later than ten (10) days prior to the date of Licensor's invoice for payment of royalties for the applicable calendar quarter. Licensee shall pay Licensor in Dollars the royalties owed (as may be adjusted pursuant to Section 5.3) with respect to Net Sales for such Calendar Quarter within thirty (30) days after the receipt of the invoice issued by Licensor for such calendar quarter.
- **5.3 Licensor's Third Party Payment Obligations.** During the Term, on a Licensed Product-by-Licensed Product basis, [***], in each case, as applicable, that is in effect on the Effective Date, [***], provided that in no event shall such royalties payable to Third Parties for such Licensed Product [***].
- **5.4 Currency; Exchange Rate.** All payments to be made under this Agreement shall be made in Dollars by bank wire transfer in immediately available funds to a bank account designated by written notice from the Party receiving the payment. The rate of exchange to be used in computing the amount of currency equivalent in Dollars shall be made at the average of the closing exchange rates reported in The Wall Street Journal (U.S., Eastern Edition) for the first, middle and last Business Days of the applicable reporting period for the payment due or, if applicable, pursuant to the method set forth in an Upstream Agreement, or any agreement between Licensee and a Third Party.
- **5.5 Late Payments.** If a Party does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due from the due date until the date of payment at a per-annum rate equal to the effective federal funds rate published by the Federal Reserve Bank of New York. Notwithstanding the foregoing, the interest set forth in this Section 5.5 shall not apply if the payment is delayed due to government restriction on currency conversion or transfer of funds out of a jurisdiction in the Territory.

5.6 Taxes.

- (a) Taxes on Income. Each Party shall be solely responsible for the payment of all Taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement. For clarity, all payment amounts in this Article 5 shall be inclusive of all Taxes, which shall be borne by Licensor and may be deducted or withheld by Licensee from the payment pursuant to Section 5.6(b) to the extent such deduction or withholding is required by applicable Law in effect at the time of payment, provided that, to the extent an Upstream Agreement does not permit withholding of Taxes, then Licensee will pay an additional amount to Licensor such that Licensor receives the same net payment owed under such Upstream Agreement.
- **(b) Tax Cooperation.** The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce Tax withholding and export or similar obligations in respect of royalties, milestone payments, and other payments made under this Agreement. To the extent Licensee is required to deduct and withhold Taxes on any payment to Licensor, Licensee shall deduct those Taxes from the remittable payment, pay the Taxes to the proper tax authority in a timely manner, and promptly send proof of payment to Licensor. Licensor shall provide Licensee any tax forms that may be reasonably necessary in order for Licensee to not withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income tax treaty. Licensor shall use reasonable efforts to provide any such tax forms to Licensee in advance of the due date. At the request and expense of Licensor, Licensee shall provide reasonable assistance to enable the recovery, to the extent permitted by Law, of withholding Taxes or similar obligations resulting from payments made under this Agreement.
- 5.7 Financial Records and Audit. Licensee shall endeavor to maintain complete and accurate records in sufficient detail to permit Licensor to confirm the accuracy of Net Sales of ATRASENTAN Licensed Product reported by Licensee under this Agreement. Upon at least sixty (60) days prior notice, such records shall be open for examination, during regular business hours, for a period of three (3) years from the creation of individual records, and not more often than once each Calendar Year, by an independent certified public accountant selected by Licensor and reasonably acceptable to Licensee, for the sole purpose of verifying for Licensor the accuracy of the financial reports provided by Licensee under this Agreement. If the audit discovers any underpayment or overpayment, the amount of such underpayment or overpayment shall be paid or refunded (as the case may be) within sixty (60) days after the account's report, plus interest (as set forth in Section 5.5) from the original due date. Licensor shall bear the cost of such audit unless such audit reveals an underpayment by Licensee of more than ten percent (10%) of the amount actually due for the time period being audited, in which case Licensee shall reimburse Licensor for the costs of such audit.

ARTICLE 6 INTELLECTUAL PROPERTY RIGHTS

6.1 Background IP. All right, title and interest in each Party's Background IP shall remain solely with such respective Party. Except for the licenses expressly granted in this Agreement (including Sections 2.1, 2.2, and 4.7), no license, right, title or interest to a Party's Background IP is transferred or granted to the other Party under this Agreement or through the performance of activities hereunder.

6.2 Inventions. As between the Parties, (a) Licensor shall solely own all Inventions invented or developed solely by or on behalf of Licensor, including its and its Affiliate's employees, contractors and/or agents, and (b) Licensee shall solely own all Inventions invented or developed solely by or on behalf of Licensee, including its and its Affiliate's employees, contractors and/or agents. The Parties shall jointly own all Inventions invented or developed jointly by both Parties. Except to the extent restricted by the licenses and other rights granted to other Party under this Agreement or any other agreement between the Parties, each Party, as joint owners, shall be entitled to practice, license, assign and otherwise exploit its interest in the jointly owned Inventions without the duty of accounting or seeking consent from the other Party.

6.3 Patent Prosecution.

- (a) As between the Parties, Licensee shall have the first right to file, prosecute and maintain all Licensed Patents and all patents Covering jointly-owned Inventions (the "Joint Patents") in the Territory, at Licensee's own cost and expense. Licensor shall have the first right to file, prosecute and maintain the Joint Patents outside the Territory, at Licensor's own cost and expense.
- (b) The prosecuting Party shall consult with the other Party and keep the other Party reasonably informed of the status of the Licensed Patents and Joint Patents and shall promptly provide the other Party with all material correspondence received from any patent authority in the Territory in connection therewith. In addition, the prosecuting Party shall promptly provide the other Party with drafts of all proposed material filings and correspondence to any patent authority with respect to the Licensed Patents in the Territory and the Joint Patents worldwide sufficiently in advance of filing or response to permit the other Party's review and comment prior to the submission of such proposed filings and correspondences. Before the prosecuting Party submits any material filing, including a new patent application, or response to such patent authorities with respect to any Licensed Rights or Joint Patents, the prosecuting Party will provide the other Party with a reasonable opportunity to review and comment on such filing or response and will incorporate any reasonable and timely comments or suggestions provided by the other Party regarding the prosecution of such Licensed Patents or Joint Patents. The Parties shall work together in good faith to coordinate the worldwide prosecution strategy of the Licensed Patents and the Joint Patents.
- (c) The prosecuting Party shall notify the other Party of any decision to cease prosecution or maintenance of any Licensed Patents or Joint Patents in the Territory. The prosecuting Party shall provide such notice at least [***] prior to any filing or payment due date, or any other due date that requires action, in connection with such Licensed Patents or Joint Patents. In such event, upon the other Party's request, the prosecuting Party shall transfer the prosecution and maintenance of such Patent Rights in the Territory to the other Party, and the other Party shall have the right to continue prosecution or maintenance of such Patent Rights in the Territory at the other Party's own expense. Upon transfer of the prosecuting Party's responsibility for prosecuting or maintaining any of the Patent Rights to the other Party under this Section 6.3(c), the prosecuting Party will promptly deliver to the other Party copies of all necessary files related to the Patent Rights with respect to which responsibility has been transferred and will take all actions and execute all documents reasonably necessary for the other Party to assume such prosecution and maintenance.

(d) Each Party shall provide the other Party all reasonable assistance and cooperation in the prosecution efforts under this Section 6.3, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution, and including with respect to obtaining patent term restoration, supplemental protection certificates or their equivalents, and patent terms extension with respect to the Licensed Patents and Joint Patents in any jurisdiction where applicable.

6.4 Patent Enforcement.

- (a) Each Party shall promptly notify the other Party if it becomes aware of any suspected, alleged, threatened, or actual infringement by a Third Party of any Licensed Patents or Joint Patents in the Territory (the "Territory Infringement"). Each Party also shall promptly notify the other Party if it becomes aware of any suspected, alleged, threatened, or actual infringement by a Third Party of any Joint Patents outside the Territory.
- (b) As between the Parties, (i) Licensee shall have the first right to bring and control any legal action in connection with any Territory Infringement within the scope of the exclusive license granted to Licensee in Section 2.1(a) or any Joint Patent in the Field in the Territory, and (ii) Licensor shall have the first right to bring and control any legal action in connection with any suspected, alleged, threatened, or actual infringement by a Third Party of any Joint Patents outside the Territory (any such action, an "Infringement Action") at its own expense and as it reasonably determines appropriate. The other Party shall have the right to be represented in any such Infringement Action by counsel of its choice at its own expense. If the Party having the first right to being an Infringement Action does not bring such Infringement Action within (i) [***] after the notice provided pursuant to Section 6.4(a) or (ii) [***] before the time limit, if any, set forth in the appropriate Laws for the filing of such actions, whichever comes first, or notifies the other Party of its decision not to bring or continue any Infringement Action, then the other Party shall have the right, but not the obligation, to bring and control such Infringement Action at its own expense as it reasonably determines appropriate.
- (c) At the request and expense of the Party bringing the action under Section 6.4(b) above, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required. In connection with any such proceeding, the Party bringing the action under Section 6.4(b) shall keep the other Party reasonably informed on the status of such action and shall not enter into any settlement admitting the invalidity of, or otherwise impairing the other Party's rights in, the Licensed Patents or Joint Patents or any of such other Party's rights in any of its Patent Rights, without the prior written consent of the other Party (not to be unreasonably conditioned, withheld or delayed).
- (d) Any recoveries resulting from an Infringement Action shall be shared by the Parties as follows: [***].
- **(e)** Licensor shall have the exclusive right to bring and control any legal action to enforce the Licensed Patents other than an Infringement Action, including any action against any infringement outside the Territory, at its own expense and as it reasonably determines

appropriate. Licensor shall have the right to retain all recoveries resulting from such action to enforce the Licensed Patents.

- **6.5 Defense of Licensed Patents and Joint Patents.** In the event that a Party receives notice of any claim alleging the invalidity or unenforceability of any Licensed Patent or Joint Patent in the Territory, such Party shall bring such claim to the attention of the other Party, including all relevant information related to such claim. The Parties, through the JSC, shall discuss such claim. Where such allegation is made in an opposition, reexamination, interference or other patent office proceeding or a declaratory judgement action, then the provisions of Section 6.3 shall apply; provided however that if a Party wishes to bring an infringement claim to enforce the Licensed Patent or Joint Patent, then the provisions of Section 6.4 shall apply. Where such allegation is made in a counterclaim to an enforcement action brought under Section 6.4, then the provisions of Section 6.4 shall apply. Each Party shall provide to the Party defending any such rights under this Section 6.5 all reasonable assistance in such enforcement, at such defending Party's request and expense. The defending Party shall keep the other Party reasonably informed of the status and progress of such efforts, and shall reasonably consider the other Party's comments on any such efforts. Without the prior written consent of the other Party (not to be unreasonably withheld), neither Party shall enter into any settlement of any claim, suit or action that it defended under this Section 6.5 that admits the invalidity or unenforceability of any Licensed Patent or Joint Patent, requires abandonment or limits the scope of any Licensed Patent or Joint Patent or would limit or restrict the ability of either Party to Develop, Manufacture or Commercialize the Licensed Product.
- 6.6 **Defense of Third Party Claims**. If a claim is brought by a Third Party alleging infringement of a patent of such Third Party by the Development, Manufacture or Commercialization of any Licensed Product, the Party first having notice of the claim or assertion shall promptly notify the other Party, the Parties shall agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute, and thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action. The Parties shall cooperate with each other in any defense of any such suit, action or proceeding. Each Party shall be entitled to represent itself in any litigation to which it is a party, at its own expense, but subject to the indemnification obligations set forth in Article 10, unless otherwise agreed upon by the Parties or as otherwise set forth in this Agreement. Neither Party shall have the right to litigate or settle any action, suit or proceeding under this Section 6.6 in a manner that (a) imposes any costs or liability on the other Party, (b) involves any admission by such other Party, or (c) limits the scope of any Intellectual Property right under this Agreement that is Controlled by such other Party, in each case of clauses (a)-(c) without such other Party's express written consent.
- **6.7 Bankruptcy Protection.** All licenses granted by either Party to the other Party under or pursuant to this Agreement are and shall otherwise be deemed to be for purposes of Section 365(n) of Title 11, United States Code or foreign equivalent laws (the "**Bankruptcy Code**") licenses of rights to "intellectual property" as defined in Section 101 of the Bankruptcy Code. Both parties shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. Upon the bankruptcy of a Party, the other Party shall further be entitled to a complete duplicate of, or complete access to, any such intellectual property, and such, if not already in its possession, shall be promptly delivered to such Party, unless the other Party elects to

continue, and continues, to perform all of its obligations under this Agreement. Upon the occurrence of any insolvency event with respect to a Party, such Party agrees that the other Party, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. All rights, powers, and remedies of a Party provided herein are in addition to and not in substitution for any and all other rights, powers, and remedies now or hereafter existing at law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code with respect to the other Party.

6.8 Trademarks.

- (a) Licensor hereby grants to Licensee an exclusive (even as to Licensor and its Affiliate) license (with the right to sublicense) under all trademarks and trade names Controlled by Licensor and used by Licensor in connection with the Licensed Product ("Licensed Trademarks") to Manufacture and Commercialize the Licensed Product in the Field in the Territory. Licensor shall own all rights in the Licensed Trademarks, and all goodwill in the Licensed Trademarks shall accrue to Licensor. Licensor shall register, maintain and enforce, at its own cost and expense, the Licensed Trademarks in the Territory as Licensor determines reasonably necessary.
- (b) In addition to (or in lieu of) the Licensed Trademarks, Licensee shall have the right to brand the Licensed Product in the Territory using Licensee related trademarks and any other trademarks and trade names (including Chinese character trademarks and trade names) Licensee determines appropriate for the Licensed Product, which may vary by jurisdiction or within a jurisdiction in the Territory ("Licensed Product Marks"), so long as not in conflict with Licensed Trademarks. Licensee shall provide Licensor with sufficient advanced notice of any proposed Licensed Product Marks and time to review and comment on such proposed Licensed Product Marks, and shall incorporate Licensor's comments thereon, to the extent reasonably possible. Licensee shall own all rights in the Licensed Product Marks, and all goodwill in the Licensed Product Marks shall accrue to Licensee. Licensee shall register, maintain and enforce, at its own cost and expense, the Licensed Product Marks in the Territory as Licensee determines reasonably necessary. Licensor shall not be granted any right, title or interest in or to the Licensed Product Marks other than the right to use for purposes of fulfilling its manufacture and packaging obligations under this Agreement, if any. For clarity, Licensed Product Marks shall not include the corporate names and logos of Licensor. Licensee shall be solely responsible for the enforcement and defense of the Licensed Product Marks in the Territory, including the cost thereof.
- **6.9 License Registration.** Licensee shall have the right to register the license granted by Licensor to Licensee hereunder with Government Authorities in the Territory, including the National Intellectual Property Administration of China; provided that if this Agreement is required to be filed with such Government Authorities in the Territory, Licensee will seek confidential treatment of the Agreement and will prepare a redacted version of this Agreement in accordance with Section 7.5. Upon Licensee's request, Licensor shall execute such documents and take such further action reasonably necessary or desirable for Licensee to register the license.

ARTICLE 7 CONFIDENTIALITY

- **7.1 Confidentiality Obligations.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, during the Term of this Agreement and [***] years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information of the other Party. The receiving Party shall keep in confidence all Confidential Information of the disclosing Party with the same degree of care it employs to maintain the confidentiality of its own Confidential Information, but no less than a reasonable degree of care.
- **7.2 Exceptions.** The obligations set forth in Section 7.1 shall not apply to any information that the receiving Party can demonstrate that such information:
- (a) is known by the receiving Party at the time of its receipt without an obligation of confidentiality, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;
- **(b)** is in the public domain before its receipt from the disclosing Party, or thereafter enters the public domain other than through the receiving Party's breach of the confidentiality obligations set forth herein;
- (c) is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party; or
- **(d)** is developed by the receiving Party independently and without use of, or reference to, any Confidential Information of the disclosing Party, as documented by the Receiving Party's business records.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

- **7.3 Authorized Disclosures.** Notwithstanding the obligations set forth in Sections 7.1 and 7.5, a Party may disclose the other Party's Confidential Information to the extent:
- (a) such disclosure is reasonably necessary: (i) for the filing, prosecution and enforcement of Patent Rights as contemplated by this Agreement; (ii) as reasonably required in generating Regulatory Materials and filing for and obtaining Regulatory Approvals as permitted by this Agreement; (iii) for the prosecuting or defending litigation as contemplated by this Agreement; or (iv) for disclosure to Third Parties bound by written obligation of confidentiality and non-use no less stringent than those set forth under this Article 7 and only to the extent necessary or appropriate in connection with the exercise of its rights or the performance of its obligations hereunder; *provided* that such Party shall remain responsible and be liable for any

violation of such confidentiality provisions by any such Third Party who receives Confidential Information pursuant to this Section 7.3(a)(iv);

- **(b)** such disclosure is reasonably necessary: (i) to such Party's directors, attorneys, independent accountants or financial advisors for the sole purpose of enabling such directors, attorneys, independent accountants or financial advisors to provide advice to such Party; or (ii) to actual or bona-fide potential investors, acquirors, securitization partners, licensees, sublicensees and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, collaboration or exercising its rights under this Agreement; *provided* that such Party shall remain responsible and be liable for any violation of such confidentiality provisions by any such Third Party who receives Confidential Information pursuant to this Section 7.3(b);
- (c) such disclosure is required by applicable Laws, judicial or administrative process, provided that in such event such Party shall promptly inform the other Party of such required disclosure and provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed pursuant to this Section 7.3(c) shall remain otherwise subject to the confidentiality and non-use provisions of this Article 7, and the Party disclosing Confidential Information pursuant to Law or court order shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order to ensure the continued confidential treatment of such Confidential Information;
- **(d)** Licensor may disclose Confidential Information to its Third Party licensors as necessary to comply with such applicable Upstream Agreements;
- (e) a Party may disclose this Agreement and its terms in securities filings with the U.S. Securities Exchange Commission or any national or regional securities exchange in any jurisdiction (each, a "Securities Regulator") or other Government Authorities to the extent required by Law after complying with the procedure set forth in this Section 7.3. In such event, the Party seeking such disclosure will prepare a draft confidential treatment request and proposed redacted version of this Agreement to request confidential treatment for this Agreement, and the other Party agrees to promptly (and in any event, no less than [***] after receipt of such confidential treatment request and proposed redactions) give its input in a reasonable manner in order to allow the Party seeking disclosure to file its request within the time lines proscribed by applicable Laws. The Party seeking such disclosure shall exercise Commercially Reasonable Efforts to obtain confidential treatment of the Agreement as represented by the redacted version reviewed by the other Party; and
- (f) each Party acknowledges that the other Party may be legally required to make public disclosures (including in filings with a Securities Regulator) of certain material developments or material information generated under this Agreement and agrees that each Party may make such disclosures as required by Law, *provided* that the Party seeking such disclosure first provides the other Party a copy of the proposed disclosure, and provided further that (except to the extent that the Party seeking disclosure is required to disclose such information to comply with Law) if the other Party demonstrates to the reasonable satisfaction of the Party seeking disclosure, within [***] of such Party's providing the copy, that the public disclosure of previously undisclosed information will materially adversely affect the Development and/or

Commercialization of the Licensed Product, the Party seeking disclosure will remove from the disclosure such specific previously undisclosed information as the other Party shall reasonably request to be removed.

If and whenever any Confidential Information is disclosed in accordance with this Section 7.3, such disclosure shall not cause any such information to cease to be Confidential Information for purposes of this Agreement, except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement).

7.4 Technical Publication.

- (a) Except to the extent required by applicable Laws, Licensee shall not publish any peer-reviewed manuscripts, or give other forms of public disclosure such as abstracts and presentations, relating to the Licensed Compound or Licensed Product, without Licensor's review. Licensee shall provide Licensor with draft of any proposed publication relating to the Licensed Compound or Licensed Product at least [***] prior to its intended submission for publication. Licensee shall consider and implement in good faith any comments thereto provided by Licensor. Upon the Licensor's request, Licensee shall remove any and all of Licensor's Confidential Information from the proposed publication, and shall delay the submission for a period up to [***] to allow time for the preparation and filing of a patent application directed to any Inventions disclosed in such publication. Licensee shall also provide Licensor a copy of the manuscript at the time of the submission. For clarity, any such publication shall be considered Licensee's Confidential Information until published.
- (b) Licensor shall provide Licensee the opportunity to review a draft of any proposed publication related to (i) the Licensed Compound or Licensed Product if any Licensee Confidential Information or any clinical data obtained from Clinical Trials in the Territory is contained in such publication or (ii) disclosures with respect to Joint Patents that have not already become public in any such publication. Licensor shall provide Licensee with draft of any such proposed publication at least [***] prior to its intended submission for publication. Licensor shall consider and implement in good faith any comments thereto provided by Licensee. Upon the Licensee's request, Licensor shall remove any and all of Licensee's Confidential Information (other than clinical data) from the proposed publication, and shall delay the submission for a period up to [***] to allow time for the preparation and filing of a patent application directed to any Inventions disclosed in such publication. Licensor shall also provide Licensee a copy of such manuscript as well as any other Licensor publications related to the Licensed Compound or Licensed Product at the time of the submission. For clarity, any such publication shall be considered Licensor's Confidential Information until published.
- 7.5 **Press Release.** The Parties shall agree on language of the press release announcing this Agreement, which shall be issued by the Parties promptly after the Effective Date at a mutually agreed date. Subject to the rest of this Section 7.5, neither Party shall use the trademark or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Law. Following the initial joint press release announcing this Agreement, either Party shall be free to disclose or publicize, without the other Party's prior written consent, the existence of this Agreement, the identity of the

other Party, and those terms of the Agreement which have already been publicly disclosed in accordance herewith.

7.6 Equitable Relief. Each Party acknowledges that a breach of this Article 7 cannot reasonably or adequately be compensated in damages in an action at Law and that such a breach may cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to seek preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of the obligations relating to Confidential Information set forth herein.

ARTICLE 8 TERM

8.1 Term. Unless earlier terminated in accordance with this Article 8, the term of this Agreement ("Term") shall commence upon the Effective Date and shall continue in full force and effect, on a Licensed Product-by-Licensed Product and jurisdiction-by-jurisdiction basis in the Territory, until the expiration of (a) for the ATRASENTAN Licensed Product, the ATRASENTAN Royalty Term in such jurisdiction, and (b) for the BION-1301 Licensed Product, the expiration of the last to expire Licensed Patent that Covers the BION-1301 Licensed Product in such jurisdiction. After the expiration (but not early termination) of the Term for a particular Licensed Product in a particular jurisdiction in the Territory, the licenses granted by Licensor to Licensee under Section 2.1, shall continue and shall become non-exclusive, fully paid, royalty free, perpetual and irrevocable in such jurisdiction in the Field.

8.2 Early Termination.

- (a) Material Breach [***]. Upon [***], Licensor will have the right, but not the obligation, to terminate this Agreement by providing written notice to Licensee within [***], which notice will (A) expressly reference this Section 8.2(a), (B) reasonably describe the alleged breach that is the basis of such termination, and (C) clearly state Licensor's intent to terminate this Agreement if the alleged breach is not cured within the [***] cure period. Notwithstanding the foregoing, Licensor will only have the right to terminate this Agreement under this Section 8.2(a) with respect to the applicable Licensed Product(s) [***], and this Agreement will remain in effect with respect to the other Licensed Products.
- **(b) Termination for Non-Payment**. Upon any material breach of this Agreement by Licensee for failing to pay any undisputed amount payable to Licensor under this Agreement, Licensor will have the right, but not the obligation, to terminate this Agreement by providing written notice to Licensee within [***], which notice will (A) expressly reference this Section 8.2(b), (B) reasonably describe the alleged breach that is the basis of such termination, and (C) clearly state Licensor's intent to terminate this Agreement if the alleged breach is not cured within the [***] cure period . In addition, if Licensee disputes (1) whether it has breached its payment obligations under this Agreement, or (2) whether it has cured such breach within the applicable cure period, then the dispute will be resolved pursuant to Section 11.8, and the applicable cure period will be tolled during the pendency of such dispute resolution procedure. Notwithstanding the foregoing, if Licensee's breach pertains to an amount owed with respect to a

particular Licensed Product (and not all Licensed Products), then Licensor will only have the right to terminate this Agreement, with respect to the applicable Licensed Product, and in such event this Agreement will remain in effect with respect to the other Licensed Products.

- **(c) Termination in the Event of [***].** In the event of [***], this Agreement will terminate on the date of [***], and without notice from, or further action by, any Party hereto.
- **(d) Termination for Certain Breaches**. Either Party may terminate this Agreement if (i) the other Party or its Affiliates [***]; or (ii) [***], and such breach is so cured within [***] after receipt of notice from the other Party.
- (e) Patent Challenge. Licensor has the right to terminate this Agreement upon written notice to Licensee in the event that Licensee or any of its Affiliates or sublicensees directly or indirectly challenges in a legal or administrative proceeding the patentability, enforceability or validity of any Licensed Patents (a "Patent Challenge") provided that (i) with respect to any sublicensee, Licensor will not have the right to terminate this Agreement under this Section 8.2(e) if Licensee (A) causes such Patent Challenge to be terminated or dismissed (or in the case of ex-parte proceedings, multi-party proceedings, or other Patent Challenges in which the challenging party does not have the power to unilaterally cause the Patent Challenge to be withdrawn, causes such sublicensee to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge), (B) terminates such sublicensee's sublicense to the Licensed Patents being challenged by the sublicensee, in each case, within [***] of Licensor's notice to Licensee under this Section 8.2(e), or (C) or any of its Affiliates or sublicensees has asserted the Patent Challenge in response to any threatened or actual claim of patent infringement with respect to the Licensed Patents by Licensor or any of its Affiliates or (sub)licensees.
- **(f) Termination for [***].** Licensor may terminate this Agreement on a Licensed Product-by-Licensed Product basis in the event that Licensee and its Affiliates and sublicensees [***]. Such termination with respect to such Licensed Product will be effective [***] after Licensee's receipt of written notice thereof, provided that, [***], then this Agreement will not terminate with respect to such Licensed Product upon the expiration of such [***] period.

8.3 Effects of Termination.

- (a) Effects of Termination Generally. Upon any termination of this Agreement with respect to a Licensed Product (each, a "Reversion Product"; with all Licensed Products being Reversion Products in the event of termination of this Agreement in its entirety), then the Parties' rights, licenses and obligations under this Agreement with respect to such Licensed Product will terminate and neither Party will have any further rights or obligations under this Agreement with respect to such Reversion Product from and after the effective date of termination, except as set forth in this Section 8.3.
- **(b) Winding Down of Activities**. If there are any on-going Development or Commercialization activities for such Reversion Product at termination or expiration of this Agreement, then the Parties will negotiate in good faith and adopt a plan to wind-down such activities in an orderly fashion or, at Licensor's election to the extent applicable, promptly transition such activities from Licensee to Licensor or its designee, with due regard for patient

safety and the rights of any subjects that are participants in any Clinical Trials for such Reversion Products, and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all applicable Law.

(c) License Grant to Licensor.

- (i) Upon termination of this Agreement, Licensee, on behalf of itself and its Affiliates hereby grants (effective on delivery of the notice of termination) to Licensor [***].
- **(d) Accrued Obligations**. Expiration or termination of this Agreement for any reason will not release either Party from any obligation or liability that, on the effective date of such expiration or termination, has already accrued to the other Party or that is attributable to a period prior to such expiration or termination.

(e) Inventory.

- (i) Appointment as Exclusive Distributor. If Licensee is Commercializing such Reversion Product in any jurisdiction in the Territory as of the effective date of termination of this Agreement, then, at Licensor's election (in its sole discretion) on a jurisdiction-by-jurisdiction basis in the Territory, until such time as all MAAs with respect to such Reversion Product in such jurisdiction have been assigned and transferred to Licensor, Licensee will appoint Licensor or its designee as its exclusive distributor of such Reversion Product in such jurisdiction and grant Licensor or its designee the right to appoint sub-distributors, to the extent not prohibited by an written agreement between Licensee or any of its Affiliates and any Third Party.
- **(ii) Licensor Buy-Back.** In the event that Licensor exercises its right to be appointed Licensee's exclusive distributor pursuant to Section 8.3(e)(i), Licensor will have the right to purchase all of Licensee's and its Affiliates' remaining inventory of Reversion Products held as of the effective date of expiration of such appointment at a price equal to (A) [***].
- (f) Transfer of Regulatory Materials and Regulatory Approvals. Following the effectiveness of any termination of this Agreement pursuant to Section 8.2, after Licensor's written request, Licensee will, assign and transfer to Licensor all Regulatory Materials and MAAs for Reversion Products that are held by or owned by Licensee or its Affiliates or sublicensees as of the effective date of termination and will take such actions and execute such other instruments, assignments, and documents as may be necessary to effect the transfer of rights under such Regulatory Materials and MAAs to Licensor. If applicable Laws or relevant Regulatory Authorities prevent or delay the transfer of ownership of any such Regulatory Filing and MAAs to Licensor, then Licensee will grant, and hereby does grant, to Licensor and its Affiliates, sublicensees, and licensees an exclusive and irrevocable right of access and right of reference to such Regulatory Filings and MAAs for Reversion Products in the Field in the Territory, as the case may be, and will reasonably cooperate with Licensor, to make the benefits of such Regulatory Materials and MAAs available to Licensor or its designee(s).
- **(g) Assignment of Third Party Agreements.** To the extent requested by Licensor, Licensee will promptly upon request (i) endeavor reasonably to assign and transfer to

Licensor or its designee all of Licensee's rights, title and interests in and to all Clinical Trial agreements, manufacturing and supply agreements, and distribution agreements (to the extent assignable) in Licensee's Control, in each case, to the extent such agreements solely relate to such Reversion Product and are necessary or useful for the Development, Manufacture, or Commercialization of such Reversion Product, and (ii) assign and transfer to Licensor or its designee all of Licensee's rights, title, and interests in and to any promotional materials, training materials, medical education materials, packaging and labeling, and all other literature or other information related to such Reversion Product and copyrights and any registrations for the foregoing, to the extent Controlled by Licensee or its Affiliates.

- (h) Return of Confidential Information. Within thirty (30) days after the effective date of termination (but not expiration) of this Agreement in its entirety, each Party will, and cause its Affiliates to (i) destroy, all tangible items solely comprising, bearing or containing any Confidential Information of the other Party that are in such first Party's or its Affiliates' possession or Control, and provide written certification of such destruction, or (ii) prepare such tangible items of the other Party's Confidential Information for shipment to such other Party, as such other Party may direct, at the first Party's expense; provided, however, that, in any event, (A) each Party may retain copies of the Confidential Information of the other Party to the extent necessary to perform its obligations or exercise its rights that survive expiration or termination of this Agreement; and (B) each Party may retain copies of the Confidential Information of the other Party for its legal archives.
- **(i) Cooperation**. Each Party will cause its Affiliates, Sublicensees, and contractors to comply with the obligations in this Section 8.3.
- **8.4 Survival**. This Section 8.4, the provisions set forth in the following Sections, as well as, to the extent applicable, any other Sections or defined terms referred to in such Sections or Articles or necessary to give them effect, will survive any expiration or termination of this Agreement in its entirety: Article 1, Section 2.7, Sections 5.2 through 5.7 (solely with respect to obligations that accrued prior to the expiration or termination of this Agreement), Section 6.2, Sections 6.4 through 6.6 (solely to the extent that any claim, action or legal proceeding has been initiated by or against a Party prior to expiration or termination of this Agreement), Section 6.7, Article 7, Section 8.1, Section 8.3, Section 8.4, Section 9.3, Article 10 and Article 11. Except as otherwise expressly provided in this Agreement, including all rights and obligations of the Parties under this Agreement, including this Section 8.4, any licenses granted under this Agreement, will terminate upon expiration or termination of this Agreement for any reason.

ARTICLE 9 REPRESENTATIONS AND WARRANTIES

- **9.1 Mutual Representations and Warranties**. Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows as of the Execution Date:
- (a) it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated or organized, and has full

power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted by it hereunder;

- **(b)** as of the Execution Date, (i) it has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate or organizational action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms;
- (c) neither it nor any of its Affiliates, nor its or their employees, officers, directors, or agents, has been, or is currently (i) debarred by the FDA or by any Regulatory Authority; (ii) is the subject of a conviction described in 21 U.S.C. § 335a, or any similar sanction; (iii) excluded, debarred, suspended, or otherwise ineligible to participate in federal health care programs or in federal procurement or non-procurement programs; (iv) listed on the FDA's Disqualified and Restricted Lists for clinical investigators; or (v) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. Each Party covenants that if, during the Term of this Agreement, it becomes aware that it or any of its or its Affiliates' employees or agents performing under this Agreement is the subject of any investigation or proceeding that could lead to that Party becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, then such Party will promptly notify the other Party.
- (d) the execution, delivery and performance of this Agreement by such Party does not breach, violate, or conflict with any agreement or any provision thereof, or any instrument or understanding, oral or written, to which such Party (or any of its Affiliates) is a party or by which such Party (or any of its Affiliates) is bound, nor violate any applicable Law of any Governmental Authority having jurisdiction over such Party (or any of its Affiliates); and
- (e) it shall, and will ensure that its respective Affiliates and sublicensees will, comply in all material aspects with all applicable Laws in the course of performing its obligations and exercising its rights under this Agreement.
- **9.2 Additional Representations and Warranties of Licensor**. Licensor represents, warrants, and covenants (as applicable) to Licensee that:
- (a) except for the Licensed Technology in-licensed by Licensor under the [***], Licensor is the sole and exclusive owner of the Licensed Technology, free and clear of all liens that would prevent or limit Licensee's exercise of its rights under the licenses granted to Licensee under Article 2, and Licensor has the right to grant to Licensee the rights and licenses as purported to be granted hereunder;
- **(b)** except for the Upstream Agreements, there are no agreements existing as of the Execution Date between Licensor (or its Affiliates) and any Third Party pursuant to which Licensor or its Affiliates are required, or would be required with the passage of time or upon

satisfaction of a condition subsequent, to make any payment to such Third Party for the Exploitation of the Licensed Compound or Licensed Product in the Field in the Territory;

- (c) To the Knowledge of Licensor, Licensor has obtained all necessary government approvals required for the grant of the license and the transfer of Licensed Know-How to Licensee, including such approvals required by applicable technology export control Laws, and Licensor will do and execute or procure to be done and have executed all such further acts, things, agreements and other documents as may be reasonably necessary to give effect to the terms of this Agreement;
- (d) Licensor and its Affiliates have not granted, and will not grant during the Term, any rights in the Licensed Technology that are inconsistent with the rights granted to Licensee under this Agreement;
- **(e)** Licensor and its Affiliates have not received any written notice (including any such notice styled as an offer to license) from any Third Party on or prior to the Execution Date asserting or alleging that the research or development of the Licensed Compound or Licensed Product infringed, misappropriated or otherwise violated the IP rights of such Third Party;
- **(f)** to the Knowledge of Licensor, the Development, Manufacture and Commercialization of the Licensed Compound and Licensed Product can be carried out as mutually contemplated by the Parties as of the Execution Date without infringing, misappropriating or otherwise violating any [***];
- **(g)** there are no pending or, to the Knowledge of Licensor, alleged or threatened, adverse actions, suits, proceedings, or claims against Licensor or its Affiliates involving the Licensed Technology, Licensed Compound or Licensed Product;
- **(h)** to the Knowledge of Licensor, no Third Party is infringing, misappropriating or otherwise violating any Licensed Technology;
- (i) Schedule 1.48 (Licensed Patents) lists all Patent Rights Controlled by Licensor and its Affiliates as of the Execution Date that Cover the Licensed Compound or the Licensed Product (including composition of matter, methods of making and using) or are necessary or reasonably useful for the Exploitation of the Licensed Compound or Licensed Product in the Territory;
- **(j)** there is no pending or, or to the Knowledge of Licensor and its Affiliates, alleged or threatened, reexamination, opposition, interference, claim or litigation, or any written communication alleging that any Licensed Patent is invalid or unenforceable anywhere in the world;
- **(k)** Licensor (including its Affiliates) and, to its Knowledge, Licensor's contractors, have complied with all applicable Laws in connection with Licensor's development of the Licensed Compound and Licensed Product, and have not used any employee, or to the Knowledge of Licensor, consultant or contractor who has been debarred by any Regulatory Authority, or to Licensor's Knowledge, is the subject of a debarment proceeding by any Regulatory Authority;

- (I) to the knowledge of Licensor, all material information provided by Licensor to Licensee for due diligence purposes in relation to this Agreement is complete and accurate in all material respects. Without limiting the foregoing, to the Knowledge of Licensor, Licensor has disclosed to Licensee and made available to Licensee for review all material non-clinical and clinical data for the Licensed Compound and Licensed Product, and all other material information (including relevant correspondence with Regulatory Authorities) in its possession or Control relating to the Licensed Compound and Licensed Product, in each case that would be material for Licensee to assess the safety and efficacy of the Licensed Compound and Licensed Product as contemplated for the proposed indications in the Development Plan;
- (m) Licensor has provided Licensee with a true and complete copy of the Upstream Agreements; the Upstream Agreements are in full force and effect; no written notice of default or termination has been received or given under the Upstream Agreements as of the Execution Date; and, to its Knowledge, there is no act or omission by Licensor or its Affiliates that would provide a right to terminate the Upstream Agreements; as of the Execution Date, Licensor has obtained all written consents and approvals that Licensor is required to obtain prior to entering into this Agreement under the terms of the Upstream Agreements; and
- (n) during the Term of this Agreement, Licensor shall maintain the Upstream Agreements in full force and effect and shall not terminate, amend, waive or otherwise modify (or consent to any of the foregoing) its rights under the Upstream Agreements in any manner that materially diminishes the rights or licenses granted to Licensee hereunder, without Licensee's express written consent.
- **9.3 Disclaimer**. EXCEPT AS EXPRESSLY STATED HEREIN, NO OTHER REPRESENTATIONS OR WARRANTIES WHATSOEVER, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR MISAPPROPRIATION IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY OR ITS AFFILIATES. ALL SUCH OTHER REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE 10 INDEMNIFICATION; LIABILITY

- **10.1 Indemnification by Licensor.** Licensor shall defend, indemnify and hold Licensee, its Affiliates and each of its and their respective officers, directors, agents and employees ("**Licensee Indemnitees**") harmless from and against any Losses that are incurred by any Licensee Indemnitee resulting from any Claims against a Licensee Indemnitee, to the extent that such Losses arise or result from:
- (a) the breach by Licensor of any of its representations, warranties, covenants, or obligations set forth herein or a violation of applicable Law while performing its obligations set forth herein;
- **(b)** the gross negligence or willful misconduct or breach of this Agreement by any of the Licensor Indemnitees; or

(c)	the Development,	Manufacture and	Commercialization	of the Licensed	Compound	and Licensed
Product by or on behalf of	Licensor, its Affiliates	, licensees and sul	blicensees (other tha	n Licensee, its A	Affiliates and	sublicensees)
outside the Territory;						

except in each case, to the extent such Claims result from any activities set forth in Section 10.2 for which Licensee is obligated to indemnify the Licensor Indemnitee.

- **10.2 Indemnification by Licensee.** Licensee shall defend, indemnify and hold Licensor, its Affiliates and each of its and their respective officers, directors, agents and employees ("**Licensor Indemnitees**") harmless from and against any Losses that are incurred by any Licensor Indemnitee resulting from any Claims against a Licensor Indemnitee, to the extent that such Losses arise or result from:
- (a) the breach by Licensee of any of its representations, warranties, covenants, or obligations set forth herein or a violation of applicable Law while performing its obligations set forth herein;
- **(b)** the gross negligence or willful misconduct or breach of this Agreement by any of the Licensee Indemnitees; or
- **(c)** the Development, Manufacture and Commercialization of the Licensed Compound and Licensed Product by or on behalf of Licensee, its Affiliates or sublicensees;

except in each case, to the extent such Claims result from any activities set forth in Section 10.1 for which Licensor is obligated to indemnify the Licensee Indemnitee.

Indemnification Procedure. If either Party is seeking indemnification under Sections 10.1 or 10.2 (the "Indemnified Party"), it shall inform the other Party (the "Indemnifying Party") of the Claim giving rise to the obligation to indemnify pursuant to such Section as soon as reasonably practicable after receiving notice of the Claim. The failure to give prompt written notice shall not, however, relieve the Indemnifying Party of its indemnification obligations, except and only to the extent that the Indemnifying Party forfeits rights or defenses by reason of such failure. The Indemnifying Party shall have the right to assume the defense or settlement of any such Claim for which it is obligated to indemnify the Indemnified Party by giving written notice to the Indemnified Party within thirty (30) days after the Indemnifying Party's receipting of a Claim notice; provided that the Indemnifying Party will not enter into any settlement that adversely affects the Indemnified Party's rights or obligations without the Indemnified Party's prior express written consent, which will not be unreasonably withheld, conditioned or delayed. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnifying Party shall retain counsel reasonably acceptable to the Indemnified Party (such acceptance not to be unreasonably withheld, conditioned or delayed) to represent the Indemnified Party and shall pay the fees and expenses of such counsel related to such proceeding. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any Claim that has been assumed by the Indemnifying Party. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent shall not be unreasonably withheld, conditioned or delayed. If the Parties cannot agree as

to the application of Section 10.1 or 10.2 as to any Claim, pending resolution of the dispute pursuant to Section 11.8, the Parties may conduct separate defenses of such Claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 10.1 or 10.2 upon resolution of the underlying Claim.

- **10.4 Mitigation of Loss.** Each Indemnified Party shall take and shall procure that its Affiliates take all such reasonable steps and action as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any Claims (or potential losses or damages) under this Article 10. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.
- 10.5 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES, NOR LOST PROFITS, ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT UNDER ANY THEORY (INCLUDING CONTRACT, NEGLIGENCE OR STRICT LIABILITY), REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 10.1 OR 10.2, DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 7, DAMAGES AVAILABLE FOR LICENSEE'S BREACH OF SECTION 2.4, OR DAMAGES AVAILABLE FOR WILLFUL MISCONDUCT, GROSS NEGLIGENCE OR FRAUDULENT ACTS OR OMISSIONS OF A PARTY.

ARTICLE 11 GENERAL PROVISIONS

Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under 11.1 or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, earthquakes or other inclement weather, epidemics and pandemics (provided however, that the Parties stipulate that the COVID-19 pandemic which is ongoing as of the Effective Date shall not constitute a Force Majeure Event except to the extent such failure or delay in performing any obligation under this Agreement is caused by the resurgence or prevalence of an existing strain or a new strain or other material mutation of the COVID-19 virus), or acts, omissions or delays in acting by any Governmental Authority (other than those imposed as a result of such Party's failure to comply with Law); provided, however, [***]. The affected Party shall notify the other Party in writing of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake and continue diligently all reasonable efforts necessary to cure such force majeure circumstances or to perform its obligations in spite of the ongoing circumstances. If the force majeure event continues, then, to the extent practicable, the affected Party will update such notice to the other Party on a weekly basis to provide updated summaries of its mitigation efforts and its estimates of when normal performance under this Agreement will be able to resume. Any time for performance under this Agreement shall be extended by the actual time of delay caused by the occurrence so

long as the nonperforming Party has not caused such event(s) to occur and takes reasonable efforts to remove the condition. In the event that the suspension of performance continues for [***] after the date such force majeure commences, the Parties shall meet to discuss in good faith how to proceed in order to accomplish the objectives of this Agreement.

- 11.2 Assignment. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, either Party may, without consent of the other Party, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate of such Party, or in connection with a Change of Control. Any attempted assignment not in accordance with the foregoing shall be null and void and of no legal effect. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their permitted assigns.
- 11.3 No Third Party Beneficiaries. No provision of this Agreement, express or implied, is intended to or will be deemed to confer upon Third Parties any right, benefit, remedy, claim, liability, reimbursement, claim of action or other right of any nature whatsoever under or by reason of this Agreement other than as expressly provided by the Parties under this Agreement and, to the extent provided in Sections 10.1 and 10.2, the Licensee Indemnitees and Licensor Indemnitees.
- **11.4 Severability.** If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.
- **11.5 Performance by Affiliates.** To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations. A Party may use one or more of its Affiliates to perform its obligations and duties or exercise its rights under this Agreement, *provided* that such Party will remain directly liable under this Agreement for the prompt payment and performance of all their respective obligations and duties under this Agreement. Any breach by an Affiliate of a Party of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.
- **11.6 Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Licensor:

Chinook Therapeutics, Inc.

400 Fairview Avenue North, Suite 900

Seattle, WA 98109

Email: legal@chinooktx.com

with a copy to:

Goodwin Procter LLP 100 Northern Avenue Boston, MA 02210 Attn: [***]

If to Licensee:

SanReno Therapeutics (Hong Kong) Limited Suite 2503, 25F, Tower 2, Century Link 1196 Century Avenue, Shanghai 200122

People's Republic of China

with a copy to:

Sidley Austin LLP

Suite 2009, 5 Corporate Avenue 150 Hubin Road, Shanghai 200021

Attn: [***]

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a Business Day (or if delivered or sent on a non-Business Day, then on the next Business Day); (b) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) Business Day following the date of mailing, if sent by mail.

11.7 Governing Law. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without reference to any rules of conflict of Laws that may require the application of the Laws of a different jurisdiction. The United Nations Conventions on Contracts for the International Sale of Goods shall not be applicable to this Agreement. Notwithstanding anything to the contrary herein and subject to Article 6, the interpretation and construction of any Patent Rights shall be governed in accordance with the Laws of the jurisdiction in which such Patent Rights were filed or granted, as the case may be.

11.8 Dispute Resolution.

(a) The Parties shall negotiate in good faith and use good faith efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof (a "**Dispute**"). If, after negotiating in good faith pursuant to the foregoing sentence, the Parties fail to reach agreement within [***] (or such longer period as agreed in writing by the Parties), then the Dispute may be referred to the Executive Officers (or their designated direct report) of the Parties for attempted resolution (other than (a) matters within the purview of the JSC, which will

be resolved in accordance with Section 3.4 (Decision-Making) and (b) matters for which this Agreement expressly provides are subject to a Party's discretion or sole decision-making authority). In the event the Chief Executive Officers (or their designated direct report) are unable to resolve such dispute, controversy or claim within [***] (or such longer period as agreed in writing by the Parties) after such matter is referred to them, then, upon the written request of either Party, such Dispute shall be finally resolved by binding arbitration administered in accordance with the Rules of Conciliation and Arbitration of the International Chamber of Commerce (the "ICC Rules") then in effect; provided that no Excluded Claim may be resolved by such binding arbitration. Judgment on the arbitration award may be entered in any court having jurisdiction thereof. Notwithstanding the foregoing, in all events, the provisions contained herein shall govern over any conflicting rules which may now or hereafter be contained in the ICC Rules. Arbitration proceedings shall be held in New York, and the language of the arbitration proceedings shall be English.

- (b) The arbitration shall be conducted by a panel of three (3) arbitrators, knowledgeable in the subject matter that is in dispute. Each Party shall name one arbitrator. The chairman of the arbitral tribunal shall be a partner of an international law firm and having experience with license agreements in the drug or biologic industry or who was a judge of a court of general jurisdiction and shall be selected by mutual nomination by the co-arbitrators within thirty (30) days after confirmation or appointment of the last of the co-arbitrators to be confirmed or appointed, or, failing such mutual nomination, shall be selected according to the ICC Rules. No arbitrator shall be or have been an Affiliate, employee, consultant, officer, director or stockholder of either Party or of an Affiliate of either Party, or have a conflict of interest under applicable rules of ethics.
- **(c)** Either Party may apply to the arbitrator for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award.
- (d) The decision by the arbitrators will be binding and conclusive upon the Parties, their successors and permitted assigns and the Parties will comply with such decision in good faith. The Parties expressly exclude any and all rights to appeal, set aside or otherwise challenge an award by the arbitrators, insofar as such exclusion can validly be made. The arbitrator shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrator's fees and any administrative fees of arbitration.
- (e) All aspects of the arbitration shall be treated as confidential. Except to the extent necessary to confirm an award or as may be required by Law or the rules of any stock exchange, neither Party nor its representatives nor a witness nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. At the request of either Party, the arbitrators shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings. In no event shall an arbitration be initiated after the date when commencement of a

legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable statute of limitations.

- (f) As used in this Section, the term "Excluded Claim" shall mean a Dispute that concerns (i) the scope, validity, enforceability, inventorship or infringement of a patent, patent application, trademark or copyright; (ii) any antitrust, anti-monopoly or competition Law or regulation, whether or not statutory; (iii) or either Party's final decision making vote in accordance with this Agreement (unless the Dispute arises from an alleged improper use of such final decision making authority).
- (g) EACH PARTY, TO THE EXTENT PERMITTED BY LAW, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES TO ARBITRATE AS SET FORTH IN THIS SECTION 11.8. THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE.
- 11.9 Entire Agreement; Amendments. This Agreement, together with the Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, with respect to the subject matter hereof are superseded by the terms of this Agreement. The Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto.
- **11.10 Headings; Language.** The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.
- **11.11 Independent Contractors.** It is expressly agreed that Licensor and Licensee shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Licensor nor Licensee shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.
- **11.12 Waiver.** No waiver of any term or condition of this Agreement shall be effective unless set forth in a written instrument duly executed by or on behalf of the waiving Party. The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.

- **11.13 Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Law.
- **11.14 Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.
- **11.15 Business Day Requirements.** In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring Business Day.
- **11.16 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate to carry out the purposes and intent of this Agreement.
- **11.17 Counterparts.** This Agreement may be executed in two or more counterparts by original signature, facsimile or PDF files, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

{REMAINDER OF PAGE INTENTIONALLY LEFT BLANK}

CHINOOK THERAPEUTICS, INC.		SANRENO THERAPEUTICS (HONG KONG) LIMITED			
By:	/s/ Eric Dobmeier	By: /s/ Jing Qian			
Name	:Eric Dobmeier	Name: Jing Qian			
Title:	Chief Executive Officer	Title: Director			
	Signature Page to License Agreement				

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Execution Date.

Schedule 1.4 - Page 1

Schedule 1.9 - Page 1

Schedule 4.3(a) - Page 1

Schedule 4.3(a) [***]

Schedule 4.3(a) - Page 2

Via Email

Alan Glicklich

Re: <u>Terms of Separation</u>

Dear Alan:

This letter confirms the agreement ("Agreement") between you and Chinook Therapeutics, Inc. (the "Company") concerning the terms of your resignation and offers you the separation compensation we discussed in exchange for a general release of claims and covenant not to sue.

- 1. <u>Resignation Date</u>: February 11, 2022, is your last day of employment with the Company (the "**Resignation Date**"). For the avoidance of doubt, and pursuant to the employment agreement between you and the Company dated October 5, 2020, attached hereto as <u>Exhibit A</u>, (the "**Employment Agreement**"), your resignation from the Company is a "**Covered Termination**" for "**Good Reason**" (both, as defined in section 1 therein).
- 2. <u>Acknowledgment of Payment of Wages</u>: By your signature below, you acknowledge that on February 11, 2022, we provided you one or more final paychecks for all wages, salary, reimbursable expenses previously submitted by you, accrued vacation as applicable) and any similar payments due you from the Company as of the Resignation Date. By signing below, you acknowledge that the Company does not owe you any other amounts. Please promptly submit for reimbursement all final outstanding expenses, if any.
- 3. <u>Separation Compensation</u>: Pursuant to section 5.2(a)-(c) of the Employment Agreement, and in exchange for your agreement to the general release and waiver of claims and covenant not to sue set forth below, your other promises herein, and your compliance with your obligations to the Company as identified in section 6 of the Employment Agreement, the Company agrees to provide you with the following:
- a. <u>Severance</u>: The Company agrees to pay you, in the first payroll period following the Effective Date (as defined below), a lump sum payment in the gross amount of \$388,000, less applicable state and federal payroll deductions, which equals twelve (12) months of your current base salary;
- b. <u>2021 Bonus</u>: In addition, the Company agrees to pay you, in the first payroll period following the Effective Date, a lump sum payment in the gross amount of \$145,500, less applicable state and federal payroll deductions, which equals the full amount of your 2021 bonus and
- c. \underline{COBRA} : Upon your timely election to continue your existing health benefits under COBRA, and consistent with the terms of COBRA and the Company's health

insurance plan, the Company will pay the insurance premiums to continue your existing health benefits through March 31, 2023. You will remain responsible for, and must continue to pay, the portion of premiums, co-payments, etc. that you would have paid had your employment continued.

d. <u>Consultation Services</u>: In addition to the payments set forth above pursuant to the Employment Agreement, and in consideration for agreeing to provide up to ten (10) hours per week of consultation time to the Company, as reasonably requested between the Resignation Date through March 31, 2022 (the "*Consultancy*"), the Company agrees to pay you within ten (10) business days following the Effective Date, a lump sum payment in the gross amount of \$52,231, less applicable state and federal payroll deductions, which equals seven (7) weeks of your current base salary.

By signing below, <u>no earlier than the Resignation Date</u>, you acknowledge that you are receiving the separation compensation outlined in this section in consideration for waiving your rights to claims referred to in this Agreement, that the separation compensation fully satisfies any Covered Termination benefits under the Employment Agreement, and that you would not otherwise be entitled to the separation compensation.

- 4. <u>Return of Company Property:</u> You hereby warrant to the Company that no later than the Resignation Date, you will return to the Company all property or data of the Company of any type whatsoever that has been in your possession or control.
- 5. <u>Post-Employment Obligations</u>: You hereby acknowledge that: (a) you continue to be bound by the attached Confidential Information and Inventions Agreement (<u>Exhibit B</u> hereto); (b) as a result of your employment with the Company, you have had access to the Company's proprietary and/or confidential information, and you will continue to hold all such information in strictest confidence and not make use of it on behalf of anyone; and (c) you must, and by your signature below confirm that you shall, deliver to the Company, no later than the Resignation Date, all documents and data of any nature containing or pertaining to such information, and not take with you, or otherwise retain in any respect, any such documents or data or any reproduction thereof.
- 6. <u>Equity Awards</u>: Pursuant to your Equity Awards with the Company and the Company's Equity Incentive Plans (hereafter collectively referred to as the "*Stock Agreements*"), you were granted options to purchase 355,322 shares of the Company's common stock (the "*Options*") and 38,316 Restricted Stock Units (the "*RSUs*"). If you sign this Agreement and it becomes effective on its terms, and immediately following the Resignation Date you continue to agree to provide consultancy services to the Company pursuant to the Consultancy, your Options and RSUs will continue to vest through March 31, 2022, at which time the Options will have vested as to 152,008 shares and the RSUs will have vested as to 12,771 shares for a total of 164,779 vested shares (the "*End Date Vested Shares*"), and the Options and RSUs will remain unvested as to 228,859 shares (the "*End Date Unvested Shares*"). You currently have exercised 20,000 of the Options, leaving 132,008 unexercised vested shares as of end of the Consultancy if you agree to provide such services (the "*End Date Unexercised Shares*"). Because your employment is terminating, none of the End Date Unvested Shares can ever vest. Your rights concerning the Options will continue to be governed by the Stock

Agreements. Per the Stock Agreements, in the event you do not agree to continue to provide services under the Consultancy, you will have 90 days following the Resignation Date to exercise the 119,550 unexercised vested Options outstanding as of the Resignation Date (the "*Unexercised Vested Shares*"). In the event you do agree to continue to provide services under the Consultancy, you will have 90 days following the end of the Consultancy period to exercise the End Date Unexercised Shares; *provided* that any of the Options that are exercised following the three-month anniversary of the Resignation Date will constitute nonqualified stock options, rather than incentive stock options. After this date, you will no longer have a right to exercise the Options as to any shares.

7. General Release and Waiver of Claims:

- a. The payments and promises set forth in this Agreement are in full satisfaction of all accrued salary, vacation pay, bonus and commission pay, profit-sharing, stock, stock options or other ownership interest in the Company, termination benefits or other compensation to which you may be entitled by virtue of your employment with the Company or your separation or resignation from the Company. To the fullest extent permitted by law, you hereby release and waive any other claims you may have against the Company and its owners, agents, officers, shareholders, employees, directors, attorneys, subscribers, subsidiaries, affiliates, successors and assigns (collectively "*Releasees*"), whether known or not known, including, without limitation, claims under any employment laws, including, but not limited to, claims of unlawful discharge, breach of contract, breach of the covenant of good faith and fair dealing, fraud, violation of public policy, defamation, physical injury, emotional distress, claims for additional compensation or benefits arising out of your employment or your separation or resignation from employment, claims under Title VII of the 1964 Civil Rights Act, as amended, the California Fair Employment and Housing Act and any other laws and/or regulations relating to employment or employment discrimination, including, without limitation, claims based on age or under the Age Discrimination in Employment Act or Older Workers Benefit Protection Act, and/or claims based on disability or under the Americans with Disabilities Act.
- b. By signing below, you expressly waive any benefits of Section 1542 of the Civil Code of the State of California, which provides as follows:

"A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY."

c. You and the Company do not intend to release claims that you may not release as a matter of law, including but not limited to claims for indemnity under California Labor Code Section 2802, or any claims for enforcement of this Agreement. To the fullest extent permitted by law, any dispute regarding the scope of this general release shall be determined by an arbitrator under the procedures set forth in the arbitration clause below.

8. <u>Covenant Not to Sue</u>:

- a. To the fullest extent permitted by law, at no time subsequent to the execution of this Agreement will you pursue, or cause or knowingly permit the prosecution, in any state, federal or foreign court, or before any local, state, federal or foreign administrative agency, or any other tribunal, of any charge, claim or action of any kind, nature and character whatsoever, known or unknown, which you may now have, have ever had, or may in the future have against Releasees, which is based in whole or in part on any matter released by this Agreement.
- b. Nothing in this section shall prohibit or impair you or the Company from complying with all applicable laws, nor shall this Agreement be construed to obligate either party to commit (or aid or abet in the commission of) any unlawful act.
- 9. <u>Protected Rights</u>: You understand that nothing in the General Release and Waiver of Claims and Covenant Not to Sue sections above, or otherwise in this Agreement, limits your ability to file a charge or complaint with the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local government agency or commission ("*Government Agencies*"). You further understand that this Agreement does not limit your ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. This Agreement does not limit your right to receive an award for information provided to any Government Agencies.
- 10. <u>Non-disparagement</u>: You agree that you will not, directly or indirectly, disparage or make negative remarks regarding Releasees or their products, services, agents, representatives, directors, officers, shareholders, attorneys, employees, vendors, affiliates, successors or assigns, or any person acting by, through, under or in concert with any of them, with any written or oral statement, including, but not limited to, any statement posted on social media (including online company review sites) or otherwise on the Internet, whether or not made anonymously or with attribution. Nothing in this section shall prohibit you from providing truthful information in response to a subpoena or other legal process. Further, nothing in this Agreement prevents you from discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that you have reason to believe is unlawful.
- 11. Arbitration: Except for any claim for injunctive relief arising out of a breach of a party's obligations to protect the other's proprietary information, the parties agree to arbitrate, in San Diego, California through JAMS, any and all disputes or claims arising out of or related to the validity, enforceability, interpretation, performance or breach of this Agreement, whether sounding in tort, contract, statutory violation or otherwise, or involving the construction or application or any of the terms, provisions, or conditions of this Agreement. Any arbitration may be initiated by a written demand to the other party. The arbitrator's decision shall be final, binding, and conclusive. The parties further agree that this Agreement is intended to be strictly construed to provide for arbitration as the sole and exclusive means for resolution of all disputes

hereunder to the fullest extent permitted by law. The parties expressly waive any entitlement to have such controversies decided by a court or a jury.

- 12. <u>Attorneys' Fees</u>: If any action is brought to enforce the terms of this Agreement, the prevailing party will be entitled to recover its reasonable attorneys' fees, costs and expenses from the other party, in addition to any other relief to which the prevailing party may be entitled.
- 13. <u>Confidentiality</u>: The contents, terms and conditions of this Agreement must be kept confidential by you and may not be disclosed except to your immediate family, accountant or attorneys or pursuant to subpoena or court order. You agree that if you are asked for information concerning this Agreement, you will state only that you and the Company reached an amicable resolution of any disputes concerning your resignation from the Company. Any breach of this confidentiality provision shall be deemed a material breach of this Agreement.
- 14. <u>No Admission of Liability</u>: This Agreement is not and shall not be construed or contended by you to be an admission or evidence of any wrongdoing or liability on the part of Releasees, their representatives, heirs, executors, attorneys, agents, partners, officers, shareholders, directors, employees, subsidiaries, affiliates, divisions, successors or assigns. This Agreement shall be afforded the maximum protection allowable under California Evidence Code Section 1152 and/or any other state or federal provisions of similar effect.
- 15. <u>Complete and Voluntary Agreement</u>: This Agreement, together with <u>Exhibits A and B</u> hereto and the Stock Agreements, constitute the entire agreement between you and Releasees with respect to the subject matter hereof and supersedes all prior negotiations and agreements, whether written or oral, relating to such subject matter. You acknowledge that neither Releasees nor their agents or attorneys have made any promise, representation or warranty whatsoever, either express or implied, written or oral, which is not contained in this Agreement for the purpose of inducing you to execute the Agreement, and you acknowledge that you have executed this Agreement in reliance only upon such promises, representations and warranties as are contained herein, and that you are executing this Agreement voluntarily, free of any duress or coercion.
- 16. <u>Severability</u>: The provisions of this Agreement are severable, and if any part of it is found to be invalid or unenforceable, the other parts shall remain fully valid and enforceable. Specifically, should a court, arbitrator, or government agency conclude that a particular claim may not be released as a matter of law, it is the intention of the parties that the general release, the waiver of unknown claims and the covenant not to sue above shall otherwise remain effective to release any and all other claims.
- 17. <u>Modification; Counterparts; Electronic/PDF Signatures</u>: It is expressly agreed that this Agreement may not be altered, amended, modified, or otherwise changed in any respect except by another written agreement that specifically refers to this Agreement, executed by authorized representatives of each of the parties to this Agreement. This Agreement may be executed in any number of counterparts, each of which shall constitute an original and all of which together shall constitute one and the same instrument. Execution of an electronic or PDF copy shall have the same force and effect as execution of an original, and a copy of a signature will be admissible in any legal proceeding as if an original.

Alan Glicklich Page 6

READ, UNDERSTOOD AND AGREED

Date: February 12, 2022

Alan Glicklich

/s/ Alan Glicklich

18. Review of Separation Agreement; Expiration of Offer: You understand that you may take up to twenty-one (21) days to consider this Agreement (the "Consideration Period"). The offer set forth in this Agreement, if not accepted by you before the end of the Consideration Period, will automatically expire. By signing below, you affirm that you were advised to consult with an attorney prior to signing this Agreement. You also understand you may revoke this Agreement within seven (7) days of signing this document and that the separation compensation to be provided to you pursuant to Section 4 will be provided only after the expiration of that seven (7) day revocation period.							
19. <u>Effective Date</u> : This Agreement is effective on the eighth (8th) day after you sign it and without revocation by you (the " <i>Effective Date</i> ").							
20. <u>Governing Law</u> : This Agreement shall be governed by and construed in accordance with the laws of the state of California.							
If you agree to abide by the terms outlined in this Agreement, please sign and return it to me. I wish you the best in your future endeavors.							
	Sincerely,						
	Chinook Therapeutics, Inc.						
	By: /s/ Eric Dobmeier Eric Dobmeier, President & CEO						

EXHIBIT A EMPLOYMENT AGREEMENT

EXHIBIT B CONFIDENTIAL INFORMATION AND INVENTIONS AGREEMENT

The following table presents the name of significant subsidiaries of Chinook Therapeutics, Inc. and the location of jurisdiction or organization for such subsidiaries.

Name:	Jurisdiction/Organization
Chinook Therapeutics U.S, Inc.	Delaware
Chinook Therapeutics Canada, Inc.	British Columbia, CA
Aduro Biotech Holdings, Europe B.V.	Netherlands
Aduro Biotech Europe B.V.	Netherlands
Aduro Netherlands Cooperatief UA	Netherlands

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-203508, 333-210016, 333-216373, 333-223382, 333-229915, 333-237034, 333-249351 and 333-255109) and the Registration Statement on Form S-3 (No. 333-255099) of Chinook Therapeutics, Inc. of our report dated March 17, 2022 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP Seattle, Washington March 17, 2022

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Eric L. Dobmeier, certify that:

- 1. I have reviewed this annual report on Form 10-K of Chinook Therapeutics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 17, 2022 /s/ Eric L. Dobmeier

Eric L. Dobmeier
President, Chief Executive Officer and Director
(Principal Executive Officer)

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Eric H. Bjerkholt, certify that:

- 1. I have reviewed this annual report on Form 10-K of Chinook Therapeutics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: Mach 17, 2022

/s/ Eric H. Bjerkholt
Eric H. Bjerkholt, M.B.A.
Chief Financial Officer
(Principal Accounting and Financial Officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Eric L. Dobmeier, President and Chief Executive Officer of Chinook Therapeutics Inc. (the "Company"), and Eric H. Bjerkholt, Chief Financial Officer of the Company, each hereby certifies, that to the best of his knowledge:

- 1. the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 17, 2022 /s/ Eric L. Dobmeier

Eric L. Dobmeier

President, Chief Executive Officer and Director

(Principal Executive Officer)

Dated: March 17, 2022 /s/ Eric H. Bjerkholt

Eric H. Bjerkholt Chief Financial Officer (Principal Accounting and Financial Officer)