

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

**FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

CinCor Pharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)
230 Third Avenue
Waltham, MA 02451
(844) 531-1834

36-4931245
(I.R.S. Employer
Identification No.)

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

Marc de Garidel
Chief Executive Officer
CinCor Pharma, Inc.
230 Third Avenue
Waltham, MA 02451
(844) 531-1834

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Ryan Sansom
Divakar Gupta
Sarah Sellers
Cooley LLP
500 Boylston Street
Boston, MA 02116
(617) 937-2300

Lisa Firenze
Glenn R. Pollner
Ryan S. Brewer
Wilmer Cutler Pickering Hale & Dorr LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION DATED _____, 2022
PRELIMINARY PROSPECTUS

Shares



CinCor Pharma, Inc.

COMMON STOCK

We are offering _____ shares of common stock. Our common stock is listed on the Nasdaq Global Market under the symbol "CINC." On _____, 2022, the last reported sale price of our common stock on the Nasdaq Global Market was \$ _____ per share. The final public offering price will be determined through negotiation between us and the lead underwriters in the offering and the recent market price used throughout this prospectus may not be indicative of the final offering price.

We are an "emerging growth company" as defined under U.S. federal securities laws and, as such, will be subject to reduced public company reporting requirements for this prospectus and future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company." Investing in our common stock involves risks. See "[Risk Factors](#)" beginning on page 13 of this prospectus.

	Per Share	Total
Public Offering Price	\$ _____	\$ _____
Underwriting Discounts and Commissions(1)	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____

(1) See the section titled "Underwriting" for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional _____ shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock against payment in New York, New York on or about _____, 2022.

Goldman Sachs & Co. LLC

The date of this prospectus is _____, 2022

TABLE OF CONTENTS

	Page
Prospectus Summary	1
Risk Factors	13
Special Note Regarding Forward-Looking Statements	70
Market and Industry Data	72
Use of Proceeds	73
Dividend Policy	74
Capitalization	75
Dilution	77
Management	79
Principal Stockholders	83
Description of Capital Stock	86
Material U.S. Federal Income Tax Consequences to Non-U.S. Holders	92
Underwriting	96
Legal Matters	102
Experts	102
Where You Can Find More Information	102
Incorporation of Certain Information by Reference	102

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained or incorporated by reference in this prospectus or in any free writing prospectuses we have prepared. We and the underwriters take no responsibility for and can provide no assurance as to the reliability of, any other information that others may provide you. We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained or incorporated by reference in this prospectus is accurate only as of the date of this prospectus or in the applicable document incorporated by reference, regardless of the time of delivery of this prospectus or of any sale of the common stock.

To the extent there is a conflict between the information contained in this prospectus, on the one hand, and the information contained in any document filed with the Securities and Exchange Commission before the date of this prospectus and incorporated by reference herein, on the other hand, you should rely on the information in this prospectus. If any statement in a document incorporated by reference is inconsistent with a statement in another document incorporated by reference having a later date, the statement in the document having the later date modifies or supersedes the earlier statement.

For investors outside of the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

All trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert their rights thereto.

PROSPECTUS SUMMARY

This summary highlights, and is qualified in its entirety by, information contained elsewhere or incorporated by reference in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the sections titled “Risk Factors” appearing in this prospectus, and those incorporated by reference from our Annual Report on Form 10-K for the year ended December 31, 2021, as revised or supplemented by our subsequent Quarterly Reports on Form 10-Q or our Current Reports on Form 8-K, as well as any amendments thereto, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the related notes incorporated by reference from our Annual Report on Form 10-K for the year ended December 31, 2021 and any subsequently filed Quarterly Reports on Form 10-Q, before making an investment decision. As used in this prospectus, unless the context otherwise requires, references to “we,” “us,” “our,” “the company,” and “CinCor” and similar references in this prospectus refer to CinCor Pharma, Inc.

OVERVIEW

We are a clinical-stage biopharmaceutical company focused on developing our lead clinical candidate, baxdrostat (CIN-107), for the treatment of hypertension and other cardio-renal diseases. Baxdrostat is a highly selective, oral small molecule inhibitor of aldosterone synthase, the enzyme responsible for the synthesis of aldosterone in the adrenal gland. Baxdrostat is designed to use a differentiated mechanism of action, direct inhibition of aldosterone synthase production, lower aldosterone activity and achieve its goal of providing an improved treatment for patients suffering from hypertension, or high blood pressure. Despite the widespread availability of multiple antihypertensive agents, there remains a significant unmet medical need as more than half of the 116 million hypertensive patients in the United States do not achieve blood pressure control. We are evaluating the efficacy and safety profile of baxdrostat as a potential treatment for the broader hypertensive population, including different subpopulations of hypertensive patients who have not achieved blood pressure control despite treatment. We are conducting five Phase 2 clinical trials designed to evaluate baxdrostat in differing populations of patients, all of whom are hypertensive. The most advanced of our clinical trials, which we refer to as our BrigHtn trial, was conducted in patients whose blood pressure is not controlled despite treatment with three or more antihypertensive agents, one of which must be a diuretic; these patients are designated as having treatment resistant hypertension, or rHTN. In June 2022, the last patient visit in the BrigHtn trial was conducted with 248 patients completing the trial. We are also conducting a separate Phase 2 clinical trial, which we refer to as our HALO trial, to evaluate baxdrostat in patients whose blood pressure is not controlled despite treatment with up to two antihypertensive agents, which is referred to as uncontrolled hypertension, or uHTN. Our HALO trial was initiated in the fourth quarter of 2021 and amended in March 2022 to represent a more comprehensive patient population as well as to enable us to better characterize the relationship between baseline aldosterone levels and blood pressure response across a broader spectrum of aldosterone values. Enrollment for our HALO trial was completed in July 2022, having randomized 249 patients. We are also conducting a Phase 2 clinical trial, which we refer to as our spark-PA trial, evaluating baxdrostat in patients with primary aldosteronism, or PA, a condition characterized by overproduction of aldosterone due to non-malignant tumors or abnormal collections of aldosterone-producing cells in the adrenal glands leads, which often presents with an aggressive form of hypertension. The spark-PA trial was initiated in 2021 and amended in May 2022 to facilitate patient recruitment. Finally, in June 2022 we enrolled our first patient into a Phase 2 clinical trial, referred to as the figHTN trial, designed to evaluate the efficacy and safety of baxdrostat in lowering the blood pressure of patients with chronic kidney disease, or CKD. The figHTN trial also includes secondary endpoints intended to explore the potential impact of baxdrostat on slowing the progression of renal disease using biomarkers. Additionally, an open-label extension clinical trial for patients previously enrolled in our HALO trial has been initiated to evaluate the long-term safety and effectiveness of baxdrostat, which we

refer to as our OLE trial. The primary objective of our OLE trial is to evaluate the safety and tolerability of baxdrostat over an extended treatment period of up to 52 weeks. The OLE trial is expected to be completed in the second half of 2023.









Aldosterone is a steroid hormone synthesized in the adrenal gland that regulates water and salt balance in the human body. It causes retention of water and salt by the kidney, described as a genomic effect that contributes to the pathogenesis of hypertension. In addition to this genomic effect, aldosterone induces certain indirect, non-genomic effects, including pro-inflammatory and pro-fibrotic effects, increases in oxidative stress, as well as cardiac muscle cell hypertrophy and remodeling. Increasing evidence shows a correlation between these non-genomic effects of aldosterone and a worsening of patient outcomes, particularly in patients who have heart disease or kidney disease. Given these potentially deleterious effects of aldosterone, inhibiting its effects is a well understood mechanism of action for the treatment of hypertension and other cardio-renal diseases, such as PA and CKD.

Hypertension is one of the world's leading causes of mortality. According to the United States Centers for Disease Control and Prevention, or the U.S. CDC, approximately 500,000 people still die every year in the United States with uncontrolled blood pressure listed as a primary or secondary cause of death. Despite decades of understanding the importance of controlling hypertension and the widespread availability of multiple approved therapies, only 43.7% of the 116 million U.S. adults with hypertension achieve blood pressure levels of less than 140/90 mm Hg. In addition, many professional medical societies have published more recent guidelines that report that blood pressures less than 130/80 mm Hg, or even lower, would improve cardiovascular outcomes in sub-groups of patients. Of those patients taking one or more antihypertensive agents, it is estimated that approximately 35% still have uncontrolled blood pressure. Although the evidence for the benefits of reducing blood pressure is overwhelming and has been consistently supported by the medical community's recommendations to drive blood pressure to lower levels, the current standard-of-care has not meaningfully changed in more than a decade, with no new classes of antihypertensive agents approved during that period.

There are multiple standard-of-care antihypertensive agents currently available, including angiotensin converting enzyme, or ACE, inhibitors and angiotensin receptor blockers, or ARBs, which are designed to reduce angiotensin activity but can also secondarily produce a lowering of aldosterone levels. Mineralocorticoid receptor antagonists, or MRAs, which block the effects of aldosterone at the mineralocorticoid receptor, typically cause aldosterone levels to rise, though they block the genomic effects triggered by aldosterone. Despite the widespread availability and use of these antihypertensive agents, many of which are available as generic products, each class of drugs currently available is associated with certain limitations, including limited efficacy, limited duration of aldosterone lowering, or significant side effects. Given both the importance of reducing aldosterone and the limitations of currently available therapies, we believe that baxdrostat has the potential to have a significant impact on the treatment paradigm for hypertension and other cardio-renal diseases.

OUR PIPELINE

We are developing baxdrostat for the treatment of multiple diseases where aldosterone plays a significant role in disease pathophysiology, including hypertension and PA. We are also exploring its utility in ameliorating complications of CKD. To support the advancement of this “pipeline-in-a-product” opportunity, we are currently conducting five Phase 2 clinical trials of baxdrostat for different indications and patient populations. The following table summarizes our baxdrostat pipeline across multiple indications.

	Indication	Phase 1	Phase 2	Phase 3	Next Anticipated Milestone
Baxdrostat (CIN-107)	Hypertension (HTN)		Treatment Resistant Hypertension (rHTN) 		EOP2 Mtg - Q4 2022
			Uncontrolled Hypertension (uHTN) 		Phase 3 in planning for 2023 initiation
				Phase 2 topline data expected 2H 2022	
	Chronic Kidney Disease (CKD) *		Chronic Kidney Disease (CKD) 		Phase 2 data expected in 2H 2023
	Primary Aldosteronism (PA)		Primary Aldosteronism 		Phase 2 topline data expected in 2H 2023
Geographic Phase 1 PK Studies					Phase 1 data expected in 2H 2023
					Phase 1 data expected in 1H 2023

* Our CKD trial is evaluating the efficacy and safety of baxdrostat as a treatment for patients with CKD who have uncontrolled blood pressure.

Baxdrostat Overview

Directly inhibiting aldosterone synthesis has long been a goal in therapeutic drug development as the relationship between elevated levels of aldosterone and the progression of multiple diseases is well understood. However, the challenge has been developing a molecule with the ability to safely inhibit aldosterone production without negatively impacting cortisol synthesis. The major enzymes responsible for the synthesis of aldosterone and cortisol share approximately 93% amino acid sequence similarity, and therefore, a highly selective aldosterone synthesis inhibitor is required to avoid inadvertently lowering serum cortisol levels. Multiple programs in development by others have been discontinued over the past several years due to, what we believe is, their product candidates’ lack of selectivity, which resulted in the simultaneous inhibition of both aldosterone and cortisol production. Off-target suppression of cortisol production has the potential to compromise stress and immunologic responses, adversely affect metabolic functions and potentially increase the risk of mortality from severe adrenal insufficiency.

Baxdrostat was designed to be highly selective in its inhibition of steroid hormone synthesis to specifically overcome the risks associated with off-target suppression of cortisol production. Baxdrostat selectively targets aldosterone synthase, which is encoded by the CYP11B2 gene while having a much lower affinity for the blocking activity of 11β-hydroxylase, the enzyme responsible for cortisol synthesis, which is encoded by the CYP11B1 gene. In multiple preclinical *in vivo* studies, baxdrostat significantly lowered aldosterone levels

without affecting cortisol levels, across a wide range of doses. Similar observations were made in two separate Phase 1 clinical trials in healthy volunteers. We observed a dose-dependent reduction of plasma aldosterone levels of up to 90% in healthy volunteers receiving single doses of baxdrostat at doses up to 360 mg, while patients receiving a dose of between 1.5 mg and 5 mg for 10 consecutive days demonstrated reductions in their plasma aldosterone levels of 65% to 71%. These reductions were compared to baseline levels measured the day prior to initial dosing and were not observed in individuals receiving a placebo. Importantly, no effects on cortisol production were observed at doses up to 360 mg, the highest dose evaluated in the single ascending dose study, or up to 5 mg once daily when administered for 10 days in our multiple ascending dose treatment study.

A robust Phase 1 clinical development program for baxdrostat has been conducted, with approximately 180 healthy volunteers dosed across multiple clinical trials to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of baxdrostat. Baxdrostat was shown to be well tolerated in healthy volunteers across all Phase 1 clinical trials conducted to date, with no serious adverse events, or SAEs, or treatment-emergent adverse events, or TEAEs, leading to treatment withdrawal associated with baxdrostat. In addition to the single ascending dose, or SAD, and multiple ascending dose, or MAD, studies detailed below, baxdrostat has been evaluated in a Phase 1 clinical trial in 14 healthy volunteers to demonstrate lack of food effect and biocompatibility from oral solution to tablet. Baxdrostat has also been evaluated in a drug-to-drug interaction Phase 1 clinical trial with metformin in 27 healthy volunteers. Metformin was well tolerated when administered alone or two hours after a dose of baxdrostat. Baxdrostat did not result in changes in metformin plasma concentrations when compared to levels following administration of metformin alone. In addition, a Phase 1 clinical trial was conducted in subjects with varying degrees of renal function. A single 10 mg dose of baxdrostat was well tolerated when administered to individuals with moderate to severe renal impairment or kidney failure (on hemodialysis). No noteworthy increases in systemic exposure or decreases in renal clearance of clodronate were observed.

Hypertension

The first indication we are pursuing for baxdrostat is hypertension, with an initial focus on the subpopulation of patients with rHTN. Hypertension, which is defined by the American College of Cardiology and the American Heart Association as resting blood pressure above 130/80 mm Hg, is generally acknowledged to be the most common preventable risk factor for premature death worldwide. Though often asymptomatic, hypertension significantly increases the risk of heart disease, stroke and kidney disease, amongst other diseases. It is estimated that as much as 20% of the global population suffers from hypertension, and the U.S. Centers for Disease Control estimated that as many as 116 million Americans could be hypertensive and that hypertension costs the United States approximately \$131 billion per year. Patients who fail to maintain blood pressure levels of 130/80 mm Hg or less, despite being compliant with at least three antihypertensive agents, of which one is a diuretic, are considered to have rHTN. The rHTN patient population represents an estimated 8% to 13% of the total hypertensive population in the United States, or approximately 10-15 million individuals. For these patients, treatment options are limited and the current standard-of-care is to introduce an MRA agent to their antihypertensive regimen. Patients with rHTN have approximately five times the number of cardiovascular events per 100 patient-years measured in hypertensive patients whose blood pressure is controlled.

We recently completed our BrigHtn trial, in hypertensive patients who failed to achieve blood pressure control on three antihypertensive agents, one of which must be a diuretic, at their maximally tolerated doses. In addition, we recently completed enrollment in our HALO trial in hypertensive patients whose blood pressure is not controlled despite treatment with up to two antihypertensive agents, referred to as uHTN. Additionally, we initiated our OLE trial for patients previously enrolled in our HALO trial to evaluate the long-term safety and effectiveness of baxdrostat. The primary objective of our OLE trial is to evaluate the safety and tolerability of baxdrostat over an extended treatment period of up to 52 weeks. The OLE trial is expected to be completed in the second half of 2023.

Primary Aldosteronism (PA)

PA is a hormonal disorder that is caused by the autonomous production of aldosterone by the adrenal gland and often leads to hypertension that can be difficult to treat. Although previously considered a rare disease, PA is now understood to be one of the more common causes of secondary hypertension, accounting for 5% to 10% of all hypertensive patients and approximately 20% to 30% of patients with rHTN, or approximately 5 to 11 million individuals in the United States. Compared to primary hypertension, PA causes more end-organ damage and is associated with higher risks of cardiovascular morbidity and mortality. Therefore, it is increasingly recognized that it is important to diagnose these patients early in their disease progression. However, PA continues to be underdiagnosed due to the complexity of the current diagnostic guidelines recommended by the Endocrine Society and the inherent variability in plasma aldosterone measurements.

The overall treatment goal in patients with PA is to prevent the morbidity and mortality associated with hypertension, normalize serum potassium levels in those patients who present with hypokalemia, and reduce renal toxicity and cardiovascular damage. In addition to antihypertensive agents, such as ACE inhibitors and ARBs, PA patients are often treated with an MRA agent, such as spironolactone, or when appropriate, by surgical resection of the adrenal gland. However, MRAs are associated with multiple adverse effects, including a variety of anti-androgenic effects.

In light of the pharmacokinetics and pharmacodynamics profile observed in Phase 1 trials of baxdrostat, we are evaluating the potential of baxdrostat as a treatment for PA in our spark-PA trial. Our spark-PA trial was initiated in 2021 and amended in May 2022 to facilitate patient recruitment in this less commonly diagnosed form of hypertension.

Chronic Kidney Disease (CKD)

CKD is a condition characterized by a gradual degradation of renal function over time as measured by glomerular filtration rate, or GFR, which measures how much blood the kidneys filter each minute, and by the presence of increasing levels of filtered protein in the urine, or proteinuria. According to the CDC, CKD afflicts approximately 15% of the U.S. adult population, or approximately 37 million people. Hypertension, diabetes and glomerulonephritis, or inflammation of the tiny filters within the kidneys, are considered to be the leading contributing factors to the development and progression of CKD. CKD has no cure, and currently available therapeutic options are designed to delay the onset of the more severe manifestations of the disease, most notably kidney failure. Patients with early-stage CKD are recommended to undertake dietary and lifestyle changes in order to improve overall health and reduce renal stress. Given the role of hypertension in CKD, many of the therapeutics prescribed to treat hypertension are also used for the treatment of CKD.

Aldosterone plays a significant role in the pathogenesis of CKD through its hypertensive effect and its non-genomic effects, which are known to enhance oxidative stress and promote inflammation and fibrosis. All of these deleterious effects are known to have an impact on reducing kidney function, especially over the multi-year course of disease progression. Multiple third-party studies and meta-analyses have demonstrated that inhibiting the effect of aldosterone reduces proteinuria, as measured by the level of albumin in the urine, and ultimately delays the progression of CKD. Reductions in systemic aldosterone levels are associated with a blood pressure lowering effect, as well as a direct effect on the progression of CKD. In April 2022, we initiated our fightN trial to evaluate the efficacy and safety of baxdrostat in lowering the blood pressure of patients with CKD, as well as exploring the potential impact of the drug on slowing the progression of renal disease using biomarkers.

OUR STRATEGY

Our strategy is focused on developing and commercializing baxdrostat for the treatment of multiple cardio-renal diseases in which aldosterone is known to play a significant role in the disease pathophysiology, including hypertension and PA. We are also exploring its utility in ameliorating complications of CKD. Key elements of our strategy include the following:

- **Advance baxdrostat through clinical development for the treatment of rHTN.** We recently completed the last clinical visit in our BrigHtn trial in patients with rHTN. While we expect to seek a label for hypertension broadly, if baxdrostat is approved for use, we plan to focus our initial commercial efforts on patients with rHTN, which represents a patient population with limited treatment options and significant unmet medical need of approximately 10-15 million individuals in the United States, approximately 5-7 million in Europe, and approximately 23-30 million in China.
- **Expand the hypertension opportunity for baxdrostat to include patients with uHTN and use as an earlier line of blood pressure therapy.** Despite the widespread availability of multiple, generic antihypertensive agents, which are often used in combination, a large number of patients are considered to have uHTN because they are unable to reach their target blood pressure goals on the therapies they are currently prescribed. There is growing evidence in scientific literature demonstrating that elevated aldosterone levels play a direct role in the pathogenesis of hypertension in the broader hypertensive population. Therefore, we believe a highly selective aldosterone synthase inhibitor, like baxdrostat, that is designed to specifically target aldosterone production may address one of the primary underlying causes of hypertension, thereby allowing more patients to achieve their target blood pressure goal with fewer antihypertensive agents. To evaluate the potential of baxdrostat as an earlier line of therapy and in a broader hypertensive patient population, we initiated our HALO trial in patients who failed to achieve blood pressure control on up to two antihypertensive agents in the fourth quarter of 2021 and amended in March 2022 to represent a more comprehensive patient population as well as to enable us to better characterize the relationship between baseline aldosterone levels and blood pressure response across a broader spectrum of aldosterone values. We completed enrollment in the HALO trial in July 2022, having randomized 249 patients.
- **Leverage the clinical development of baxdrostat in hypertension, if successful, to efficiently develop baxdrostat for the treatment of PA.** PA results from the autonomous production of excess aldosterone and affects approximately 5-10% of the total hypertensive population in the United States. This population is associated with worse outcomes and higher risks of cardiovascular events than the general hypertensive population. The overproduction of aldosterone in patients with PA is caused by unilateral or bilateral adrenal adenoma, and in some cases, adrenal carcinoma. Therefore, the ideal non-surgical treatment of patients with PA would involve both the normalization of blood pressure and reduction of aldosterone synthesis to normal levels. By addressing these elements, the risk of long-term cardiovascular and renal complications may be reduced. Baxdrostat has, in clinical trials, exhibited highly specific and potent inhibitory activity of human aldosterone synthase, the enzyme responsible for aldosterone production and could provide a precisely targeted approach to treating patients with PA.
- **Develop baxdrostat as a potentially differentiated treatment for CKD by impacting disease progression.** Multiple third-party clinical trials and meta-analyses have demonstrated that blocking the effect of aldosterone reduces proteinuria and delays the progression of CKD. Long-term use of current standard-of-care agents blocking activity in the renin angiotensin-aldosterone system, or RAAS, pathway for CKD is associated with aldosterone breakthrough, where patients experience aldosterone levels reverting back to or exceeding baseline levels which may lead to poorer patient outcomes. Based on the results of our preclinical and Phase 1 clinical trials of baxdrostat, we initiated our figHTN trial in hypertensive patients with CKD in April 2022. The

figHTN trial is designed to evaluate the efficacy and safety of baxdrostat in lowering the blood pressure of patients with CKD, as well as explore the potential impact of the drug on slowing the progression of renal disease using biomarkers. The first patient in our figHTN trial was randomized in June 2022.

- **Opportunistically evaluate strategic partnerships to maximize the value of baxdrostat.** As we advance the development of baxdrostat across multiple diseases and continue to generate additional non-clinical and clinical data, we plan to evaluate the path for realizing the potential value of baxdrostat, including in combination with other treatments for certain indications, such as CKD. For certain geographies, we may opportunistically enter into strategic partnerships, inside and outside of the United States, to accelerate development activities in order to realize the commercial potential of baxdrostat. Lastly, in disease areas where aldosterone has been shown to play a significant role in disease progression, such as heart failure, which we do not currently plan to pursue on our own, we may also seek to partner with one or more third parties in order to expand the indications where aldosterone lowering might benefit patients and further broaden the commercial potential of baxdrostat.

RISKS ASSOCIATED WITH OUR BUSINESS

- We have incurred significant operating losses since our inception. We expect to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.
- We have a limited operating history and no history of commercializing products, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- Even if this offering is successful, we will require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate our development of baxdrostat or other operations.
- Our business is entirely dependent at this time on the success of one drug, baxdrostat, for which we are currently pursuing clinical development in various clinical trials. Our future success is substantially dependent on the successful clinical development and regulatory approval of baxdrostat. If we are not able to obtain required regulatory approvals for baxdrostat or any future product candidates, we will not be able to commercialize baxdrostat or any future product candidates and our ability to generate revenue will be adversely affected.
- Interim, “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We may not be successful in our efforts to expand our pipeline beyond baxdrostat for hypertension and PA.
- Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials and we cannot assure you that any ongoing, planned or future clinical trials will lead to results sufficient to obtain the necessary regulatory approvals.
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control. We have found and may continue to find it difficult to enroll patients in our Phase 2 spark-PA clinical trial of baxdrostat in PA.
- We have, and intend to continue to, rely on third parties to conduct, supervise and monitor our existing clinical trials and potential future clinical trials for product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

- We have, and intend to continue to, rely on third parties to produce clinical and commercial supplies of baxdrostat and any future product candidates.
- Our business, operations and clinical development timelines and plans may be adversely affected by the evolving and ongoing COVID-19 pandemic.
- We may face substantial competition, which may result in others developing or commercializing drugs before or more successfully than we do.
- Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of baxdrostat or any future product candidates. If we or any future collaborators are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or they will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.
- Our success depends in part on our ability to 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 INITIAL PUBLIC OFFERING

On January 11, 2022, we completed an initial public offering of our common stock pursuant to which we issued and sold 13,290,813 shares of common stock, including the partial exercise by the underwriters of their option to purchase up to 1,190,813 additional shares of common stock, at a public offering price of \$16.00 per share. We received aggregate net proceeds of \$193.2 million, after deducting underwriting discounts and commissions of \$14.9 million and offering expenses of approximately \$4.5 million.

CORPORATE INFORMATION

We were incorporated under the laws of the State of Delaware in March 2018 as a subsidiary of CinRx Pharma, LLC, CinRx, and we were spun out as an independent company in May 2019. Our principal executive offices are located at City Point, 230 Third Avenue, 6th floor, Waltham, Massachusetts 02451 and our telephone number is (844) 531-1834. Our website address is www.cincor.com. The information contained on, or accessible through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained in, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock. We have included our website in this prospectus solely as an inactive textual reference.

THE OFFERING

Common stock offered by us	shares.
Common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise in full their option to purchase additional shares).
Option to purchase additional shares offered by us	We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of common stock.
Use of proceeds	<p>We estimate that the net proceeds from this offering will be approximately \$ million, or approximately \$ million if the underwriters exercise in full their option to purchase additional shares of common stock, assuming a public offering price of \$ per share, the last reported sale price of our common stock on the Nasdaq Global Market on , 2022, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We intend to use the net proceeds from this offering, plus cash and cash equivalents on hand, to fund the clinical development of baxdrostat, as well as initial preparations for commercialization, if approved, and to fund the manufacture of clinical supply, non-clinical studies and related activities and for working capital and general corporate purposes.</p> <p>See the section titled "Use of Proceeds" beginning for additional information.</p>
Risk factors	<p>You should read the section titled "Risk Factors" beginning on page 13 of this prospectus, and those incorporated by reference from our Annual Report on Form 10-K for the year ended December 31, 2021, as revised or supplemented by our subsequent Quarterly Reports on Form 10-Q or our Current Reports on Form 8-K, as well as any amendments thereto, for a discussion of factors you should consider carefully, together with all the other information included in this prospectus, before deciding to invest in our common stock.</p>
Nasdaq Global Market symbol	"CINC"
<p>The number of shares of our common stock to be outstanding after this offering is based on 37,709,912 shares of our common stock outstanding as of March 31, 2022, and excludes:</p> <ul style="list-style-type: none">• 2,685,597 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of March 31, 2022, at a weighted-average exercise price of \$6.96 per share;	

- shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted subsequent to March 31, 2022, at a weighted-average exercise price of \$ per share;
- 30,148 shares of our common stock issuable upon the vesting of outstanding restricted stock units as of March 31, 2022;
- 4,071,916 shares of our common stock reserved for future issuance under the 2022 Equity Incentive Plan, or the 2022 Plan, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2022 Plan; and
- 355,000 shares of our common stock reserved for future issuance under our 2022 Employee Stock Purchase Plan, or the ESPP, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

Unless otherwise indicated, all information contained in this prospectus, including the number of shares of common stock that will be outstanding after this offering, assumes or gives effect to:

- no exercise of outstanding options or vesting of outstanding restricted stock units after March 31, 2022; and
- no exercise of the underwriters' option to purchase additional shares of common stock from us.

SUMMARY FINANCIAL DATA

The following tables set forth our summary financial data for the periods indicated. We have derived the statements of operations and comprehensive loss data for the years ended December 31, 2020 and 2021 from our audited financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2021 and incorporated by reference into this prospectus. The condensed statements of operations and comprehensive loss data for the three months ended March 31, 2021 and 2022 and the condensed balance sheet data as of March 31, 2022, have been derived from our unaudited condensed financial statements contained in our Quarterly Report on Form 10-Q for the three months ended March 31, 2022 and incorporated by reference into this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information in those unaudited condensed financial statements. Our historical results are not necessarily indicative of the results that should be expected in the future and our operating results for the three months ended March 31, 2022, are not necessarily indicative of the results that may be expected for the full year ended December 31, 2022, or any other interim periods or any future year or period.

You should read the following summary financial data together with our financial statements and the related notes thereto and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" incorporated by reference from our Annual Report on Form 10-K for the year ended December 31, 2021 and our Quarterly Report on Form 10-Q for the three months ended March 31, 2022. The summary financial data in this section are not intended to replace our financial statements and are qualified in their entirety by our financial statements and related notes incorporated by reference into this prospectus.

	Year Ended		Three Months Ended	
	December 31, 2021	December 31, 2020	March 31, 2022 (unaudited)	March 31, 2021 (unaudited)
(in thousands, except share and per share data)				
Statement of Operations and Comprehensive Loss Data:				
Loss Data:				
Operating expenses:				
Research and development	\$ 21,514	\$ 19,162	\$ 9,674	\$ 3,489
General and administrative	20,996	1,963	4,030	924
Total operating expenses	42,510	21,125	13,704	4,413
Loss from operations	(42,510)	(21,125)	(13,704)	(4,413)
Other (income) expense:				
Interest income	(22)	(37)	(51)	(4)
Change in fair value of warrant derivative liabilities	7,880	1,210	3,044	1,210
Total other expense, net	7,858	1,173	2,993	1,206
Net loss	(50,368)	\$ (22,298)	(16,697)	(5,619)
Net loss per share attributable to common stockholders, basic and diluted ⁽¹⁾	\$ (32.52)	\$ (17.84)	\$ (0.50)	\$ (4.49)
Weighted average shares number of common shares used to compute net loss per share attributable to common stockholders, basic and diluted ⁽¹⁾	1,548,677	1,250,000	33,433,596	1,250,000

(1) See Note 8 of the notes to our audited financial statements incorporated by reference into this prospectus from our Annual Report on Form 10-K for the year ended December 31, 2021, and Note 7 of the notes to

our unaudited condensed financial statements incorporated by reference into this prospectus from our Quarterly Report on Form 10-Q for the three months ended March 31, 2022 for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.

	AS OF MARCH 31, 2022	
	ACTUAL	AS ADJUSTED ⁽¹⁾
	(unaudited)	
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents	\$164,602	\$
Marketable securities	149,558	
Working capital ⁽²⁾	315,962	
Total assets	321,648	
Total liabilities	5,686	
Accumulated deficit	(94,400)	
Total stockholders' equity	315,962	

- (1) The as adjusted column reflects the sale of _____ shares of common stock in this offering at the public offering price of \$ _____ per share, the last reported sale price of our common stock on the Nasdaq Global Market on _____, 2022., after deducting underwriting fees and commissions and estimated offering expenses payable by us.
- (2) We define working capital as current assets less current liabilities. It should be noted that working capital is not a measure of operating performance or liquidity defined by U.S. generally accepted accounting principles and may not be comparable to similarly titled measures presented by other companies.

The as adjusted information discussed above is illustrative only and will depend on the actual public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed public offering price of \$ _____ per share, the last reported sale price of our common stock on the Nasdaq Global Market on _____, 2022, would increase or decrease each of cash and cash equivalents, working capital, total assets and total stockholders' equity by \$ _____ million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions. We may also increase or decrease the number of shares of common stock we are offering. Each increase or decrease of 1.0 million in the number of shares of common stock offered by us would increase or decrease each of cash and cash equivalents, working capital, total assets and total stockholders' equity by \$ _____ million, assuming that the assumed public offering price remains the same, and after deducting underwriting discounts and commissions.

RISK FACTORS

Investing in our shares of common stock involves a high degree of risk. You should carefully consider the risks described below and those discussed under the Section titled “Risk Factors” contained in our Annual Report on Form 10-K for the year ended December 31, 2021 incorporated by reference in this prospectus, as well as the other information contained or incorporated by reference into this prospectus, including our financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant operating losses since our inception. We expect to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we will continue to incur significant research and development and other expenses related to our clinical development and ongoing operations. Since inception in 2018, we have incurred significant operating losses. Our net loss was \$50.4 million and \$22.3 million for the years ended December 31, 2021 and 2020, respectively, and \$16.7 million and \$5.6 million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, we had an accumulated deficit of \$94.4 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Since our inception, we have focused primarily on raising capital, organizing and staffing our company, business planning, and acquiring and progressing our lead product candidate, baxdrostat (CIN-107), through clinical development after in-licensing the compound from F. Hoffmann-La Roche Ltd and Hoffmann La-Roche Inc., whom we collectively refer to in this prospectus as Roche, in 2019. It could be several years, if ever, before we have a commercialized drug. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our expenses will increase substantially if, and as, we:

- continue our ongoing and planned development of baxdrostat, including our Phase 2 clinical trials evaluating the safety and efficacy of baxdrostat on treatment-resistant hypertension, or rHTN, uncontrolled hypertension, or uHTN, primary aldosteronism, or PA and in hypertensive patients with chronic kidney diseases, or CKD;
- initiate clinical trials for baxdrostat for any additional cardio-renal indications we may pursue;
- seek marketing approvals for baxdrostat for the treatment of hypertension, PA, and any future product candidates that successfully complete clinical trials;
- maintain, protect and expand our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- incur additional legal, accounting and other expenses associated with operating as a public company;
- establish a sales, marketing, manufacturing and distribution capability to commercialize baxdrostat or any future product candidate for which we may obtain marketing approval; and

- build a portfolio of product candidates through development, or the acquisition or in-license of drugs, product candidates or technologies.

To become and remain profitable, we must succeed in developing and eventually commercializing drugs that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials of baxdrostat for the treatment of hypertension, PA, and any future indications, and other product candidates that we may decide to pursue, obtaining regulatory approval, procuring commercial-scale manufacturing, marketing and selling baxdrostat and any such future products for which we may obtain regulatory approval, as well as discovering or acquiring and then developing additional product candidates. We are only in the preliminary stages of some of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability.

Our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or EMA, or other regulatory authorities to perform studies in addition to those we currently expect, or if there are any delays in the initiation and completion of our clinical trials or the development of baxdrostat or any future product candidates.

Even 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 our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our common stock could also cause you to lose all or part of your investment.

We have a limited operating history and no history of commercializing products, which 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 company founded in 2018 and spun-out as a separate company from CinRx Pharma, LLC, or CinRx, in 2019. Our operations to date have been largely focused on raising capital, organizing and staffing our company, business planning, and acquiring and progressing our lead product candidate, baxdrostat, through clinical development after in-licensing the compound from Roche in 2019. As an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as ours. 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 or a history of successfully developing and commercializing pharmaceutical products.

We may encounter additional and unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We may also face additional costs of building out internal accounting, legal, compliance and other operational and administrative functions. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Additionally, we expect our financial condition and operating results to continue to fluctuate from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Even if this offering is successful, we may require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate our development of baxdrostat or other operations.

Based on our research and development plans, we expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations through . However, we may need to obtain substantial additional funding in connection with our continuing operations and planned activities, including to complete the clinical development of, and seek regulatory approval for, baxdrostat in any indication. Our future capital requirements will depend on many factors, including:

- the timing, progress and results of our ongoing and planned clinical trials of baxdrostat for the treatment of hypertension, PA, as well as any additional cardio-renal indications;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of baxdrostat for additional indications or any future product candidates that we may pursue;
- our ability to establish collaborations on favorable terms, if at all;
- the costs, timing and outcome of the regulatory review of baxdrostat and any future product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for baxdrostat and any future product candidates for which we may receive marketing approval;
- the revenue, if any, received from commercial sales of baxdrostat and any future product candidates for which we may receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the costs of operating as a public company.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, baxdrostat and any future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether terminate our research and development programs or future commercialization efforts. We may also need to seek collaborators for baxdrostat and any future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to baxdrostat and any future product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition, and results of operations and cause the price of our common stock to decline. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the continued disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic and geopolitical events, including the conflict between Russia and Ukraine. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Raising additional capital may cause dilution to our stockholders, including purchasers of shares of our common stock in this offering, restrict our operations or require us to relinquish rights to baxdrostat or any future product candidates.

We expect our expenses to increase in connection with our planned operations. Until such time, if ever, as we can generate substantial revenue from baxdrostat or any future product candidates, we expect to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. Although we are not currently eligible to file a shelf registration statement on Form S-3, we intend to do so when we are eligible, which would potentially allow greater financing flexibility. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of baxdrostat or any future product candidates.

If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, 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 capital when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts, or grant rights to develop and market baxdrostat or any future product candidates that we would otherwise develop and market ourselves.

Risks Related to the Clinical Development of Baxdrostat or Future Product Candidates

Our business is entirely dependent on the success of one clinical development program, baxdrostat, for which we are currently pursuing clinical development in various clinical trials. Our future success is substantially dependent on the successful clinical development and regulatory approval of baxdrostat. If we are not able to obtain required regulatory approvals for baxdrostat or any future product candidates, we will not be able to commercialize baxdrostat or any future product candidates and our ability to generate revenue will be adversely affected.

Baxdrostat is currently our only product candidate and we have not licensed, acquired, or invented any other product candidates for preclinical or clinical evaluation. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and that therefore may be able to better sustain a failure of a lead candidate. The success of our business, including our ability to finance our company and generate any revenue in the future, will, at this point, depend entirely on the successful development, regulatory approval and commercialization of baxdrostat, which may never occur. Neither we nor any future collaborator is permitted to market any drug product candidates in the United States or abroad until we receive regulatory approval from the FDA or applicable foreign regulatory agency. The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Prior to obtaining approval to commercialize baxdrostat and any other product candidate in the United States or abroad, we must demonstrate with substantial evidence from well controlled clinical trials, and to the

satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for baxdrostat is promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies, including human factor studies, or clinical trials for baxdrostat either prior to or post-approval, or it may object to elements of our clinical development program. In addition, the FDA typically refers applications for novel drugs, like baxdrostat and potentially any future product candidates, to an advisory committee composed of outside experts. The FDA is not bound by the recommendation of the advisory committee, but it considers such recommendation when making its decision.

Of the large number of products in development, only a small percentage successfully complete the FDA or comparable foreign regulatory authorities' approval processes and are commercialized. The lengthy approval or marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval or marketing authorization to market baxdrostat or any future product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We have invested a significant portion of our time and financial resources in the development of baxdrostat. Our business is dependent on our ability to successfully complete development of, obtain regulatory approval for, and, if approved, successfully commercialize baxdrostat and any future product candidates in a timely manner.

Even if we eventually complete clinical testing and receive approval of a new drug application, or NDA, or foreign marketing application for baxdrostat and any future product candidates, the FDA or the comparable foreign regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the comparable foreign regulatory authorities also may approve or authorize for marketing a product candidate for a more limited indication or patient population that we originally request, and the FDA or comparable foreign regulatory authorities may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of baxdrostat or any future product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

In addition, the FDA and comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may not be reliable data, may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, "top-line" or preliminary data from our clinical trials. Interim data from ongoing clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. For example, in August 2021, we conducted a review of blinded, preliminary safety data from 124 patients in our BrigHtn trial who had either completed 12 weeks of treatment, or withdrew from the trial. The purpose of this blinded data review was to enable an assessment of the overall management and conduct of the trial, without unblinding any individual patient data. Due to the preliminary and blinded nature of the data, this interim data set was not subject to the standard quality control measures typically associated with final clinical trial results. Due to the blinded nature of the BrigHtn trial, we did not know at the time if participants receiving baxdrostat would experience any decrease in blood pressure, or if the decreases in blood pressure, if any, differed from participants receiving a placebo. In addition, at the time the BrigHtn trial was ongoing, we did not know whether treatment with baxdrostat would

lower blood pressure in a clinically meaningful manner until all clinical trials we intend to complete prior to submitting a request for marketing authorization have been conducted and reviewed by the FDA. Furthermore, this preliminary type of data is not subject to the same quality control measures as final data, which creates a risk that the final results could be materially different from the preliminary results observed in this blinded data review.

Additionally, we may utilize an “open-label” clinical trial design. For example, once patients conclude the HALO trial, they may be moved into a one-year “open-label” extension trial during which patients will continue to receive doses of baxdrostat. The primary purpose of this open-label study is to obtain data on the safety of baxdrostat when patients use the drug for up to one year. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open label trial may not be predictive of future clinical trial results with baxdrostat or any future product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

We may not be successful in our efforts to expand our pipeline beyond baxdrostat for hypertension and PA.

We intend to advance the development of baxdrostat across multiple cardio-renal indications and progress these indications through clinical development. We may not be able to expand the scope of cardio-renal indications for baxdrostat beyond hypertension, PA or leverage our expertise and experience with hypertension and PA to other cardio-renal indications. We may not be able to develop baxdrostat for other indications in a manner that is safe and effective. Even if we are successful in continuing to expand baxdrostat to other indications and further build our pipeline, the potential indications that we identify may not be suitable for clinical development, including as a result of safety, tolerability, efficacy or other characteristics that indicate that they are unlikely to receive marketing approval, achieve market acceptance or obtain reimbursements from third-party payors. If we do not successfully execute on our strategy of expanding our product pipeline, it could significantly harm our financial position and adversely affect the trading price of our common stock.

Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials and we cannot assure you that any ongoing, planned or future clinical trials will lead to results sufficient for the necessary regulatory approvals.

Success in preclinical testing and earlier clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical studies and earlier clinical trials does not ensure that later efficacy trials will be successful, nor does it predict final results. For example, we have only recently completed our first Phase 2 clinical trial, and there can be no guarantee that we will be able to complete our other Phase 2 clinical trials evaluating baxdrostat. In addition, we have not yet completed a Phase 3 clinical trial evaluating the safety and efficacy of baxdrostat in any indication. Baxdrostat and any future product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an

organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

We may encounter substantial delays or difficulties in our clinical trials.

We may not commercialize, market, promote or sell any product candidate without obtaining marketing approval from the FDA or comparable foreign regulatory authorities, and we may never receive such approvals. It is impossible to predict when or if baxdrostat or any future product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of baxdrostat or any future product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidate in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize baxdrostat and any future product candidates, including:

- delays in reaching a consensus with regulatory authorities on design or implementation of our clinical trials;
- regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites;
- the number of patients required for clinical trials of baxdrostat or any future product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, patients may drop out of these clinical trials at a higher rate than we anticipate or fail to return for post-treatment follow-up or we may fail to recruit suitable patients to participate in a trial;
- clinical trials of baxdrostat or any future product candidates may produce negative or inconclusive results;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a baxdrostat or any future product candidates or after an inspection of our clinical trial operations, trial sites or manufacturing facilities;
- occurrence of serious adverse events associated with baxdrostat or any future product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- interruptions resulting from public health emergencies, including those related to the COVID-19 pandemic; or

- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs.

For example, in May 2022 we amended the trial protocol of our spark-PA clinical trial to facilitate the enrollment of patients due to difficulties encountered under the original trial design associated with the prolonged period of elevated blood pressure during washout of existing antihypertensive agents that was called for by the original trial protocol, which prevented us from enrolling patients. We cannot be assured that we will not continue to experience difficulties in enrolling patients in our spark-PA trial. Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future drug sales or other sources. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring competing drugs to market before we do, which could impair our ability to successfully commercialize baxdrostat or any future product candidates and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether all of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

Further, we, the FDA or an IRB may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our investigational new drug applications, or INDs, or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of baxdrostat or any future product candidates could be negatively impacted, and our ability to generate revenues from baxdrostat or any future product candidates may be delayed.

Clinical trials are very expensive, time consuming and difficult to design and implement.

Baxdrostat and any future product candidates we may decide to pursue will require clinical testing before we are prepared to submit an NDA for regulatory approval. We cannot predict with any certainty if or when we

might submit an NDA for regulatory approval for baxdrostat or any future product candidate or whether any such NDA will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA or comparable foreign regulatory authorities may not agree with our proposed endpoints for any future clinical trial of baxdrostat or any future product candidates, which may delay the commencement of our clinical trials. The clinical trial process is also time consuming. We estimate that the successful completion of clinical trials for baxdrostat and any future product candidates will take several years to complete. Furthermore, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials.

Certain of the indications we seek to treat are often underdiagnosed and it may be difficult to identify and enroll patients with these indications. If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients with other trials. Certain of the indications we are pursuing are often underdiagnosed, which may further limit the number of patients available to participate in our clinical trials. For example, despite being one of the more common causes of secondary hypertension, PA continues to be underdiagnosed due to the complexity of the current diagnostic guidelines recommended by the Endocrine Society.

Clinical trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, EMA or foreign regulatory authorities. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- the eligibility criteria for the trial in question;
- the size of the patient population and process for identifying patients;
- the perceived risks and benefits of the product candidate in the trial;
- the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials;
- the willingness of patients to be enrolled in our clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- potential disruptions caused by the COVID-19 pandemic, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors, in addition to any impacts from geopolitical events, including those attributable to the ongoing conflict between Russia and Ukraine;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we currently rely and expect to rely in the future on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

Depending on the data from our ongoing Phase 2 figHTN and spark-PA clinical trials, higher doses of baxdrostat may be needed to treat the patients in those clinical trials than were used in the BrighTn and HALO trials. If true, the FDA may require us to investigate the safety of these higher doses in additional patients for a longer period of time as part of our overall safety database, which could delay our development of baxdrostat or be too expensive for us to continue development.

Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control. We have found, and may continue to find, it difficult to enroll patients in our Phase 2 spark-PA clinical trial of baxdrostat in PA.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. If the actual number of patients with rHTN, uHTN, PA, hypertensive patients with CKD, or any other indications that we may pursue for baxdrostat or future product candidates, is smaller than we anticipate, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of baxdrostat and any future product candidates. Furthermore, certain of the indications we are pursuing may be underdiagnosed, which may further limit the number of patients available to participate in our clinical trials. For example, despite being one of the more common causes of secondary hypertension, we believe PA continues to be underdiagnosed due to the complexity of the current diagnostic guidelines recommended by the Endocrine Society. In addition, enrollment in our spark-PA trial has been slower than anticipated and we recently amended the trial design protocol to remove the placebo arm of the trial, with the goal of alleviating patients' and physicians' concerns about the prolonged period of elevated blood pressure which may be experienced by patients during washout of existing antihypertensive agents that was originally needed to re-confirm the diagnosis of PA, followed by the possibility of randomization into a placebo arm. However, we cannot be assured that we will not continue to experience difficulties in enrolling patients in our spark-PA trial. Even once enrolled we may be unable to retain a sufficient number of patients to complete some of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data, the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication, the proximity of patients to clinical sites, the experience and capabilities of the clinical sites to recruit the correct patients, and the eligibility criteria for the trial. Patient enrollment may also continue to be affected by the ongoing COVID-19 pandemic, which could be due to the prioritization of hospitalization resources toward this pandemic, exposure of healthcare providers to COVID-19 and difficulties for patients to access clinical trial sites and comply with clinical trial protocols.

Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. In addition, any negative results we may report in clinical trials of baxdrostat and any future product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop baxdrostat or any future product candidates or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development activities, such as

manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause baxdrostat or any future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, including comparability testing to bridge earlier clinical data obtained from baxdrostat produced under earlier manufacturing methods or formulations, and regulatory authorities may disagree on the interpretation of results from this testing. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of baxdrostat or any future product candidates and jeopardize our ability to commence sales and generate revenue.

Our business, operations and clinical development timelines and plans may be adversely affected by the evolving and ongoing COVID-19 pandemic.

Our business and operations may be adversely affected by the effects of the recent and evolving COVID-19 virus, which was declared by the World Health Organization as a global pandemic. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including public health directives and orders in the United States and the European Union that, among other things and for various periods of time, directed individuals to shelter at their places of residence, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings and events and ordered cessation of non-essential travel. Future remote work policies and similar government orders or other restrictions on the conduct of business operations related to the COVID-19 pandemic may negatively impact productivity and may disrupt our ongoing research and development activities and our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Further, such orders also may impact the availability or cost of materials, which would disrupt our supply chain and manufacturing efforts and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities.

Although our current and planned clinical trials have not been significantly impacted by the COVID-19 pandemic to date, we may experience related disruptions in the future that could severely impact our clinical trials, including:

- delays, difficulties or a suspension in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- interruptions in our ability to manufacture and deliver drug supply for trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic that may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- interruption of key clinical trial activities, such as clinical trial site monitoring, and the ability or willingness of subjects to travel to trial sites due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA to accept data from clinical trials in these affected geographies.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of this prospectus, such as the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease and the availability, timing and effectiveness of a vaccine, both domestically and globally. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this “Risk Factors” section.

Baxdrostat or any future product candidate may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their doctor. Typically, it is not possible to determine whether the product candidate being studied caused these conditions as the frequency of these adverse events in the placebo-control population is unknown until the trial is unblinded. Regulatory authorities may draw different conclusions or require additional testing determine the likely drug-related causality of any adverse events that are reported in the trials.

In addition, it is possible that as we test baxdrostat or any future product candidates in larger, longer and more extensive clinical trials on larger more diverse groups of patients, or as use of baxdrostat or any future product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects or patients. Many times, side effects are only detectable after investigational drugs are tested in large-scale pivotal trials, which we as an organization have never conducted, or in some cases, after they are made available to patients on a commercial scale after approval. Any adverse effects encountered in our preclinical studies or clinical trials, whether or not drug-related, could affect patient enrollment or the ability of enrolled patients to complete the trial or result in potential product liability claims. If additional clinical experience indicates that baxdrostat or any future product candidates have side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition.

As an organization, we have never completed pivotal clinical trials, and we may be unable to do so for baxdrostat or any product candidates we may develop.

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA and other regulatory agencies to market baxdrostat or any future product candidates. Carrying out later-stage clinical trials and the submission of a successful NDA is a complicated process. As an organization, we have not

previously completed any later stage or pivotal clinical trials and have limited experience in preparing, submitting and prosecuting regulatory filings. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA submission and approval of baxdrostat for treatment resistant hypertension. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials could prevent us from or delay us in commercializing baxdrostat.

We may explore strategic collaborations that may never materialize, or we may be required to relinquish important rights to and control over the development of baxdrostat or any future product candidate to any future collaborators.

We intend to periodically explore a variety of possible strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations can be complicated and time consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic collaborations because of the numerous risks and uncertainties associated with establishing them.

Future collaborations could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our stockholders' percentage ownership of our company;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- strategic collaborators may select indications or design clinical trials in a way that may be less successful than if we were doing so;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of baxdrostat or any future product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research or development of baxdrostat or any future product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

- business combinations or significant changes in a strategic collaborator's business strategy may adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Risks Related to Our Dependence on Third Parties

We have, and intend to continue to, rely on third parties to conduct, supervise and monitor our existing clinical trials and potential future clinical trials for product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We have engaged CROs to conduct our Phase 2 clinical trials in patients with rHTN, uHTN, hypertensive patients with CDK and PA, and our ongoing Phase 1 clinical pharmacology studies, and we expect to engage CROs for future clinical trials of baxdrostat and any future product candidates. We expect to continue to rely on third parties, including clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials, and we do not currently have the ability to independently conduct any clinical trials ourselves. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, the performance of our CROs may also be interrupted by the ongoing COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO staff who are healthcare providers to COVID-19 or prioritization of resources toward the COVID-19 pandemic, in addition to potential impacts from geopolitical events, including those attributable to the ongoing conflict between Russia and Ukraine.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance. We rely upon CROs to monitor and manage data for our clinical programs. We expect to control only certain aspects of the activities of our CROs. Nevertheless, we will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the good laboratory practices, or GLPs, and GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for baxdrostat or any future product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or our CROs fail to comply with 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. Accordingly, if our CROs fail to comply with these regulations or fail to

recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process. We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Our reliance on third parties to conduct clinical trials will result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with CROs and other third parties can be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Such parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- experience business disruptions from public health emergencies or other events, such as the COVID-19 pandemic, and accompanying shelter in place orders or other measures; or
- undergo changes in priorities or become financially distressed.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, fail to comply with regulatory requirements, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

While we will have agreements governing their activities, our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities. If these CROs, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for baxdrostat or any future product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize baxdrostat or any future product candidates. In such an event, our financial results and the commercial prospects for baxdrostat or any future product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

In addition, quarantines, shelter-in-place, and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to the COVID-19 pandemic or other infectious diseases could impact personnel at our CROs, which could disrupt our clinical timelines, which could have a material adverse impact on our business, prospects, financial condition, and results of operations.

We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we

may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of baxdrostat and any future product candidates.

We have, and intend to continue to, rely on third parties to produce clinical and commercial supplies of baxdrostat and any future product candidates.

We do not own or operate facilities for drug manufacturing, storage and distribution, or testing. We are, and will continue to be, dependent on third parties to manufacture the clinical supplies of baxdrostat and any future product candidates. The facilities used by our CMOs to manufacture baxdrostat and any future product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs for manufacture of active drug substances and finished product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure and/or maintain regulatory approval for baxdrostat or any future product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. We intend to use multiple third parties to produce, store and distribute clinical and commercial supply of our drug product and drug substance. As such, we will need to demonstrate to the FDA that the drug product and drug substance from these contract manufacturers are comparable, which may include conducting additional equivalence studies. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of baxdrostat or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market baxdrostat, if approved. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of baxdrostat or any future product candidates.

Further, we also will rely on third-party manufacturers to supply us with sufficient quantities of baxdrostat and any future product candidates, if approved, for commercialization. We do not yet have a commercial supply agreement for commercial quantities of drug substance or drug product. If we are not able to meet market demand for any approved product, it would negatively affect our ability to generate revenue, harm our reputation, and could have a material and adverse effect on our business and financial condition. Increasing the scale of production inherently creates increased risk of manufacturing errors, and we may not be able to adequately inspect every device that is produced, and it is possible that individual devices may fail to perform as designed. Manufacturing errors could negatively impact market acceptance of any of baxdrostat or any future product candidates that receive approval, result in negative press coverage, or increase our liability.

Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured baxdrostat ourselves, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- our third-party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;

- our third-party manufacturers may fail to comply with cGMP-compliance and other inspections by the FDA or other comparable regulatory authorities;
- our inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;
- breach, termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- our third-party manufacturers may not devote sufficient resources to our product candidate;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidate;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

In addition, if we enter into a strategic collaboration with a third party for the commercialization of baxdrostat or any future product candidate, we will not be able to control the amount of time or resources that they devote to such efforts. If any strategic collaborator does not commit adequate resources to the marketing and distribution of baxdrostat or any future product candidate, it could limit our potential revenues.

Any of these events could lead to clinical trial delays, failure to obtain regulatory approval or affect our ability to successfully commercialize baxdrostat or any future product candidates once approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure, or total or partial suspension of production.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs, delay our programs or limit supply of baxdrostat.

Developing commercially viable manufacturing processes for baxdrostat is a difficult and uncertain task and requires significant expertise and capital investment. We are still in the early stages of developing and implementing manufacturing processes for baxdrostat. Our ability to consistently and reliably manufacture baxdrostat is essential to our success, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including cost overruns, potential problems with process scale-up, process reproducibility, stability issues, consistency and timely availability of reagents or raw materials. Furthermore, we have significant dependence on CMOs for our manufacturing processes, which adds additional risks to our manufacturing capabilities. Additionally, we do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidate, and the actual cost to manufacture and process our product candidate could materially and adversely affect the commercial viability of our product candidate. As a result, we may never be able to develop a commercially viable product.

The process of successfully manufacturing products for clinical testing and commercialization may be particularly challenging, even if such products otherwise prove to be safe and effective. The manufacture of our product candidates involves complex processes. Some of these processes require specialized equipment and highly skilled and trained personnel. For example, one of the raw materials we use in the manufacture of our clinical supply requires the use of a high pressure reactor which is a very specialized piece of equipment, and limits our choice of a supplier or suppliers.

Any adverse developments affecting manufacturing operations for our product candidate may result in lot failures, inventory shortages, shipment delays, product withdrawals or recalls or other interruptions in supply which could delay the development of our product candidate. If we are unable to obtain sufficient supply of our

product candidate, whether due to production shortages or other supply interruptions resulting from the ongoing COVID-19 pandemic or otherwise, our clinical trials or regulatory approval may be delayed. We may also have to write off inventory, incur other charges and expenses for supply of product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. In addition, parts of the supply chain may have long lead times or may come from a small number of suppliers. If we are not able to appropriately manage our supply chain our ability to successfully produce our product candidate could be delayed or harmed. Inability to meet the demand for our product candidate could damage our reputation and the reputation of our product candidate among physicians, healthcare payors, patients or the medical community that supports our product candidate development efforts, including hospitals and outpatient clinics.

Furthermore, the manufacturing facilities in which our product candidate will be made could be adversely affected by earthquakes and other natural disasters, equipment failures, labor shortages, power failures, health epidemics such as the COVID-19 pandemic, geopolitical events such as the conflict between Russia and Ukraine, the global supply chain, international trade relations, political turmoil, warfare, terrorist attacks and numerous other factors. If any of these events were to occur and impact our manufacturing facilities, our business would be materially and adversely affected.

We have engaged Medpace Holdings, Inc., a former related party, to assist us with certain of our clinical trials which may expose us to significant regulatory risks. If there are any data integrity issues, we may be required to repeat such studies or required to contract with other CROs, and our clinical development plans will be significantly delayed.

Dr. Troendle a former member of our board of directors, is the chief executive officer and chairman of the board of directors of Medpace Holdings, Inc., or Medpace, and Jonathan Isaacsohn, M.D., FACC, our former Chief Scientific Officer and former member of our board of directors, is an officer of Medpace. We have engaged Medpace to provide us with certain clinical trial related services pursuant to a master services agreement. Relying on a former related party CRO to assist us with our clinical development plans and with the development of data that is used as the basis to support regulatory approval can expose us to significant regulatory risks.

If we are unable to continue receiving clinical trial services from Medpace on acceptable terms, or should we or Medpace cease to continue to work together for any reason, a transition to an alternative CRO could result in delays and increased costs, and may impact our clinical development timelines during such a transition period, any of which could have a material adverse effect on our business, financial condition and results of operations.

We may seek collaborations with third parties for the development or commercialization of baxdrostat and any future product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may seek third-party collaborators for the development and commercialization of baxdrostat or any future product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators for any such arrangements include regional and national pharmaceutical companies and biotechnology companies. If we enter into any additional such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any 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 products, 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. 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 additional 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 such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, 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 revenue.

Risks Related to the Commercialization of Baxdrostat and any Future Product Candidates

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell baxdrostat or any future product candidates, we may not be successful in commercializing baxdrostat or any future product candidates, if and when they are approved.

To successfully commercialize baxdrostat or any future product candidate that may result from our development programs, we will need to build out our sales and marketing capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract field force to market any product candidate we may develop will be expensive and time-consuming and could delay any drug launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may seek to enter into collaborations with other entities to use their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any current or future collaborators do not commit sufficient resources to commercialize baxdrostat, or any future product candidates, or we are unable to develop the necessary capabilities on our own, we may be unable to generate sufficient revenue to sustain our business. We may compete with many companies that currently have extensive, experienced and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We will likely also face competition if we seek third parties to assist us with the sales and marketing efforts of baxdrostat and any future product candidates. 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.

Even if baxdrostat or any future product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if baxdrostat or any future product candidates receive marketing approval, they may fail to gain market acceptance by physicians, patients, third-party payors and others in the medical community. If such product candidates do not achieve an adequate level of acceptance, we may not generate significant drug revenue and may not become profitable. The degree of market acceptance of baxdrostat or any future product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the convenience and ease of administration compared to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- the efficacy and potential advantages compared to alternative treatments and therapies;
- the effectiveness of sales and marketing efforts;
- the prevalence and severity of any side effects;
- the strength of our relationships with patient communities;
- the cost of treatment in relation to alternative treatments and therapies, including any similar generic treatments;
- our ability to offer such drug for sale at competitive prices;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- any restrictions on the use of the drug together with other medications; and
- the awareness and support from key opinion leaders in cardiology.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of baxdrostat or any future product candidates may require significant resources and may never be successful. Because we expect sales of baxdrostat or any future product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of these product candidates to find market acceptance would harm our business.

If the market opportunities for baxdrostat are smaller than we estimate, our business may suffer.

Our eligible patient population may differ significantly from the actual market addressable by baxdrostat. Our projections of both the number of people who have these conditions, as well as the subset of people with these diseases who have the potential to benefit from treatment with baxdrostat, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, insurance claims databases or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Furthermore, certain of the indications we are pursuing may be underdiagnosed, which may further limit the eligible patient population. For example, PA continues to be underdiagnosed despite being one of the more common causes of secondary hypertension due to the complexity of the current diagnostic guidelines recommended by the Endocrine Society. Likewise, the potentially addressable patient population for baxdrostat may be limited or may not be amenable to treatment with baxdrostat, and new patients may become increasingly difficult to identify or access. If the market opportunities for baxdrostat are smaller than we estimate, our business and results of operations could be adversely affected.

We may face substantial competition, which may result in others developing or commercializing drugs before or more successfully than us.

The development and commercialization of new drugs is highly competitive. We may face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

In particular, we face competition from companies in the pharmaceutical, biotechnology and other related markets that are pursuing the development of treatments for hypertension, PA and CKD. Our competitors include Mineralys Therapeutics, Damian Pharma AG, Idorsia Ltd., Quantum Genomics, Ionis Pharmaceuticals, Inc., Alnylam Pharmaceuticals, Inc., Sihuan Pharmaceutical and KBP BioSciences. More established companies may

have a competitive advantage over us due to their greater size, resources and institutional experience. In particular, these companies have greater experience and expertise in securing reimbursement, government contracts and relationships with key opinion leaders, conducting testing and clinical trials, obtaining and maintaining regulatory approvals and distribution relationships to market products and marketing approved drugs. These companies also have significantly greater research and marketing capabilities than we do. If we are not able to compete effectively against existing and potential competitors, our business and financial condition may be harmed.

As a result of these factors, our competitors may obtain regulatory approval of their drugs before we are able to, which may limit our ability to develop or commercialize baxdrostat and any future product candidates. Our competitors may also develop therapies that are safer, more effective, more widely accepted or less expensive than ours, and may also be more successful than we in manufacturing and marketing their drugs. These advantages could render baxdrostat obsolete or non-competitive before we can recover the costs of such product candidates' development and commercialization.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we commercialize baxdrostat or any future product candidates outside of the United States, a variety of risks associated with international operations could harm our business.

We intend to seek approval to market baxdrostat outside of the United States, and may do so for future product candidates. If we market approved products outside of the United States, we expect that we will be subject to additional risks in commercialization including:

- different regulatory requirements for approval of therapies in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including increasing inflation rates, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from pandemics and public health emergencies, including those related to COVID-19 pandemic, geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in and outside of Europe with which we will need to comply. Many biopharmaceutical companies have found the process of marketing their own products in foreign countries to be very challenging.

Healthcare insurance coverage and adequate reimbursement may not be available for baxdrostat or any future product candidates, if approved, which could make it difficult for us to gain market acceptance.

Market acceptance and sales of baxdrostat or any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide for which therapies reimbursement is available, and establish reimbursement levels. While 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 coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Therefore, one payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage, and adequate reimbursement, for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug manufacturers provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, baxdrostat or any future product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize baxdrostat or any future product candidates that we develop.

Outside the United States, the commercialization of therapeutics is 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 baxdrostat, if approved. In many countries, particularly the countries of the European Union, medical product prices 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 a product receives marketing approval. 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, product prices 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 baxdrostat or any future product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of baxdrostat.

We face an inherent risk of product liability exposure related to the testing of baxdrostat or any future product candidates in clinical trials and may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- increased insurance costs;
- the inability to commercialize any product candidate that we may develop; and
- injury to our reputation and significant negative media attention.

Although we maintain product liability insurance coverage with maximum coverage of \$5.0 million per incident and an aggregate loss limit of \$5.0 million, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Regulatory Matters

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of baxdrostat or any future product candidates. If we or any future collaborators are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or they will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

The activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale and distribution, export and import, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable regulatory authorities in other countries. Failure to obtain marketing approval for baxdrostat or any future product candidates will prevent us from commercializing them. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. baxdrostat or any future 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.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, 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. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of baxdrostat or any future product candidates. Any marketing approval we or our collaborators ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Finally, disruptions at the FDA and other agencies may prolong 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, the United States government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Accordingly, if we or any future collaborators experience delays in obtaining approval or if we or they fail to obtain approval of baxdrostat or any future product candidates, the commercial prospects for them may be harmed, and our ability to generate revenues will be materially impaired.

Even if we obtain regulatory approval for baxdrostat or any future product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain regulatory approvals for baxdrostat or any future product candidates, such approvals will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for baxdrostat or any future product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and surveillance to monitor the quality, safety and efficacy of the drug. Such regulatory requirements may differ from country to country depending on where we have received regulatory approval.

In addition, drug manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

Baxdrostat or any future product candidates could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties, if we or our collaborators fail to comply with regulatory requirements or if we or they experience unanticipated problems with such product candidates, when and if it is approved.

Baxdrostat or any future product candidate for which we or our collaborators obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information

and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a risk evaluation and mitigation strategy.

The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

Non-compliance with European Union 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 the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Failure to obtain marketing approval in foreign jurisdictions would prevent baxdrostat or any future product candidate product candidates from being marketed in such jurisdictions.

In order to market and sell our medicines in the European Union and many other jurisdictions, we or our third-party collaborators 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 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 of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. We or any future third-party collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize baxdrostat or any future product candidate in any market.

Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom, should we choose to do so, as a result of the recent withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom withdrew from the European Union, effective December 31, 2020. On December 24, 2020, the United Kingdom and European Union entered into a Trade and Cooperation Agreement. The agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction. Since the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing any product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for any product candidates, which could significantly and materially harm our business.

Our relationships with customers, physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws, data privacy and security laws, transparency laws and other healthcare laws that may constrain the business or financial arrangements and relationships through which we research, sell, market, and distribute our products, if we obtain marketing approval. We will also be subject to healthcare regulation and enforcement by the U.S. federal government and the states and any other countries in which we conduct our business, including our research, and the sales, marketing and distribution of baxdrostat or any future products once they have obtained marketing authorization. For additional information on the healthcare laws and regulations that we may be subject to, see “Business—Government Regulation and Product Approval.”

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. 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, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations 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. 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. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have a material adverse effect on our ability to compete in the marketplace.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, on June 17, 2021 the United States Supreme Court dismissed a challenge on procedural grounds that argued the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the PPACA will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, as amended, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and, following passage of subsequent legislation, including the BBA and the Infrastructure Investment and Jobs Act, will continue 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. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. In January 2013, the American Taxpayer Relief Act of 2012 was enacted which, 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.

Further, in the United States there has been heightened governmental scrutiny over the manner in which manufacturers set prices under government payor programs, and review the relationship between pricing and manufacturer patient programs. On November 20, 2020, the U.S. Department of Health & Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration

from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2027. At the federal level, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. It is unclear whether these or similar policy initiatives will be implemented in the future. Nonetheless, we expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for baxdrostat or any future product candidates, if approved, or additional pricing pressures.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing or new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, baxdrostat or any future product candidates we may develop may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. For additional information on the healthcare reform, see “Business—Government Regulation and Product Approval.”

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions is subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. To date, there have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for products. To those ends, President Trump issued several executive orders intended to lower the costs of prescription drug products. Certain of these orders are reflected in recently promulgated regulations, including an interim final rule implementing President Trump’s most favored nation model. However, as a result of litigation challenging the most favored nation model, on December 27, 2021, the Centers for Medicare & Medicaid Services, or CMS, published a final rule that rescinded the Most Favored Nation model interim final rule. Further, on September 24, 2020, the Trump Administration finalized a rulemaking allowing states or certain other non-federal government entities to submit importation program proposals to the FDA for review and approval. Applicants are required to demonstrate that their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. The FDA concurrently issued a final rule and guidance to providing pathways for states to build and submit plans to import their own FDA-approved drugs that are authorized for sale in other countries (multi-market approved products).

At the state level, individual states are increasingly aggressive in 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. In addition, regional health care organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for baxdrostat or any future product candidates, once approved, or put pressure on our product pricing. We expect that additional state

and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for baxdrostat or any future product candidates or additional pricing pressures.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. 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 baxdrostat or any future product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Even if we obtain and maintain approval for baxdrostat or any future product candidates from the FDA, we may never obtain approval of baxdrostat or any future product candidates outside of the United States, which would limit our market opportunities and could harm our business.

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of baxdrostat or any future product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable foreign regulatory authorities also must approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for any product candidates, if approved, is also subject to approval. Obtaining approval for baxdrostat or any future product candidates in the European Union from the European Commission following the opinion of the European Medicines Agency, if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. Even if a product candidate is approved, the FDA or the European Commission, as the case may be, may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of baxdrostat or any future product candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for baxdrostat may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of baxdrostat or any future product candidates will be harmed and our business, financial condition, results of operations and prospects could be harmed.

We, any future collaborators and our service providers may be subject to stringent and changing obligations related to data privacy and data security and our actual or perceived failure to comply with such obligations could lead us to regulatory investigations or actions; litigation fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

We, our collaborators or our service providers may maintain or have access to a large quantity of sensitive information, including confidential business, patient health and other personally identifiable information in connection with our preclinical studies, and we are or may become subject to laws, orders, regulations, or

regulatory guidance governing the privacy and security of such information. The regulatory framework for privacy, information security, data protection and data processing worldwide is, and is likely to remain, uncertain for the foreseeable future, and it is possible that these or other actual or alleged obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other rules or our practices. Any significant change in data protection laws or data protection obligations could increase our costs and could require us to modify our products or operations, possibly in a material manner, and may limit our ability to develop baxdrostat or any future product candidates.

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 federal, state and local health information privacy laws, security breach notification laws and consumer protection laws. Each of these laws is subject to varying interpretations and constantly evolving. By way of example, the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act, or collectively HIPAA, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information upon “covered entities” (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, and their covered subcontractors. HIPAA also mandates the reporting of certain breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. When HIPAA is not applicable, 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 FTCA, 15 U.S.C § 45(a). The Federal Trade Commission, or 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 may merit stronger safeguards.

In addition, and when applicable, certain state laws govern the privacy and security of health and other personal information, some of which are more stringent than HIPAA. The California Consumer Privacy Act of 2018, or the CCPA, imposes obligations on businesses to which it applies. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to \$7,500 per violation). In addition, the California Privacy Rights Act of 2020, or the CPRA, effective January 1, 2023, will expand the CCPA. For example, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CCPA (as amended), which could increase the risk of an enforcement action. Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which differ from the CPRA and become effective in 2023. Connecticut and Utah have also passed similar state laws, and other states likely will follow in the future. There is also the reasonable possibility of a U.S. national privacy law that may contain additional or different obligations that could impact our business. If we become subject to new data privacy laws, at the state level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors). Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union’s General Data Protection Regulation, or the GDPR, and the United Kingdom’s GDPR, or the UK GDPR, impose strict requirements for processing the personal data of individuals located, respectively within the European Economic Area, or the EEA, and the United Kingdom, or the UK. We may elect to conduct other Phase 1 or Phase 2 clinical trials for baxdrostat in countries outside of the United States, including in the European Union, which could

subject us to European data protection laws, including GDPR. We may also elect to do so for future product candidates. Under the GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to our processing of their personal data. In addition, certain jurisdictions have enacted data localization laws and cross-border personal information transfer laws, which could make it more difficult for us to transfer personal information across jurisdictions (such as transferring or receiving personal information that originates in the EEA or UK). Existing mechanisms that facilitate cross-border personal information transfers may change or be invalidated.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model.

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations. In addition, any such failure or perceived failure could result in public statements against us by consumer advocacy groups, the media or others, which may cause us material reputational harm.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. The FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We cannot ensure that our employees and third-party intermediaries will comply with such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

Further, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

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

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of baxdrostat and any future product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry hazardous waste insurance coverage.

We are subject to U.S. export and import controls, and sanctions laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations, which could harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions.

Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences

Risks Related to Intellectual Property Matters

Our success depends in part on our ability to 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 protection of our proprietary technologies and baxdrostat or any future product candidates, their respective components, formulations, combination therapies, methods used to manufacture them, methods of treatment, and any other proprietary technologies we develop, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing baxdrostat and any future product candidates is dependent upon the extent to which we have rights under valid and enforceable patents 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 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 output 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 third parties and are reliant on our licensors.

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 baxdrostat or any future product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. 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 issued patent claims. If the breadth or strength of protection provided by the patent applications we hold with respect to baxdrostat or any future product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, baxdrostat or any future product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market baxdrostat or any future product candidates under patent protection would be reduced.

Because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensor was the first to file any patent applications related to baxdrostat or any future product candidates. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all.

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 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 the claims of issued patents or pending patent applications of our competitors that we believe are relevant to our commercial activities, and consider that we are free to operate in relation to baxdrostat or any future product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our commercial efforts or may potentially result in baxdrostat or our future product candidates infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which 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 products.

Recent 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. Under the Leahy-Smith America Invents Act, or America Invents Act, enacted in 2013, the United States moved from a "first to invent" to a "first-to-file" 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. A third party that files a patent application in the U.S. Patent and Trademark Office, or the USPTO, after March 2013, but before us, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Because patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to baxdrostat, any future product candidates or other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patent applications.

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. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal district courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO post-grant proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a federal district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a federal district court action. Therefore, 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 patents issuing from those patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The effects of these changes are uncertain as the USPTO recently developed 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, 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 specific patents discussed herein have not been determined and would need to be reviewed. However, 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, all of which could have a material adverse effect on our business and financial condition.

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 compositions of baxdrostat or any future product candidates but that are not covered by the claims of our patents;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors’ patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents by, for example, developing similar or alternative technologies or products in a non-infringing manner;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products 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 cover baxdrostat or any future 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 which design around our patents, or become hostile to us 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;
- we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates 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.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We engage reputable law firms and other professionals to help us comply. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will have to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned patents and/or applications and any patent rights we may own or license in the future. We rely on outside counsel and third parties to pay these fees due to non-U.S. patent agencies. We engage reputable law firms and other professionals to help us comply. Non-compliance 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. If we fail to maintain the patents and patent applications covering our products or technologies, we may not be able to stop a competitor from marketing products that are the same as or similar to baxdrostat or any future product candidates, which would have a material adverse effect on our business. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance 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. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

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

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Patents have a limited term. In most countries, including the United States, the expiration of a patent is generally 20 years after its first effective non-provisional filing date. However, depending upon the timing, duration and specifics of FDA marketing approval of baxdrostat, the back-up compound to baxdrostat, or any future product candidates, one or more of any U.S. patents we may be issued or have licensed may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments.

The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA-approved product as compensation for the patent term lost during 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 and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of baxdrostat or any future product candidates. However, we may not be granted an extension because of, for example, 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 we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our competitive position, business, financial condition, results of operations, and prospects could be harmed, possibly materially.

If there are delays in obtaining regulatory approvals or other additional delays, the period of time during which we can market baxdrostat or any future product candidates under patent protection could be further

reduced. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. Once the patent term has expired, we may be open to competition from similar or generic products. The launch of a generic version of one of our products in particular would be likely to result in an immediate and substantial reduction in the demand for that product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their drug earlier than might otherwise be the case, which could result in material harm to our business.

Intellectual property rights do not necessarily address all potential threats to our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business. The following examples are illustrative:

- others may be able to make compounds or formulations that are similar to baxdrostat or any future product candidates but that are not covered by the claims of any patents, should they issue, that we own or license;
- we or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license;
- we might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our patent applications will not lead to issued patents;
- issued patents that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our issued patents, future trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, trademarks, copyrights or other intellectual property. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover baxdrostat, any future product candidates or other proprietary technologies we may develop. The outcome 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 or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on baxdrostat, any future product candidates or other proprietary technologies we may develop.

There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. 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 litigation. 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, it could have a substantial adverse effect on the price of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of future collaborators, if any, to develop, manufacture, market and sell baxdrostat or any future product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to baxdrostat or any future product candidates and technology, including interference proceedings, post-grant review and inter partes review before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal district court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing baxdrostat or any future product candidates or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

We may in the future pursue invalidity proceedings with respect to third-party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. If we do not prevail in the patent proceedings, the third parties may assert a claim of patent infringement directed at baxdrostat or any future product candidates.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that one or more former employees, collaborators or other third parties has an interest in our patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing baxdrostat, any future product candidates or other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or

right to use, intellectual property that is important to baxdrostat, any future product candidates or other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development of baxdrostat or any future product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize baxdrostat or any future product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

The growth of our business may depend in part on our ability to acquire, in-license or use third-party proprietary rights. For example, baxdrostat or any future product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing our compounds and 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 baxdrostat or any future 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-owner's interest to 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 that we identify as necessary or important to 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 that 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.

We rely on intellectual property licensed from third parties. We face risks with respect to such reliance, including the risk that we could lose these rights that are important to our business if we fail to comply with our obligations under these licenses.

We rely on a license agreement with Roche, or the Roche Agreement, pursuant to which we received exclusive, worldwide, royalty-bearing license under certain patents and specified know-how owned or controlled by Roche and Roche's interest in joint patents and covering certain specified small molecule aldosterone synthase inhibitors, including our product candidate, baxdrostat. The Roche Agreement imposes diligence, milestone payment, royalty payment and other obligations on us. We may in the future in-license additional third-party intellectual property rights on which we may similarly rely. Such licenses may impose diligence, milestone payment, royalty payment and other obligations on us. Any termination of the Roche Agreement or any future licenses could result in the loss of significant rights and could harm our ability to commercialize baxdrostat or any future product candidates. See "Business—License Agreement with Roche" for additional information regarding the Roche Agreement.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- 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 baxdrostat or any future product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

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 product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

Our current and any potential future licensors might conclude that we have materially breached our license agreements and might therefore terminate the relevant license agreements, thereby removing our ability to develop and commercialize products and technology covered by such license agreements. If any of our current or future inbound license agreements are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products that are covered by such license agreements and underlying patents, which might be identical to our products or product candidates. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects. Our business also would suffer if any current or future licensors fail to abide by the terms of the license or fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

Any licensor of ours may have relied on third-party consultants or collaborators or on funds from third parties, such as the United States government, such that such licensor is not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants or advisors are currently, or were previously, employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try

to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims are likely to be expensive to pursue and there can be no assurance that we would prevail in any event. Failure to secure ownership of intellectual property could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our future product candidates.

The United States enacted and implemented wide ranging patent reform legislation in 2013. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

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 could be less extensive than those in the United States. In some cases, we may not be able to obtain patent protection for certain technology outside 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, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection 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 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 enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan and China, may have a higher standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

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.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Reliance on third parties requires us to share our proprietary information, which increases the possibility that such information will be misappropriated or disclosed.

We rely on third parties to develop and manufacture baxdrostat, and we intend to continue to rely on third parties for the development, manufacture or commercialization of baxdrostat or any future product candidate. Since we must, at times, share proprietary information with these parties, we seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share confidential information increases the risk that such information become known by our competitors, is inadvertently incorporated into the technology of others, or is disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how, a competitor's discovery of our know-how or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our know-how. Despite our efforts to protect our know-how, we may not be able to prevent the unauthorized disclosure or use of our technical know-how by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or

violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third-party illegally obtained and is using our proprietary information, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect proprietary information.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of baxdrostat or any future product candidates that are approved for marketing from the products of our competitors. We have been granted CinCor trademark status in the U.S. and U.K., as well as Australia, Brazil, Canada, China, Israel, India, Japan, Republic of Korea, Mexico, Norway, New Zealand, Russian Federation and Turkey under the Madrid Protocol. We have not yet selected trademarks for baxdrostat or any future product candidate and have not yet begun the process of applying to register trademarks for baxdrostat or any other product candidate. The pending application for our house mark CinCor, and for any subsequent trademarks we apply to register, may not be approved. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are challenged, we could be forced to rebrand our products or our company, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with baxdrostat or any future product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

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

In addition to seeking patent and trademark protection for baxdrostat, we also rely on confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, to maintain our competitive position. Trade secrets and know-how can be difficult to protect. In particular, the trade secrets and know-how in connection with our development programs and other proprietary technology we may develop may over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel with scientific positions in academic and industry.

We seek to protect our proprietary information, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to it, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated proprietary information is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or are unwilling to protect trade secrets.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing baxdrostat or any future product candidate. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to baxdrostat, any future product candidates or other proprietary technologies we may develop. Such an outcome could have a materially adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our proprietary information. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our proprietary information were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical and business expertise of Marc de Garidel, our Chief Executive Officer, as well as other members of our senior management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may currently terminate their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of baxdrostat, commercialization, manufacturing and sales and marketing personnel, will be critical to our success.

The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize baxdrostat. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We have in the past hired part-time employees or used consultants, and anticipate we will continue to do so in the future. As a result, certain of our employees, officers, directors or consultants may not devote all of their time to our business, and may from time to time serve as employees, officers, directors and consultants of other companies. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to retain and recruit qualified scientists and advisors, or if any of our key executives, key employees or key consultants discontinues his or her employment or consulting relationship with us, it may delay our growth strategy, development efforts or otherwise harm our business.

We expect to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of June 30, 2022, we had 21 full-time employees and no part-time employees. As the clinical development of baxdrostat progresses and as we move towards submission of a NDA, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and, if baxdrostat or any future product candidates receives marketing approval, we may add sales, marketing and distribution functions. 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. 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.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial statements in a timely manner, which may adversely affect our business, investor confidence in our company and the market value of our common stock.

A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. Although we are not yet subject to the certification or attestation requirements of Section 404 of the Sarbanes-Oxley Act, in the course of reviewing our annual financial statements for our initial public offering, management and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting with respect to the accumulation, tracking, and disclosure of our outstanding common stock that was deemed to be remediated as of the date of this filing. As a result, of such material weakness, there were adjustments to the disclosure of common stock and resulting impact on our net loss per share required in our 2020 and 2019 financial statements.

While we were able to remediate our prior material weakness, there can be no assurance that we will not have material weaknesses in the future. If we fail to meet the demands placed upon us as a public company,

including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results, or report them within the timeframes required by law or Nasdaq. Failure to comply with Section 404 could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. There is no assurance that we will be able to remediate a material weakness in a timely manner, or at all, or that in the future, additional material weaknesses will not exist or otherwise be discovered. If other material weaknesses or other deficiencies occur, our ability to accurately and timely report our financial position could be impaired, which could result in late filings of our required reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, restatements of our financial statements, a decline in the price of our common stock, suspension or delisting of our common stock from Nasdaq, and could adversely affect our reputation, results of operations and financial condition.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may be compromised, which could result in adverse consequences, including but not limited to regulatory investigations or actions; litigation; fines and penalties; reputational harm; loss of revenue or profits; a significant disruption of our product development programs and our ability to operate our business effectively or other adverse consequences.

In the ordinary course of our business, we may collect, store, use, transmit, disclose, or otherwise process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets. We may rely upon third parties (such as service providers) for our data processing-related activities. We may share or receive sensitive data with or from third parties. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. We may also face ongoing challenges to ensure that our own internal computer systems can be protected appropriately against these risks.

Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. These threats come from a variety of sources. In addition to traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors now engage in attacks. We, as well as our collaborators, contractors or consultants or other third parties, may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data. A security incident could disrupt our ability (and that of third parties upon whom we rely) to provide our services. For example, the loss of clinical trial data from completed or future clinical trials by us or our CROs could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and data.

Despite our efforts to ensure the security, privacy, integrity, confidentiality, availability, and authenticity information technology networks and systems, processing and information, we may not be able to anticipate or to implement effective preventive and remedial measures against all data security and privacy threats because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred.

We may have contractual and other legal obligations to notify relevant stakeholders of security incidents. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security breaches involving certain types of data. Such mandatory disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our services, deter new customers for using our services, and negatively impact our ability to grow and operate our business.

We may not have adequate insurance coverage to protect us from or to mitigate liabilities arising out of our privacy and security practices. If the impacts of a security incident, or the successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), it could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage, cyber coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to all or part of any future claim or loss. Our risks are likely to increase as we continue to expand, grow our customer base, and process, store, and transmit increasingly large amounts of proprietary and sensitive data.

Our employees, principal investigators, consultants and commercial partners 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 FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, 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 restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, 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 government 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 ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws,

contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

We have had a number of related party transactions with our former affiliates, which may result in a conflict of interest involving certain of our current and former management and directors.

Historically, we have engaged in a number and variety of transactions with our former affiliates, including CinRx and Medpace. While we believe that these transactions were made on terms that were not less favorable to us than those obtainable on an arm's length basis, there was no independent determination of that fact. In the future, we may continue to enter into transactions with our former affiliates, and some of these transactions may be significant. Related party transactions present difficult conflicts of interest, could result in disadvantages to our company, and may impair investor confidence, which could materially and adversely affect us. Related party transactions could also cause us to become materially dependent on related parties in the ongoing conduct of our business, and related parties may be motivated by personal interests to pursue courses of action that are not necessarily in the best interests of our company and our stockholders. For further information please see the section titled "Certain Relationships and Related Party Transactions" of our Annual Report on Form 10-K for year ended December 31, 2021 incorporated by reference into this prospectus.

Risks Related to This Offering and Ownership of Our Common Stock

The market price of shares of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of shares of our common stock in this offering.

The market price of shares of our common stock may be volatile. The stock market in general and the market for biopharmaceutical and pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above your purchase price. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, the market price for shares of our common stock may be influenced by the following:

- the commencement, enrollment or results of our planned or future clinical trials of baxdrostat and any future product candidates or those of our competitors;
- the success of competitive drugs or therapies;
- regulatory or legal developments in the United States and other countries;
- the success of competitive products or technologies;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to baxdrostat and any future product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate drug supply for any approved drug or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;

- changes in the structure of healthcare payment systems, including coverage and adequate reimbursement for any approved drug;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad, including those related to the COVID-19 pandemic, the conflict between Russia and Ukraine and related sanctions against Russia, increasing inflation rates, and interest rate changes; and
- investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for shares of our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including recently in connection with the ongoing COVID-19 pandemic, the conflict between Russia and Ukraine and related sanctions against Russia, increasing inflation rates, and interest rate changes, which have resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic and conflict between Russia and Ukraine, may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock.

In addition, in the past, companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

Concentration of ownership of shares of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based upon our common stock outstanding as of March 31, 2022, upon the completion of this offering, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before this offering will, in the aggregate, beneficially own shares representing approximately % of our outstanding common stock (assuming the number of shares offered by us as set forth on the cover page of this prospectus remains the same and no purchases of shares in this offering by any members of this group). If our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock acted together, they may be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in the management of our company in ways with which other stockholders disagree.

If you purchase shares of our common stock in this offering, you will suffer immediate dilution of your investment.

The public offering price of our common stock will be substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. Based on an assumed public offering price of \$ per share, the last reported sale price of our common stock on the Nasdaq Global Market on , 2022, you will experience immediate dilution of \$ per share, representing the difference between our pro forma as adjusted net tangible book value per share after this offering and the public offering price per share. After this offering, we will also have outstanding options to purchase shares of our common stock with exercise prices lower than the public offering price. To the extent these outstanding options are exercised, there will be further dilution to investors in this offering. See the section titled “Dilution” for additional information.

We have broad discretion in the use of our cash and cash equivalents, including the net proceeds from this offering, and may use them ineffectively, in ways in which you do not agree or in ways that do not increase the value of your investment.

Our management will have broad discretion in the application of our cash and cash equivalents, including the net proceeds from this offering, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply our cash and cash equivalents effectively could result in financial losses that could have a negative impact on our business, cause the price of our common stock to decline and delay the development of baxdrostat. Pending their use, we may invest our cash and cash equivalents, including the net proceeds from this offering, in a manner that does not produce income or that loses value. See the section titled “Use of Proceeds” for additional information.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is performing well.

Sales of a substantial number of our common stock in the public market could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding shares of our common stock based on the number of shares outstanding as of March 31, 2022 assuming no exercise by the underwriters of their option to purchase additional common stock. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. The remaining shares are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold after the offering as described in the section titled “Underwriting.” In addition, we filed a registration statement on Form S-8 under the Securities Act of 1933, as amended, or the Securities Act, registering the issuance of 7,142,652 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, and the restrictions of Rule 144 in the case of our affiliates.

Additionally, certain holders of our common stock have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves. If we were to register all of these shares, they can be freely sold in the public market, subject to volume limitations applicable to affiliates. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors are elected each year;
- stockholders are not entitled to remove directors other than by a 66 2/3% vote and only for cause;
- stockholders are not permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America is the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation, or our restated certificate, provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action asserting a breach of fiduciary duty;
- any claim or cause of action against us arising under the Delaware General Corporation Law;

- any claim or cause of action arising under or seeking to interpret our restated certificate of incorporation, or our amended and restated bylaws; and
- any claim or cause of action against us that is governed by the internal affairs doctrine.

The provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our restated certificate of incorporation further provides that the federal district courts of the United States of America is the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may result in increased costs for investors to bring a claim. Further, these exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

Our portfolio of marketable securities is subject to market, interest and credit risk that may reduce its value.

We maintain a portfolio of marketable securities. Changes in the value of our portfolio of marketable securities could adversely affect our earnings. In particular, the value of our investments may decline due to increases in interest rates, downgrades of the bonds and other securities included in our portfolio, instability in the global financial markets that reduces the liquidity of securities included in our portfolio, declines in the value of collateral underlying the securities included in our portfolio and other factors. In addition, the ongoing COVID-19 pandemic and the ongoing military conflict between Ukraine and Russia and related sanctions against Russia have and may continue to have an adverse effect on the financial markets in some or all countries worldwide. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks through diversification of our investments and continuous monitoring of our portfolio's overall risk profile, the value of our investments may nevertheless decline.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset a portion of future taxable income, if any, until such unused losses expire, if ever. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period, the corporation's ability to use its pre-change net operating loss carryforwards (NOLs) and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We have not performed an analysis to assess whether an ownership change has occurred. There is also a risk that due to regulatory changes, such as

suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act, or the TCJA, as modified by the Coronavirus Aid, Relief and Economic Security Act, the CARES Act, NOLs generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs generally will be limited in taxable years beginning after December 31, 2020 to 80% of current year taxable income. The TCJA, as modified by the CARES Act, generally eliminates the ability to carry back any NOLs to prior taxable years for tax years beginning after December 31, 2020. Additionally, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary drugs, intellectual property rights, technologies or businesses, as deemed appropriate to carry out our business plan. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and drugs of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing drug programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or drugs sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we engage in future acquisitions or strategic partnerships, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or drugs that may be important to the development of our business.

If research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our share price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or financial analysts publish about us or our business. We do not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrade our shares or issue other unfavorable commentary or research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our shares could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an “emerging growth company,” or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile. We may take advantage of some or all of these reporting exemptions until we are no longer an EGC. We will remain an EGC until the earlier of (i) the fifth fiscal year following the completion of our initial public offering, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 billion, (iii) the last day of the first fiscal year in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter, and (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, EGCs can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not EGCs.

Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We have and will in the future incur increased costs as a result of operating as a public company, and our management has and will in the future be required to devote substantial time to new compliance initiatives.

As a public company, we have and will in the future incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and rules subsequently implemented by the SEC and The Nasdaq Stock Market LLC, or Nasdaq, have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel must devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations has increased our legal and financial compliance costs and make some activities more time consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, as of our current fiscal year ending December 31, 2022 we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an EGC, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Prior to our initial public offering, we had never been required to test our internal control within a specified period. Accordingly, despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains or incorporates statements that constitute forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections titled “Prospectus Summary,” “Risk Factors,” and elsewhere appearing in this prospectus and in the sections titled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business” in our Annual Report on Form 10-K for the year ended December 31, 2021 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, as applicable, which are incorporated by reference in this prospectus. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “estimate,” “believe,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions intended to identify statements about the future. These statements speak only as of the date of this prospectus or in the applicable document incorporated by reference and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include, without limitation, statements about the following:

- the timing, progress and results of our preclinical studies and clinical trials of baxdrostat and any future product candidates, including statements regarding the timing of our planned IND submissions, initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the timing of any submission of filings for regulatory approval of, and our ability to obtain and maintain regulatory approvals for, baxdrostat and any future product candidates;
- our ability to identify patients with the diseases treated by our product candidate and to enroll these patients in our clinical trials;
- our expectations regarding the size of the patient populations, market acceptance and opportunity for and clinical utility of baxdrostat and any future product candidates, if approved for commercial use;
- business disruptions affecting the initiation, patient enrollment, development and operation of our clinical trials, including a public health emergency, such as the COVID-19 pandemic, or geopolitical events, including the ongoing military conflict between Russia and Ukraine, and related sanctions against Russia;
- our expectations regarding the scope of any approved indication for baxdrostat or any future product candidate;
- our ability to successfully commercialize baxdrostat or any future product candidate, if approved;
- our expectations regarding the potential market size and the rate and degree of market acceptance for baxdrostat or any future product candidates that we develop;
- the effects of competition with respect to baxdrostat or any future product candidates, as well as innovations by current and future competitors in our industry;
- our ability to fund our working capital requirements;
- our intellectual property position, including the scope of protection we are able to establish, maintain and enforce for intellectual property rights covering baxdrostat;

- our financial performance and our ability to effectively manage our anticipated growth; and
- our ability to obtain additional funding for our operations and our expected use of proceeds from this offering.

The foregoing list of forward-looking statements is not exhaustive. You should refer to the “Risk Factors” section of this prospectus, incorporated by reference from our Annual Report on Form 10-K for the year ended December 31, 2021, as revised or supplemented by our subsequent Quarterly Reports on Form 10-Q or our Current Report on Form 8-K, as well as any amendments thereto, and the other documents incorporated by reference into this prospectus may include additional factors that could harm our business and financial performance. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus and the documents incorporated by reference into this prospectus will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should, however, review the factors and risks and other information we describe in the reports we will file from time to time with the SEC after the date of this prospectus.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, the events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements.

You should read this prospectus, the documents incorporated by reference into this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

MARKET AND INDUSTRY DATA

We are responsible for the disclosure contained in this prospectus and the documents incorporated by reference into this prospectus. However, this prospectus and the documents incorporated by reference into this prospectus contain industry, statistical and market data derived from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. All of the market data used in this prospectus and the documents incorporated by reference into this prospectus involve a number of assumptions and limitations, and the sources of such data cannot guarantee the accuracy or completeness of such information. While we are not aware of any misstatements regarding the third-party information and we believe that each of these studies and publications is reliable, the industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section titled "Risk Factors" appearing in this prospectus, and those incorporated by reference from our Annual Report on Form 10-K for the year ended December 31, 2021, as revised or supplemented by our subsequent Quarterly Reports on Form 10-Q or our Current Reports on Form 8-K, as well as any amendments thereto. These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately \$ _____ million, or approximately \$ _____ million if the underwriters exercise in full their option to purchase additional shares from us, in each case after deducting the underwriting discounts and commissions and estimated offering expenses payable by us and based on an assumed public offering price of \$ _____ per share, the last reported sale price of our common stock on the Nasdaq Global Market on _____, 2022.

Each \$1.00 increase or decrease in the assumed public offering price of \$ _____ per share, the last reported sale price of our common stock on the Nasdaq Global Market on _____, 2022, would increase or decrease the net proceeds to us from this offering by approximately \$ _____ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions payable by us. We may also increase or decrease the number of shares we are offering. Each 1,000,000 share increase or decrease in the number of shares offered by us would increase or decrease the net proceeds to us from this offering by approximately \$ _____ million, assuming that the assumed public offering price remains the same, and after deducting underwriting discounts and commissions payable by us.

We intend to use the net proceeds of this offering, plus cash and cash equivalents on hand, to fund the clinical development of baxdrostat, as well as initial preparations for commercialization, if approved, and to fund the manufacture of clinical supply, non-clinical studies and related activities and for working capital and general corporate purposes.

Based on our planned use of the net proceeds from this offering and our existing cash and cash equivalents and marketable securities, we estimate that such funds will be sufficient to fund our operating expenses and capital expenditure requirements through _____. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. The expected net proceeds from this offering, together with our existing cash and cash equivalents and marketable securities, will not be sufficient for us to fund baxdrostat through regulatory approval in any indication, and we will need to raise additional capital to complete the development and commercialization, if approved, of baxdrostat for hypertension as well as any indication expansion opportunities.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the net proceeds to in-license, acquire or invest in additional businesses, technologies, products or assets. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering. See “Risk Factors—Risks Related to This Offering and Ownership of Our Common Stock—We have broad discretion in the use of our cash and cash equivalents, including the net proceeds from this offering, and may use them ineffectively, in ways in which you do not agree or in ways that do not increase the value of your investment.”

Pending our use of proceeds from this offering, we plan to invest these net proceeds in a variety of capital preservation instruments, including money market funds that invest primarily in short-term U.S. government securities and short term marketable securities that are primarily invested in fixed income securities.

DIVIDEND POLICY

We have never declared or paid any dividends on our capital stock. We currently intend to retain all available funds and any future earnings for the operation and expansion of our business and, therefore, we do not anticipate declaring or paying cash dividends in the foreseeable future. The payment of dividends will be at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payment of dividends present in any future debt agreements and other factors that our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash and cash equivalents, marketable securities and our capitalization as of March 31, 2022:

- on an actual basis; and
- on an adjusted basis to give effect to our issuance and sale of _____ shares of common stock in this offering at an assumed public offering price of \$ _____ per share, the last reported sale price of our common stock on the Nasdaq Global Market on _____, 2022, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the closing of this offering will depend on the actual public offering price and other terms of this offering determined at pricing. You should read this table together with our financial statements and the notes related thereto and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2021 and our Quarterly Report on Form 10-Q for the three months ended March 31, 2022, and other financial information contained in this prospectus.

	As of March 31, 2022	
	Actual	As Adjusted ⁽¹⁾
	(in thousands, except share and per share amounts)	
Cash and cash equivalents and marketable securities	\$314,160	\$
Stockholders’ equity:		
Common stock, \$0.00001 par value; 1,000,000,000 shares authorized and 37,709,912 shares issued and outstanding, actual; 1,000,000,000 shares authorized and shares issued and outstanding, as adjusted		0.3
Additional paid-in capital	410,680	
Accumulated deficit	(94,400)	
Accumulated other comprehensive loss		(318)
Total stockholders’ equity	315,962	
Total capitalization	\$630,122	\$

(1) Each \$1.00 increase or decrease in the assumed public offering price of \$ _____ per share, the last reported sale price of our common stock on the Nasdaq Global Market on _____, 2022, would increase or decrease the as adjusted amount of each of cash and cash equivalents, marketable securities, additional paid-in capital, total stockholders’ (deficit) equity and total capitalization by \$ _____ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million in the number of shares offered by us would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, marketable securities, additional paid-in capital, total stockholders’ (deficit) equity and total capitalization by \$ _____ million, assuming no change in the assumed public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock to be outstanding after this offering in the table above is based on the 37,709,912 shares of our common stock outstanding as of March 31, 2022, and excludes:

- 2,685,597 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of March 31, 2022, at a weighted-average exercise price of \$6.96 per share;
- shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted subsequent to March 31, 2022, at a weighted-average exercise price of \$ per share;
- 30,148 shares of our common stock issuable upon the vesting of outstanding restricted stock units as of March 31, 2022;
- 4,071,916 shares of our common stock reserved for future issuance under the 2022 Plan, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2022 Plan; and
- 355,000 shares of our common stock reserved for future issuance under the ESPP, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the public offering price per share and the as adjusted net tangible book value per share of our common stock after this offering.

As of March 31, 2022, we had a historical net tangible book value of \$316.0 million, or \$8.38 per share of common stock. Our historical net tangible book value per share represents total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding as of March 31, 2022.

After giving effect to the sale of _____ shares of common stock in this offering at an assumed public offering price of \$ _____ per share, the last reported sale price of our common stock on the Nasdaq Global Market on _____, 2022, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of March 31, 2021 would have been \$ _____ million, or \$ _____ per share. This amount represents an immediate increase in the net tangible book value of \$ _____ per share to our existing stockholders and immediate dilution of \$ _____ per share to new investors in this offering. We determine dilution by subtracting the as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of common stock in this offering.

The following table illustrates this dilution:

Assumed public offering price per share	\$
Historical net tangible book value per share as March 31, 2022	\$8.38
Increase in as adjusted net tangible book value per share attributable to new investors participating in this offering	\$
As adjusted net tangible book value per share after this offering	\$
Dilution per share to new investors participating in this offering	\$

The dilution information discussed above is illustrative only and will change based on the actual public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed public offering price of \$ _____ per share, the last reported sale price of our common stock on the Nasdaq Global Market on _____, 2022, would increase or decrease the as adjusted net tangible book value per share after this offering by \$ _____, and dilution in net tangible book value per share to new investors by \$ _____, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase of 1,000,000 shares in the number of shares we are offering would increase the as adjusted net tangible book value per share after this offering by \$ _____ and decrease the dilution per share to new investors participating in this offering by \$ _____, assuming no change in the assumed public offering price per share and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A decrease of 1,000,000 shares in the number of shares we are offering would decrease the as adjusted net tangible book value per share after this offering by \$ _____ and increase the dilution per share to new investors participating in this offering by \$ _____, assuming no change in the assumed public offering price per share and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares of our common stock in full, the as adjusted net tangible book value after this offering would be \$ _____ per share, the increase in net tangible book value would be \$ _____ per share and the dilution to new investors would be \$ _____ per share, in each case assuming an public offering price of \$ _____ per share, the last reported sale price of our common stock on the Nasdaq Global Market on _____, 2022.

The number of shares of our common stock to be outstanding after this offering is based on the 37,709,912 shares of our common stock outstanding as of March 31, 2022 and excludes:

- 2,685,597 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of March 31, 2022, at a weighted-average exercise price of \$6.96 per share;
- _____ shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted subsequent to March 31, 2022, at a weighted-average exercise price of \$ _____ per share;
- 30,148 shares of our common stock issuable upon the vesting of outstanding restricted stock units as of March 31, 2022
- 4,071,916 shares of our common stock reserved for future issuance under the 2022 Plan, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2022 Plan; and
- 355,000 shares of our common stock reserved for future issuance under the ESPP, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

To the extent that stock options are exercised, new stock options are issued under our equity incentive plan or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

MANAGEMENT

Executive Officers and Directors

The following table provides information regarding our current executive officers and directors, including their ages, as of July 31, 2022.

Name	Age	Position(s)
Executive Officers		
Marc de Garidel	64	Chief Executive Officer and Director
Mary Theresa Coelho, M.B.A.	61	Executive Vice President, Chief Financial Officer and Chief Business Development Officer
Catherine Pearce, M.B.A., D.HSc.	46	Chief Operating Officer
Mason Freeman, M.D.	71	Chief Medical Officer
Non-Employee Directors		
James I. Healy, M.D., Ph.D.	57	Chairman of the Board of Directors
David Allison, Ph.D.	40	Director
Maina Bhaman, M.B.A.	50	Director
Troy Ignelzi	54	Director
June Lee, M.D.	56	Director
Jason Pitts, Ph.D.	36	Director
John F. Thero	61	Director

Executive Officers

Marc de Garidel has served as our Chief Executive Officer and a member of our board of directors since July 2021. Prior to being appointed as our Chief Executive Officer, he served as the chief executive officer of AZTherapies, Inc. from September 2020 to April 2021, and as a member of the board of directors of AZTherapies, Inc. until August 2021. Mr. de Garidel currently serves on the board of directors of Claris Biotherapeutics, Inc. Prior to September 2020, Mr. de Garidel served as the chief executive officer of Corvidia Therapeutics, Inc. from January 2018 until their acquisition by Novo Nordisk A/S in August 2020. Mr. de Garidel also served as the chief executive officer of Ipsen SA from November 2010 to July 2016, and has served as the chairman of Ipsen’s board of directors since November 2010. Mr. de Garidel started his career at Eli Lilly pharmaceutical group in 1983, where he held various roles of increasing responsibility before joining Amgen Inc., in 1995 as its chief financial officer in Europe. Mr. de Garidel graduated from the Ecole Spéciale des Travaux Publics and obtained a master of international management at Thunderbird School of Global Management. We believe Mr. de Garidel’s substantial leadership experience in the biotechnology industry qualifies him to serve on our board of directors.

Mary Theresa Coelho, M.B.A., has served as our Executive Vice President, Chief Financial Officer and Chief Business Development Officer since November 2021. Previously, Ms. Coelho served as the executive vice president, chief financial officer and treasurer of BioDelivery Sciences International, Inc. from January 2019 to November 2021 and as chief financial officer and treasurer at Balchem Corporation from October 2017 to October 2018. In addition, she also served as chief operating officer for Diversey, Inc., from September 2017 to October 2017 and held senior finance positions at Diversey Care, a division of Sealed Air Corporation from October 2014 through August 2017, including as chief financial officer and vice president of global commercial excellence. She has served on the board of directors of First Wave BioPharma Inc since August 2021, and currently serves as chair of the audit committee and member of the compensation committee for First Wave BioPharma Inc. Ms. Coelho earned an M.B.A. in finance from IBMEC in Brazil and a B.A. in both economics and international relations, summa cum laude, from the American University School of International Service.

Catherine Pearce, M.B.A., D.HSc., co-founded our company in 2018 and has served as our Chief Operating Officer since May 2019. Previously, Ms. Pearce served as both the chief operating officer of CinRx and the vice president, strategic alliances at Medpace from September 2015 until August 2021. Ms. Pearce also served as the vice president, research and development at Teva Pharmaceutical Industries Ltd. from April 2013 until September 2015. Ms. Pearce was appointed to the board of trustees of Xavier University in May 2022. Ms. Pearce has a B.S. and an M.B.A. from Xavier University and a doctorate of health sciences from Nova Southeastern University.

Mason Freeman, M.D., has served as our Chief Medical Officer since March 2022 and was our Executive Vice President, Clinical Development from August 2021 through March 2022, and as a member of our scientific advisory board since June 2019. Dr. Freeman also serves as a venture partner at 5AM Venture Management, LLC, a position he has held since May 2008. In addition, Dr. Freeman serves as the director of the Massachusetts General Hospital's Translational Research Center. Previously, Dr. Freeman served as a member of the board of directors of scPharmaceuticals Inc. from July 2018 to December 2020 and Crinetics Pharmaceuticals, Inc. from November 2015 to July 2019. Dr. Freeman holds a B.A. from Harvard College and an M.D. from the University of California, San Francisco.

Non-Employee Directors

David Allison, Ph.D., has served as a member of our board of directors since May 2019. Dr. Allison has served as a partner at 5AM Venture Management, LLC since July 2018, and as a principal at 5AM Venture Management, LLC since August 2016. Dr. Allison previously served as a principal at Versant Ventures Management, LLC, or Versant Ventures, from April 2014 to August 2016. Prior to Versant Ventures, Dr. Allison worked at Split Rock Partners, LLC as a principal from August 2009 to August 2014, and at PTV Healthcare Capital as a senior associate from 2006 to 2009. Dr. Allison currently serves on the boards of directors of various private companies and as lead director and compensation committee member at Impel Neuropharma, Inc. Dr. Allison received a Ph.D. in bioengineering from Rice University and a B.S.E in biomedical engineering from The University of Iowa. We believe that Dr. Allison is qualified to serve on our board of directors based on his expertise in corporate governance, financing and financial matters and his investment experience in the health care industry.

Maina Bhaman, M.B.A., has served as a member of our board of directors since May 2019. Ms. Bhaman has been a general partner of Sofinnova Partners SAS, or Sofinnova Partners, since January 2018. Prior to joining Sofinnova Partners, she was director of healthcare investment at Touchstone Innovations LLC (formerly Imperial Innovations) in London from April 2006 to November 2017. Ms. Bhaman is currently on the board of directors of four private biopharmaceutical companies, Catamaran Bio, Inc., ENYO Pharma SA, Myricx Pharma Ltd., Mironid Ltd. Ms. Bhaman has a B.S. from the University of Texas at Austin and an M.B.A. from the Imperial Business School in London. We believe that Ms. Bhaman is qualified to serve on our board of directors based on her experience in the biopharmaceutical industry, including as a long-term healthcare investor.

James I. Healy, M.D., Ph.D., has served as a member of our board of directors since May 2019. Dr. Healy has been a general partner of Sofinnova Investments, Inc., a biotech investment firm, since June 2000. Prior to June 2000, Dr. Healy held various positions at Sanderling Ventures, Bayer Healthcare Pharmaceuticals LLC and ISTA Pharmaceuticals, Inc. Dr. Healy is currently on the board of directors of Bolt BioTherapeutics, Inc., Karuna Therapeutics, Inc., Natera, Inc., Y-mAbs Therapeutics, Inc., and one private company. Previously, he served as a board member of Amarin Corporation, Ascendis Pharma A/S, Auris Medical Holding AG, Edge Therapeutics, Inc., Hyperion Therapeutics, Inc., InterMune, Inc., Anthera Pharmaceuticals, Inc., Durata Therapeutics, Inc., CoTherix, Inc., Iterum Therapeutics, plc, Movetis NV, NuCana plc, ObsEva SA, and several private companies. In 2011, Dr. Healy won the IBF Risk Innovator Award and was named as one of the industry's top leading Life Science investors in 2013 by Forbes Magazine. Dr. Healy has a B.A. in molecular biology and a B.A. in Scandinavian studies from the University of California, Berkeley, and has an M.D. and Ph.D. in immunology from Stanford University School of Medicine. We believe that Dr. Healy is qualified to serve on our board of

directors due to his extensive experience in the biopharmaceutical industry, including as a venture capital investor and a member of the boards of directors of other biopharmaceutical companies.

Troy Ignelzi has served as a member of our board of directors since May 2021. Mr. Ignelzi has served as the chief financial officer of Karuna Therapeutics, Inc. since March 2019. Prior to that, Mr. Ignelzi was the chief financial officer of scPharmaceuticals Inc. from March 2016 to February 2019, and provided consulting services to scPharmaceuticals Inc. in February and March 2016. Mr. Ignelzi previously served as chief financial officer and as a member of the executive leadership teams at Juventas Therapeutics Inc., a privately held biotechnology company, from October 2014 to February 2016. From October 2013 to October 2014, Mr. Ignelzi served as senior vice president of operations and business development of Pharmalex GmbH. Prior to Pharmalex, Mr. Ignelzi was vice president of business development at Esperion Therapeutics, Inc., a public pharmaceutical company, from January 2009 to September 2013. Mr. Ignelzi is currently on the board of directors of several private companies. Mr. Ignelzi has a B.S. in accounting from Ferris State University. We believe Mr. Ignelzi's experience in corporate finance and the biopharmaceutical industry qualifies him to serve on our board of directors.

June Lee, M.D., has served as a member of our board of directors since January 2022. Dr. Lee has served as a venture partner at 5AM Venture Management, LLC since July 2022. Dr. Lee was most recently founder and chief executive officer of Esker Therapeutics until September 2021. Dr. Lee previously served as the executive vice president and chief development officer of MyoKardia, Inc. from January 2019 to June 2020, and was the chief operating officer from February 2017 until January 2019, and the chief development officer from October 2017 to January 2019. From April 2011 until February 2017, Dr. Lee served on the faculty of the University of California, San Francisco, or UCSF, where she was director of the Catalyst program at the Clinical and Translational Science Institute and a professor in the School of Medicine, and was responsible for overall strategy and operations for enabling and supporting translational research at the university. Catalyst is an internal UCSF accelerator for therapeutics, devices, diagnostics, and digital health technologies. Prior to UCSF, Dr. Lee was a disease area lead, early clinical development, at Genentech, Inc. from 2006 to 2011, where she was responsible for all strategy and activities as well as management of staff, budget, and resource allocation in the early clinical development group in multiple therapeutic areas. Dr. Lee served as a medical director in the clinical development group at Genentech, Inc. from 2004 to 2006, where she was responsible for clinical activities for licensed product of the company. She currently serves on Johns Hopkins University Center for Therapeutic Translation's Advisory Board, serves on the board of directors of Tenaya Therapeutics Inc, Eledon Pharmaceuticals Inc. and GenEdit, and is a member of the Scientific Advisory Board for Foresite Labs. Dr. Lee holds a B.A. in chemistry from Johns Hopkins University and an M.D. from the University of California, Davis. We believe that Dr. Lee is qualified to serve on our board of directors based on her expertise in clinical development and the biopharmaceutical industry.

Jason Pitts, Ph.D., has served as a member of our board of directors since September 2021. Dr. Pitts has served as a vice president at General Atlantic since March 2021. Dr. Pitts previously was employed by Sofinnova Investments, serving as a principal from June 2019 to January 2021 and an associate from January 2018 to May 2019. Prior to joining Sofinnova Investments, Dr. Pitts worked at McKinsey & Company as an associate from February 2016 to January 2018. Dr. Pitts received a B.S. in neuroscience from Cornell University and a Ph.D. in neuroscience from Rockefeller University. We believe that Dr. Pitts is qualified to serve on our board of directors based on his expertise in corporate governance, financing and financial matters and his investment experience in the health care industry.

John F. Thero has served as a member of our board of directors since May 2021. Mr. Thero was the president and chief executive officer of Amarin Corporation plc from January 2014 through July 2021 after previously serving as that company's president, commencing in 2010 and its chief financial officer, commencing in 2009. Mr. Thero also served on the board of directors of Amarin Corporation plc throughout his tenure as its chief executive officer. Prior to his tenure at Amarin Corporation plc, Mr. Thero served in executive level positions at multiple public and private companies including ViaCell, Inc., where he served as chief financial

officer, and Abiomed, Inc., where he served as chief financial officer and senior vice president of business operations, among other positions of increasing responsibility. Mr. Thero began his professional career at Arthur Andersen LLP. Mr. Thero has served on the board of directors of Cyteir Therapeutics, Inc. since February 2022. He previously served on the board of directors of Chiasma, Inc. from November 2015 through August 2021. Mr. Thero has a B.A. in economics and accounting from The College of the Holy Cross. In 2019, Mr. Thero was awarded EY's Entrepreneur of the Year for Life Sciences. We believe Mr. Thero is qualified to serve on our board of directors based on his operational and financial background, including his over 25 years' experience in the life sciences industry.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock as of June 30, 2022 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC. Under these rules, beneficial ownership includes any shares of common stock as to which the individual or entity has sole or shared voting power or investment power. Applicable percentage ownership before the offering is based on _____ shares of common stock outstanding as of June 30, 2022. Applicable percentage ownership after the offering is based on _____ shares of common stock outstanding, after giving effect to the sale of _____ shares of our common stock by us in this offering and assuming no exercise of the underwriters' option to purchase additional shares. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options held by such person that are currently exercisable or will become exercisable within 60 days of June 30, 2022 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless noted otherwise, the address of all listed stockholders is c/o CinCor Pharma, Inc., 230 Third Avenue, Waltham, MA 02451.

Name of Beneficial Owner	Number of Shares Beneficially Owned ⁽¹⁾	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
5% Stockholders			
Sofinnova Venture Partners X, L.P. ⁽²⁾	5,573,949	%	%
Entities affiliated with 5AM Ventures VI, L.P. ⁽³⁾	4,337,646		
General Atlantic (CIN), L.P. ⁽⁴⁾	4,126,470		
Sofinnova Capital IX ⁽⁵⁾	4,087,646		
CinRx Pharma LLC ⁽⁶⁾	3,630,103		
Adage Capital Partners, L.P. ⁽⁷⁾	2,140,546		
venBio Global Strategic Fund III, L.P. ⁽⁸⁾	1,980,706		
Named Executive Officers and Directors			
Marc de Garidel ⁽⁹⁾	377,500		
Mary Theresa Coelho, M.B.A. ⁽⁹⁾	22,058		
Mason Freeman, M.D. ⁽⁹⁾	66,502		
David Allison, Ph.D. ⁽¹⁰⁾	31,330		
James I. Healy, M.D., Ph.D. ⁽¹¹⁾	5,603,360		
Jason Pitts, Ph.D.	—		
John F. Thero ⁽¹²⁾	70,931		
June Lee, M.D.	—		
Maina Bhaman, M.B.A.	—		
Troy Ignelzi ⁽¹²⁾	70,931		
All current executive officers and directors as a group (11 persons)	6,419,497	%	%

* Represents beneficial ownership of less than one percent.

- (1) This table is based upon information supplied by officers and directors and Schedules 13D and 13G and Forms 3 and 4 filed with the SEC. Except as indicated by the footnotes below, we believe, based on information furnished to us, that each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.
- (2) Consists of 5,573,949 shares of common stock. James Healy, a member of our board of directors, and Maha Katabi are the managing members of Sofinnova Management X, L.L.C., or SM X, the general partner of Sofinnova Venture Partners X, L.P., or SVP X, and may be deemed to have shared voting and investment control over the shares held by SVP X. Each of such individuals disclaims beneficial ownership of such shares except to the extent of their pecuniary interest therein. The address of Sofinnova Venture Partners X, L.P. is c/o Sofinnova Investments, Inc., 3000 Sand Hill Road, Building 4-Suite 250, Menlo Park, CA 94025.
- (3) Consists of 3,841,323 shares of common stock held by 5AM Ventures VI, L.P., or 5AM Ventures VI, and 496,323 of common stock common stock held by 5AM Opportunities I, L.P., or 5AM Opportunities I. David Allison, a member of our board of directors, is also a partner at 5AM Venture Management, LLC and has no voting or dispositive power over the shares held by 5AM Ventures VI or 5AM Opportunities I. Andrew Schwab and Dr. Kush Parmar are the managing members of 5AM Partners VI, LLC, or 5AM Partners, the general partner of 5AM Ventures VI and may be deemed to have shared voting and investment control over the shares held by 5AM Ventures VI. Andrew Schwab and Dr. Kush Parmar are the managing members of 5AM Opportunities I (GP), LLC, or 5AM Opportunities, the general partner of 5AM Opportunities I and may be deemed to have shared voting and investment control over the shares held by 5AM Opportunities I. The address for all entities and individuals referenced in this footnote is 501 2nd Street, Suite 350, San Francisco, CA 94107.
- (4) Consists of 4,126,470 shares of common stock. General Atlantic (SPV) GP, LLC, or GA LLC, is the general partner of General Atlantic (CIN), L.P., or GA CIN. GA CIN is ultimately controlled by the management committee of GASC MGP, LLC, or the GA Management Committee, of which is comprised of 9 members. Each of the members of the GA Management Committee disclaims ownership of all such shares except to the extent he or she has a pecuniary interest therein. Jason Pitts, a member of our board of directors, is also a vice president of General Atlantic and disclaims ownership of all such shares except to the extent he has a pecuniary interest therein. The address of General Atlantic (CIN), L.P. is c/o General Atlantic Service Company, L.P., 55 East 52nd Street, 33rd Floor, New York, NY 10055.
- (5) Consists of 4,087,646 shares of common stock. Sofinnova Partners SAS, or Sofinnova Partners, is the management company of Sofinnova Capital IX, or SC IX. Each of Antoine Papiernik, Denis Lucquin, Monique Saulnier, Graziano Seghezzi and Henriette Richter is a managing partner of Sofinnova Partners and may be deemed to have shared voting and investment control over the shares held by SC IX. Each of such individuals disclaims beneficial ownership of such shares except to the extent of their pecuniary interest therein. The address of Sofinnova Capital IX is 7 Boulevard Haussmann 75009 Paris, France.
- (6) Consists of 3,630,103 shares of common stock. Each of Jon Isaacsohn, M.D., FACC, August Troendle, M.D., M.B.A., Jesse Geiger and Steve Ewald is a member of the Board of Managers of CinRx and may be deemed to have shared voting and investment control over the shares held by CinRx. Each of such individuals disclaims beneficial ownership of such shares except to the extent of their pecuniary interest therein. The address of CinRx Pharma, LLC is 5375 Medpace Way Cincinnati, OH 45227.
- (7) Consists of 2,140,546 shares of common stock. Adage Capital Partners GP, L.L.C., or ACPGP, is the general partner of Adage Capital Partners, L.P., or ACP, and Adage Capital Advisors, L.L.C., or ACA, is the managing member of ACPGP. Each of Robert Atchinson and Phillip Gross is a managing member of ACA. Each of these persons and entities may be deemed to have shared voting and investment control over the shares held by ACP. The address for all entities and individuals referenced in this footnote is 200 Clarendon Street, 52nd Floor, Boston, MA 02116.
- (8) Consists of 1,980,706 shares of common stock. venBio Global Strategic GP III, L.P., or General Partner III, is the sole general partner of venBio Global Strategic Fund III, L.P., or Fund III, and venBio Global Strategic GP III, Ltd., or GP Ltd. III, is the sole general partner of General Partner III. Each of Robert Adelman, Corey Goodman and Aaron Royston are directors of GP Ltd. III. Each of these persons and entities may be deemed to have shared voting and investment control over the shares held by Fund III. The

address for all entities and individuals referenced in this footnote is c/o venBio Partners, LLC, 1700 Owens Street, Suite 595, San Francisco, CA 94158.

- (9) Consists of shares of common stock issuable upon the exercise of options within 60 days of June 30, 2022.
- (10) Consists of 31,330 shares of common stock issuable upon the exercise of options that are early exercisable, but subject to repurchase right until vested, within 60 days of June 30, 2022.
- (11) Consists of (a) 5,573,949 shares of common stock held by SVP X and (b) 29,411 shares of common stock issuable upon the exercise of options held by Dr. Healy that are early exercisable, but subject to repurchase right until vested, within 60 days of June 30, 2022.
- (12) Consists of (a) 58,823 shares of common stock issuable upon the exercise of options that are early exercisable, but subject to repurchase right until vested, within 60 days of June 30, 2022, and (b) 12,108 shares of common stock issuable upon the exercise of options within 60 days of June 30, 2022.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock, certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws, and certain provisions of Delaware law are summaries. You should also refer to the amended and restated certificate of incorporation and the amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is part.

General

Our amended and restated certificate of incorporation, or our restated certificate, authorizes us to issue up to 1,000,000,000 shares of common stock, \$0.00001 par value per share, and 10,000,000 shares of preferred stock, \$0.00001 par value per share, all of which shares of preferred stock will be undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time.

Common Stock

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. The affirmative vote of holders of at least 66²/₃% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, is required to amend certain provisions of our restated certificate, including provisions relating to amending our amended and restated bylaws, or our restated bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive forum.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the right of the holders of shares of any series of preferred stock that we may designate in the future.

Preferred Stock

Our board of directors has the authority under our restated certificate, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock.

There are no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock following the completion of this offering.

Options

As of March 31, 2022, there were options to purchase 2,685,597 shares of common stock outstanding.

Restricted Stock Units

As of March 31, 2022, there were restricted stock unit grants to purchase 30,148 shares of common stock outstanding.

Registration Rights

We and certain holders of our common stock have entered into an amended and restated investors' rights agreement. The registration rights provisions of this agreement provide those holders with demand, piggyback and Form S-3 registration rights with respect to the shares of common stock currently held by them. These shares are collectively referred to herein as registrable securities.

Demand Registration Rights

At any time beginning 180 days following the effective date of the registration statement for our initial public offering, the holders of a majority of registrable securities then outstanding have the right to demand that we file a registration statement covering at least 10% of the registrable securities then outstanding. We are obligated to effect at most two registrations in response to these demand registration rights. These demand registration rights are subject to specified conditions and limitations, including the right of the underwriters, if any, to limit the number of shares included in any such registration under specified circumstances. Upon such a request, we are required to effect the registration as soon as practicable, but in any event no later than 60 days after the receipt of such request.

Piggyback Registration Rights

If we propose to register any of our common stock under the Securities Act either for our own account or for the account of other stockholders, the holders of registrable securities will each be entitled to notice of the registration and will be entitled to include their shares of common stock in the registration statement. These piggyback registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under specified circumstances, and do not apply to a registration relating to any equity incentive plan, stock purchase or similar plan, a transaction under Rule 145 of the Securities Act, a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the registrable securities or a registration related to common stock issued upon conversion of debt securities.

Registration on Form S-3

At any time after we become eligible to file a registration statement on Form S-3, the holders of at least 20% of the registrable securities then outstanding will be entitled to request to have such shares registered by us on a Form S-3 registration statement. These Form S-3 registration rights are subject to other specified conditions and limitations, including the condition that the anticipated aggregate offering price, net of certain selling expenses, is at least \$1.0 million. Upon receipt of this request, the holders of registrable securities will each be entitled to participate in this registration. We will not be required to effect such a registration if, within the preceding twelve month period, we have already effected two registrations on Form S-3 for the holders of registrable securities.

Expenses of Registration

We are required to pay all expenses, including fees and expenses of one counsel to represent the selling stockholders, relating to any demand, piggyback or Form S-3 registration, other than underwriting discounts and commissions, stock transfer taxes and any additional fees of counsel for the selling stockholders, subject to specified conditions and limitations. We are not required to pay registration expenses if a demand registration request is withdrawn at the request of the holders of a majority of registrable securities then outstanding, unless holders of a majority of the registrable securities agree to forfeit their right to one demand registration.

The amended and restated investors' rights agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling stockholders in the event of material misstatements or omissions in the applicable registration statement attributable to us, and the selling stockholders are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them, subject to certain limitations.

Termination of Registration Rights

The registration rights granted under the amended and restated investors' rights agreement will terminate with respect to any particular stockholder upon the earlier of (i) the closing of a deemed liquidation event, as defined in our certificate of incorporation; (ii) with respect to each stockholder, at such time such stockholder is able to sell all of its shares pursuant to Rule 144 or another similar exemption under the Securities Act during a three-month period without registration; and (iii) the third anniversary of our initial public offering.

Anti-Takeover Provisions

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66²/₃% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder (in one transaction or a series of transactions);
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or of such subsidiary to the interested stockholder;
- any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Our restated certificate provides for our board of directors to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our restated certificate and our restated bylaws also provide that directors may be removed by the stockholders only for cause upon the vote of 66²/₃% or more of our outstanding common stock. Furthermore, the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

Under our restated certificate and restated bylaws our stockholders do not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Our restated certificate and restated bylaws also provide that all stockholder actions must be effected at a duly called meeting of stockholders and eliminates the right of stockholders to act by written consent without a meeting. Our restated bylaws also provide that only our Chairman of the board, Chief Executive Officer or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

Our restated bylaws also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and will specify requirements as to the form and content of a stockholder’s notice.

Our restated certificate and restated bylaws provide that the stockholders cannot amend many of the provisions described above except by a vote of 66²/₃% or more of our outstanding common stock.

As described in “—Preferred Stock” above, our restated certificate gives our board of directors the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control.

The combination of these provisions makes it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our restated certificate provides that the Court of Chancery of the state of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our restated certificate, or our restated bylaws; or
- any action asserting a claim against us that is governed by the internal affairs doctrine.

The provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our restated certificate also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our restated certificate. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage

lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our restated certificate to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Our restated certificate further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue Brooklyn, NY 11219.

Listing

Our common stock is listed on the Nasdaq Global Market under the trading symbol "CINC."

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of certain material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the ownership and disposition of our common stock offered pursuant to this prospectus. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, the alternative minimum tax, or the special tax accounting rules under Section 451(b) of the Code, and does not address any U.S. federal non-income tax consequences such as estate or gift tax consequences or any tax consequences arising under any state, local, or non-U.S. tax laws, or any other U.S. federal tax laws. This discussion is based on the Code and applicable Treasury Regulations promulgated thereunder, judicial decisions and published rulings, and administrative pronouncements of the Internal Revenue Service, or IRS, all as in effect as of the date hereof. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock offered by this prospectus and who hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a particular holder in light of such holder’s particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other entities or arrangements treated as partnerships, pass-throughs, or disregarded entities for U.S. federal income tax purposes (and investors therein), S corporations or other pass-through entities (including hybrid entities);
- “controlled foreign corporations;”
- “passive foreign investment companies;”
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers or dealers in securities;
- persons who have elected to mark securities to market;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons that acquired our common stock through the exercise of employee stock options or otherwise as compensation or through a tax-qualified retirement plan;
- persons that acquired our common stock pursuant to the exercise of warrants or conversion rights under convertible instruments;
- persons who hold common stock that constitutes “qualified small business stock” under Section 1202 of the Code, or “Section 1244 stock” under Section 1244 of the Code;
- persons who acquired our common stock in a transaction subject to the gain rollover provisions of the Code (including Section 1045 of the Code);
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;

- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner and the activities of the partnership. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING, AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, OR NON-U.S. TAX LAWS AND ANY U.S. FEDERAL NON-INCOME TAX LAWS, OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of Non-U.S. Holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is not a “U.S. person” or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

Distributions on Our Common Stock

As described in the section titled “Dividend Policy,” we have not paid and do not anticipate paying dividends in the foreseeable future. However, if we make cash or other property distributions on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts that exceed such current and accumulated earnings and profits and, therefore, are not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder’s tax basis in our common stock, but not below zero. Any amount distributed in excess of basis will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under the section titled “Gain on Disposition of Our Common Stock” below.

Subject to the discussions below regarding effectively connected income, backup withholding, and Sections 1471 through 1474 of the Code, or FATCA, dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder

must furnish us or the applicable withholding agent with a valid IRS Form W-8BEN or IRS Form W-8BEN-E (or applicable successor form) certifying such holder's qualification for the reduced rate. This certification must be provided to us or the applicable withholding agent before the payment of dividends and must be updated periodically. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or the applicable withholding agent, either directly or through other intermediaries.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder's U.S. trade or business (and are attributable to such holder's permanent establishment or fixed base in the United States, if required by an applicable tax treaty), the non-U.S. holder will generally be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent.

However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on Disposition of Our Common Stock

Subject to the discussions below regarding backup withholding and FATCA, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a "United States real property interest" by reason of our status as a United States real property holding corporation, or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock, and our common stock is not regularly traded on an established securities market as defined by applicable Treasury Regulations.

Determining whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests. We do not believe that we are, or have been, and do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a non-U.S. holder of our common stock may not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of distributions on our common stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply even if no withholding was required (because the distributions were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty) and regardless of whether such distributions constitute dividends. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-8ECI, or certain other requirements are met. Backup withholding may apply if the payor has actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

Withholding on Foreign Entities

FATCA imposes a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA applies to dividends paid on our common stock and, subject to the proposed Treasury Regulations described below, also applies to gross proceeds from sales or other dispositions of our common stock. The U.S. Treasury Department released proposed Treasury Regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a disposition of our common stock. In its preamble to such proposed Treasury Regulations, the U.S. Treasury Department stated that taxpayers (including applicable withholding agents) may generally rely on the proposed Treasury Regulations until final regulations are issued.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

UNDERWRITING

We and the underwriters have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, the underwriters have agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC is the representative of the underwriters.

Underwriter	Number of Shares
Goldman Sachs & Co. LLC	
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional _____ shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days from the date of this prospectus. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional _____ shares of common stock from us.

Per Share	No Exercise	Full Exercise
Total	\$	\$

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover page of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to \$ _____ per share from the initial public offering price. After the initial offering of the shares, the representative may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We, our executive officers and directors and certain of our significant stockholders have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of our or their common stock or securities convertible into or exchangeable for shares of our common stock during the period from the date of this prospectus continuing through the date 90 days after the date of this prospectus, except with the prior written consent of the representative. This agreement does not apply to any existing employee benefit plans.

Our common stock is listed on the Nasdaq Global Market under the symbol "CINC."

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A "covered short position" is a short position that is not greater than the amount of additional shares for which the underwriters' option described above may be exercised. The underwriters may cover any covered short position by either exercising their option or purchasing shares in the

open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. "Naked" short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representative has repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of our common stock. As a result, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the Nasdaq Global Market, in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$. We have agreed to reimburse the underwriters for certain of its expenses in an amount up to \$.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters and their affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. The underwriters and their affiliates may in the future provide a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they will receive customary fees and expenses.

In the ordinary course of its various business activities, the underwriters and their affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for its own account and for the accounts of its customers, and such investment and trading activities may involve or relate to assets, securities or instruments of the issuer (directly, as collateral securing other obligations or otherwise) or persons and entities with relationships with the issuer. The underwriters and their affiliates may also communicate independent investment recommendations, market color or trading ideas or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

European Economic Area

In relation to each Member State of the European Economic Area, each a Relevant State, no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication

of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant State at any time:

- (a) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representative for any such offer; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the shares shall require the company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to the shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

- (a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representative for any such offer; or
- (c) in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the shares shall require the company or any underwriter to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Canada

The shares may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) (Companies (Winding Up and Miscellaneous Provisions) Ordinance) or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (Securities and Futures Ordinance), or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the SFA)) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (ii) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (iii) where no consideration is or will be given for the transfer, (iv) where the transfer is by operation of law, (v) as specified in Section 276(7) of the SFA, or (vi) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore (Regulation 32).

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (ii) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (iii) where no consideration is or will be given for the transfer, (iv) where the transfer is by operation of law, (v) as specified in Section 276(7) of the SFA, or (vi) as specified in Regulation 32.

Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended) (the FIEA). The shares may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (ASIC), in relation to the offering. This offering document does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the Corporations Act), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the Exempt Investors) who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This offering document contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this offering document is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Dubai International Financial Centre

This offering document relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (DFSA). This offering document is intended for distribution only to persons

of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth in this prospectus and has no responsibility for the offering document. The shares to which this offering document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this offering document you should consult an authorized financial advisor.

Switzerland

We have not and will not register with the Swiss Financial Market Supervisory Authority (FINMA) as a foreign collective investment scheme pursuant to Article 119 of the Federal Act on Collective Investment Scheme of 23 June 2006, as amended (CISA), and accordingly the shares being offered pursuant to this prospectus have not and will not be approved, and may not be licenseable, with FINMA. Therefore, the shares have not been authorized for distribution by FINMA as a foreign collective investment scheme pursuant to Article 119 CISA and the shares offered hereby may not be offered to the public (as this term is defined in Article 3 CISA) in or from Switzerland. The shares may solely be offered to “qualified investors,” as this term is defined in Article 10 CISA, and in the circumstances set out in Article 3 of the Ordinance on Collective Investment Scheme of 22 November 2006, as amended (CISO), such that there is no public offer. Investors, however, do not benefit from protection under CISA or CISO or supervision by FINMA. This prospectus and any other materials relating to the shares are strictly personal and confidential to each offeree and do not constitute an offer to any other person. This prospectus may only be used by those qualified investors to whom it has been handed out in connection with the offer described in this prospectus and may neither directly or indirectly be distributed or made available to any person or entity other than its recipients. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in Switzerland or from Switzerland. This prospectus does not constitute an issue prospectus as that term is understood pursuant to Article 652a and/or 1156 of the Swiss Federal Code of Obligations. We have not applied for a listing of the shares on the SIX Swiss Exchange or any other regulated securities market in Switzerland, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the listing rules of the SIX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SIX Swiss Exchange.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Cooley LLP, Boston, Massachusetts. Certain legal matters will be passed upon for the underwriters by Wilmer Cutler Pickering Hale & Dorr LLP, New York, New York.

EXPERTS

The financial statements of CinCor Pharma, Inc. for the years ended December 31, 2021 and 2020 appearing in CinCor Pharma, Inc.'s Annual Report on Form 10-K for the year December 31, 2021 have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon included therein, and incorporated by reference herein. Such financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to our company and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the internet at the SEC's website at www.sec.gov. Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available at www.sec.gov.

We also maintain a website at www.cincor.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus. We have included our website in this prospectus solely as an inactive textual reference.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus.

We incorporate by reference into this prospectus and the registration statement of which this prospectus form a part the information or documents listed below that we have filed with the SEC, and any future filings we will make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act after the date of the initial filing of the registration statement of which this prospectus is a part and prior to effectiveness of such registration statement:

- our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 22, 2022;

- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 filed with the SEC on May 10, 2022; and
- our Current Reports on Form 8-K, filed with the SEC on January 11, 2022 and January 28, 2022; and
- the description of our common stock which is registered under Section 12 of the Exchange Act, in our registration statement on Form 8-A, filed on January 4, 2022, including any amendment or reports filed for the purposes of updating this description.

We will furnish at no cost to you, on written or oral request, a copy of any or all of the reports or documents incorporated by reference in this prospectus, including exhibits to these documents. You should direct any requests for documents to CinCor Pharma, Inc., 230 Third Avenue, Waltham, MA 02451.

You also may access these filings on our website at www.cincor.com. We do not incorporate the information on our website into this prospectus or any supplement to this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus or any supplement to this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus or any supplement to this prospectus).

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

You may read our SEC filings, including the registration statement, over the internet at the SEC's website at www.sec.gov. We are subject to the information and reporting requirements of the Exchange Act, and, in accordance with this law, we must file periodic reports, proxy statements and other information with the SEC. These reports, proxy statements and other information are available on the website of the SEC referred to above.

Shares

CinCor Pharma, Inc.

Common Stock

CINCOR

Goldman Sachs & Co. LLC

PART II**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission, or SEC, registration fee and the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee.

	<u>Amount</u>
SEC registration fee	\$
FINRA filing fee	
Accountants' fees and expenses	
Legal fees and expenses	
Transfer agent's fees and expenses	
Printing and engraving expenses	
Miscellaneous	
Total expenses	<u>\$</u>

Item 14. Indemnification of Directors and Officers.

We are incorporated under the laws of the State of Delaware. Section 102 of the Delaware General Corporation Law permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit.

Section 145 of the Delaware General Corporation Law provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

As permitted by the Delaware General Corporation Law, our amended and restated certificate of incorporation and bylaws provide that: (i) we are required to indemnify our directors to the fullest extent permitted by the Delaware General Corporation Law; (ii) we may, in our discretion, indemnify our officers, employees and agents as set forth in the Delaware General Corporation Law; (iii) we are required, upon satisfaction of certain conditions, to advance all expenses incurred by our directors in connection with certain legal proceedings; (iv) the rights conferred in the bylaws are not exclusive; and (v) we are authorized to enter into indemnification agreements with our directors, officers, employees and agents.

We have entered into indemnification agreements with each of our directors and executive officers that require us to indemnify them against expenses, judgments, fines, settlements and other amounts that any such person becomes legally obligated to pay (including with respect to a derivative action) in connection with any proceeding, whether actual or threatened, to which such person may be made a party by reason of the fact that such person is or was a director or officer of us or any of our affiliates, provided such person acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, our best interests. The indemnification agreements also set forth certain procedures that apply in the event of a claim for indemnification thereunder. We entered into similar indemnification agreements with our executive officers prior to the completion of this offering. At present, no litigation or proceeding is pending that involves any of our directors or officers regarding which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

We maintain a directors' and officers' liability insurance policy. The policy insures directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses us for those losses for which we have lawfully indemnified the directors and officers. The policy contains various exclusions.

In addition, the underwriting agreement filed as Exhibit 1.1 to this Registration Statement provides for indemnification by the underwriters of us and our officers and directors for certain liabilities arising under the Securities Act, or otherwise. Our amended and restated investors' rights agreement with certain investors also provides for cross-indemnification in connection with the registration of our common stock on behalf of such investors.

Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information regarding all unregistered securities sold by us since January 1, 2019 through the date of the prospectus that forms a part of this registration statement.

Issuances of Capital Stock

In May 2019, we issued an aggregate of 1,250,000 shares of our common stock to CinRx Pharma, LLC at a purchase price of \$0.000034 per share, for aggregate consideration of \$42.50.

In May 2019 and August 2020, we issued an aggregate of 35,714,282 shares of our Series A preferred stock to Sofinnova Venture Partners X, L.P., Sofinnova Capital IX, 5AM Ventures VI, L.P. and CinRx Pharma, LLC at a purchase price of \$1.40 per share, for aggregate consideration of approximately \$50.0million.

In September 2021 and October 2021, we issued and sold an aggregate of 35,716,249 shares of our Series B preferred stock to 22 investors at a purchase price of \$4.00 per share, for aggregate consideration of approximately \$142.9 million.

In December 2021, we issued 764,705 shares of our common stock to CinRx Pharma, LLC pursuant to the settlement agreement and release with CinRx.

Issuances Pursuant to our Equity Plans

From our inception in January 2019 through January 6, 2022, we granted options under our 2019 Stock Option Plan to purchase an aggregate of 3,477,890 shares of common stock, at a weighted average exercise price of \$5.85 per share, to our employees and consultants. Of these, 542,636 shares have been issued upon the exercise of options.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise specified above, we believe these transactions were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D or Regulation S promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Issuance of Roche Warrant

In September 2021, we issued a third warrant to purchase common stock to Roche Finance Ltd. in connection with our Series B preferred stock financing, which was exercisable for 113,610 shares of our common stock at an exercise price of \$0.04 per share. We previously issued the first Roche Warrant, which was issued in connection with our Series A preferred stock financing, was exercisable for 411,765 shares of our common stock. The second Roche Warrant, issued in connection with our Series A preferred stock financing, was exercisable for 329,552 shares of our common stock. The Roche Warrants were collectively exercisable for 854,927 shares of our common stock at an exercise price of \$0.04 per share. The Roche Warrants automatically net exercised in whole immediately prior to the effectiveness of our registration statement first registering our securities under Section 12 of the Exchange Act.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

The exhibits listed below are filed as part of this registration.

Exhibit Number	Description	Form	File No.
1.1*	Form of Underwriting Agreement, including Form of Lock-up Agreement.		
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-41201
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-41201
4.1	Amended and Restated Investor Rights Agreement among the Registrant and certain of its stockholders, dated February 15, 2019.	S-1	333-261738
5.1*	Opinion of Cooley LLP.		
10.1+	2019 Stock Option Plan.	S-1/A	333-261738
10.2+	2022 Equity Incentive Plan and Forms of Option Grant Notice and Agreement, Exercise Notice, Early Exercise Notice and Restricted Stock Award Notice.	S-1/A	333-261738
10.3+	2022 Employee Stock Purchase Plan.	S-1/A	333-261738

[Table of Contents](#)

Exhibit Number	Description	Form	File No.	Number
10.4+	Form of Indemnification Agreement with Executive Officers and Directors.	S-1	333-261738	10.4
10.5†	License Agreement, dated as of May 13, 2019, by and among the Registrant, F. Hoffman-La Roche Ltd and Hoffmann-La Roche Inc.	S-1	333-261738	10.5
10.6	Voting Agreement and Proxy, dated as December 22, 2021, by and between the Registrant and CinRx Pharma, LLC.	S-1/A	333-261738	10.7
10.7+	Amended and Restated Executive Employment Agreement, dated as December 29, 2021, by and between the Registrant and Marc de Garidel.	S-1/A	333-261738	10.8
10.8+	Amended and Restated Executive Employment Agreement, dated as December 30, 2021, by and between the Registrant and Mary Theresa Coelho.	S-1/A	333-261738	10.9
10.9+	Amended and Restated Executive Employment Agreement, dated as December 29, 2021, by and between the Registrant and Mason Freeman.	S-1/A	333-261738	10.10
10.10+	Amended and Restated Executive Employment Agreement, dated as December 29, 2021, by and between the Registrant and Catherine Pearce.	S-1/A	333-261738	10.11
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm.			
23.2*	Consent of Cooley LLP (included in Exhibit 5.1).			
24.1	Power of Attorney (included on signature page).			
107.1*	Filing Fee Table			

* To be filed by amendment.

+ Indicates management contract or compensatory plan.

† Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and are the type that the Registrant treats as private or confidential.

(b) Financial Statement Schedules.

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification

against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Waltham, Massachusetts, on this _____ day of _____, 2022.

CINCOR PHARMA, INC.

By: _____
 Marc de Garidel
 Chief Executive Officer

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Marc de Garidel and Mary Theresa Coelho, and each of them, as his or her true and lawful agents, proxies and attorneys-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to (i) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this registration statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this registration statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____	Chief Executive Officer and Director (Principal Executive)	, 2022
Marc de Garidel		
_____	Chief Financial Officer and Chief Business Development Officer (Principal Financial Officer and Principal Accounting Officer)	, 2022
Mary Theresa Coelho, M.B.A.		
_____	Director and Chairman of the Board	, 2022
James I. Healy, M.D., Ph.D.		
_____	Director	, 2022
David Allison, Ph.D.		
_____	Director	, 2022
Maina Bhaman, M.B.A.		
_____	Director	, 2022
Troy Ignelzi		
_____	Director	, 2022
June Lee, M.D.		
_____	Director	, 2022
Jason Pitts, Ph.D.		
_____	Director	, 2022
John F. Thero		