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

FORM 10-K

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2020

OR

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

FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NUMBER 001-36485

ARDELYX, INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE	26-1303944
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(I.R.S. EMPLOYER IDENTIFICATION NO.)

34175 ARDENWOOD BLVD., FREMONT, CALIFORNIA 94555
400 FIFTH AVE., SUITE 210, WALTHAM, MASSACHUSETTS 02451
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES, INCLUDING ZIP CODE)

(510) 745-1700
(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	ARDX	The Nasdaq Global Market

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

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

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

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definition 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 ☒	Small reporting company ☒
	Emerging growth company ☐

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

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

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

The aggregate market value of the Registrant's common stock held by non-affiliates of the Registrant as of the last business day of the Registrant's most recently completed second fiscal quarter, June 30, 2020, based on the last reported sales price of the Registrant's common stock of $6.92 per share was $611,732,242.

The number of shares of Registrant's Common Stock outstanding as of March 3, 2021, was 98,680,264.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Registrant's Definitive Proxy Statement for its 2021 Annual Meeting of Stockholders, which will be filed with the Commission within 120 days of December 31, 2020, the close of the Registrant's 2020 fiscal year, are incorporated by reference into Part III of this Report.

ARDELYX, INC.
FORM 10-K FOR THE FISCAL YEAR ENDED DECEMBER 31, 2020
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NOTE REGARDING FORWARD-LOOKING STATEMENTS

Unless the context requires otherwise, in this Annual Report on Form 10-K the terms “Ardelyx”, “we,” “us,” “our” and “the Company” refer to Ardelyx, Inc.

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would,” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding our plans for and our participation in the commercialization of tenapanor for the control of serum phosphorus in chronic kidney disease, or CKD, patients on dialysis, including our expectations regarding our plans to build our own sales and marketing organization to market and sell tenapanor for such indication;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates;
- our plans with respect RDX013 and to our pre-clinical programs;
- our ability to identify and validate targets and novel drug candidates using our proprietary drug discovery and design platform including the Ardelyx Primary Enterocyte and Colonocyte Culture System, or APECCS, or any other proprietary drug discovery and design platform we develop for the identification, screening, testing, design and development of new product candidates for the treatment of renal diseases;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our financial performance; and
- developments and projections relating to our competitors and our industry.

Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the “ITEM 1A. RISK FACTORS” section and elsewhere in this Annual Report on Form 10-K. Except as required by law, we assume no obligation to update any forward-looking statement publicly, or to revise any forward-looking statement to reflect events or developments occurring after the date of this Annual Report on Form 10-K, even if new information becomes available in the future. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in any such forward-looking statement.

ITEM 1. BUSINESS

Company Overview

We are a specialized biopharmaceutical company focused on developing first-in-class medicines to improve treatment for people with kidney and cardiorenal diseases. This includes patients with chronic kidney disease (”CKD”) on dialysis suffering from elevated serum phosphorus, or hyperphosphatemia; and CKD patients and/or heart failure patients with elevated serum potassium, or hyperkalemia. Our lead product candidate, tenapanor, is a first-in-class medicine for which we submitted a New Drug Application (“NDA”) to the U.S. Food and Drug Administration (“FDA”) in June 2020 for the control of serum phosphorus in adult patients with CKD on dialysis. In September 2020 the FDA accepted the filing of our NDA and set a Prescription Drug User Fee Act (“PDUFA”) date of April 29, 2021. Tenapanor has a unique mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3, or NHE3. This results in the tightening of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption.

OUR PRODUCT PIPELINE

Tenapanor: A New Approach for The Control of Serum Phosphorus in CKD Patients on Dialysis

Our portfolio is led by the development of tenapanor, a first-in-class medicine for the control of serum phosphorus in adult patients with CKD on dialysis. Tenapanor for the control of serum phosphorus has a unique mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3 (“NHE3”). This results in the tightening of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption. On September 15, 2020 we announced that the FDA accepted the filing of our NDA for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis. The acceptance of our NDA represents the next critical step toward bringing to market a completely new approach to the management of hyperphosphatemia. The FDA has set a PDUFA date of April 29, 2021. We continue to advance commercial preparations for the launch of tenapanor for this indication. The NDA is supported by three successful Phase 3 trials involving over 1,000 patients that evaluated the use of tenapanor for the control of serum phosphorus in CKD patients on dialysis, with two trials evaluating tenapanor as monotherapy and one trial evaluating tenapanor as part of a dual mechanism approach with phosphate binders.

We have established agreements with Kyowa Kirin Co., Ltd. (“KKC”) in Japan, Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. (“Fosun Pharma”) in China and Knight Therapeutics, Inc. (“Knight”) in Canada for the development and commercialization of tenapanor for certain indications in their respective territories.

In December 2019, we reported statistically significant topline efficacy results from our second monotherapy Phase 3 clinical trial, the PHREEDOM trial, which evaluated tenapanor for the control of serum phosphorus in CKD patients on dialysis. The PHREEDOM trial followed a successful monotherapy Phase 3 clinical trial completed in 2017, the BLOCK trial, which achieved statistical significance for the primary endpoint. The only adverse event reported in these Phase 3 trials in greater than 5% of patients was diarrhea, with an incidence rate of 52% in the PHREEDOM trial and 39% in the BLOCK trial, with most incidences in each trial being mild to moderate in nature. PHREEDOM is a one-year study with a 26-week open-label treatment period and a 12-week double-blind, placebo-controlled randomized withdrawal period followed by a 14-week open-label safety extension period. An active safety control group, for safety analysis only, received sevelamer, open-label, for the entire 52-week study period. Patients completing the PHREEDOM trial from both the tenapanor arm and the sevelamer active safety control arm had the option to participate in NORMALIZE, an ongoing open-label 18-month extension study.

In June 2020, we announced positive results from a planned analysis from our ongoing NORMALIZE extension study evaluating tenapanor, as monotherapy or in combination with sevelamer, to achieve serum phosphorus levels in the normal range (2.5 – 4.5 mg/dL) in patients with CKD on dialysis. The NORMALIZE extension study allowed patients from our PHREEDOM study to continue therapy with tenapanor and enabled those patients in the PHREEDOM safety control arm receiving sevelamer carbonate to transition to tenapanor. The data from the planned interim analysis demonstrated that the foundational use of tenapanor as monotherapy or in combination with sevelamer carbonate produces a significant

phosphorus-lowering effect with a mean serum phosphorous reduction of 2.33 mg/dL, from a mean baseline phosphorus of 7.27 mg/dL at the beginning of the PHREEDOM trial to a mean of 4.94 mg/dL at the time of this analysis.

In September 2019, we reported positive results from the AMPLIFY trial, a Phase 3 study evaluating tenapanor in patients with CKD on dialysis who had uncontrolled hyperphosphatemia despite phosphate binder treatment. In this trial, approximately twice the number of patients achieved the serum phosphorus treatment goal of less than 5.5 mg/dL with tenapanor and phosphate binders versus phosphate binders alone. The only adverse event with a placebo-adjusted rate greater than 3% was diarrhea, with an incidence rate of 43%, with most being mild to moderate in nature.

Tenapanor, if approved, would be the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake. It is not a phosphate binder. Tenapanor is a novel, potent, small molecule, that has been shown in our phase 3 studies to treat hyperphosphatemia as monotherapy and as part of a dual mechanism approach. Additionally, we believe tenapanor could greatly improve patient adherence and compliance with one single pill dosed twice daily in contrast to current therapies where typically multiple pills are taken before every meal.

RDX013 Program: Small Molecule for Treating Hyperkalemia

We are also advancing a small molecule potassium secretagogue program, RDX013, for the potential treatment of hyperkalemia. Hyperkalemia is a common problem in patients with heart and kidney disease, particularly in patients taking customary blood pressure medications known as renin-angiotensin-aldosterone system (“RAAS”) inhibitors. Similar to what we have done with tenapanor in developing a non-binder approach for the treatment of elevated serum phosphate levels, RDX013 is designed to target the underlying biological mechanisms of potassium secretion to lower elevated potassium. While currently available therapies are all ion exchange agents, RDX013 is a first in class secretagogue that has been shown in preclinical and Phase 1 studies to harness and amplify the body’s natural mechanism for colonic potassium secretion. We have initiated a Phase 2 study to evaluate the safety and pharmacodynamics of RDX013 at different doses and to assess the safety and efficacy of treatment with RDX013 at the selected optimal dose in patients with hyperkalemia.

IBSRELA® (tenapanor) for Irritable Bowel Syndrome with Constipation (IBS-C)

In addition to the development of tenapanor for hyperphosphatemia, we have developed tenapanor for the treatment of patients with IBS-C. In September 2019, we received FDA approval of IBSRELA® (tenapanor) for the treatment of IBS-C in adults. IBS-C is a burdensome gastrointestinal (“GI”) disorder characterized by significant abdominal pain, constipation, straining during bowel movements, bloating and/or gas.

We expect to continue to incur substantial operating losses for the foreseeable future as a result of costs associated with the following activities: our continued development of tenapanor for the control of serum phosphorus in CKD patients on dialysis; our preparations for, and, if approved, the commercialization of tenapanor in the United States for the control of serum phosphorus in CKD patients on dialysis, including significantly increased personnel costs associated with our commercial team; the performance of certain activities required as a result of our NDA approval of tenapanor for IBS-C; the continued development of RDX013; and the advancement of our research programs into the preclinical stage. To date, we have funded our operations from the sale and issuance of common stock and convertible preferred stock, funds from our collaboration partnerships, and funds from our Loan Agreement with Solar Capital Ltd. and Western Alliance Bank.

RDX020 Program: Small molecule for Treating Metabolic Acidosis

We have an ongoing discovery program targeting the inhibition of bicarbonate exchange inhibitor for the treatment of metabolic acidosis, a highly prevalent comorbidity in CKD patients that is strongly correlated with disease progression and adverse outcomes. We have identified lead compounds that are potent, selective and proprietary inhibitors of bicarbonate secretion.

Since commencing operations in October 2007, substantially all our efforts have been dedicated to our research and development ("R&D") activities, including developing our clinical product candidate tenapanor and developing our proprietary drug discovery and design platform. We have not generated any revenues from product sales. As of December 31, 2020, we had an accumulated deficit of $554.8 million.

OUR COMMERCIAL STRATEGY

We currently intend to build a multi-product company that commercializes its cardiorenal products in the United States. We have executed ex-U.S. collaborations with established industry leaders to efficiently bring tenapanor for hyperphosphatemia and IBS-C to patients in specific territories outside of the Unites States. We continue to evaluate our strategy for the commercialization of tenapanor in other ex-U.S. territories, as well as our U.S. commercialization strategy for tenapanor for IBS-C. We currently have three collaboration partnerships: with Kyowa Kirin Co., Ltd. ("KKC") for commercialization of tenapanor for the treatment of cardiorenal diseases, including hyperphosphatemia, in Japan; with Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. ("Fosun Pharma") for the commercialization of tenapanor for the treatment of IBS-C and hyperphosphatemia in China; and with Knight Therapeutics, Inc. ("Knight") for commercialization of tenapanor for the treatment of IBS-C and hyperphosphatemia in Canada.

O**UR PROPRIETARY DRUG DISCOVERY AND DESIGN PLATFORM**

We have developed a proprietary drug discovery and design platform to enable the identification, screening, testing, design and development of new product candidates. Our platform integrates two critical concepts: (i) our proprietary chemistry capabilities that enable us to design and optimize gut-restricted compounds, and (ii) our APECCs stem cell platform developed to emulate, in a miniaturized format, the function and structure of cells of specific segments of the intestine. In line with our overall strategy to focus on our cardiorenal pipeline, our research supports tenapanor, RDX013 and other potential cardiorenal opportunities.

OUR STRATEGIC PARTNERSHIPS

License Agreement with KKC

In November 2017, we entered into a License Agreement (the "2017 KKC Agreement") with KKC under which we granted KKC an exclusive license to develop and commercialize tenapanor in Japan for the treatment of cardiorenal diseases and conditions, excluding cancer (the "KKC Field"). We retained the rights to tenapanor outside of Japan, and also retained the rights to tenapanor in Japan for indications other than those in the KKC Field. Pursuant to the 2017 KKC Agreement, KKC is responsible for all of the development and commercialization costs for tenapanor in the KKC Field in Japan.

Under the 2017 KKC Agreement, we are responsible for supplying the tenapanor drug substance for KKC's use in development and commercialization throughout the term of the 2017 KKC Agreement, provided that KKC may exercise an option to manufacture the tenapanor drug substance under certain conditions.

Under the terms of the 2017 KKC Agreement, we received a $30.0 million upfront payment and are eligible to receive up to $55.0 million in total development milestones, of which we have received $5.0 million to date. Additionally, under the 2017 KKC Agreement we are eligible to receive up to 8.5 billion yen in commercialization milestones, worth up to $82.4 million at the exchange rate on December 31, 2020, and royalties based on aggregate annual net sales of the licensed products at a high teens percentage, subject to certain single digit reductions under certain circumstances described in the 2017 KKC Agreement.

The 2017 KKC Agreement will continue until all of KKC's applicable payment obligations under the 2017 KKC Agreement have been performed or have expired, or the agreement is earlier terminated. Under the terms of the 2017 KKC Agreement, we and KKC each have the right to terminate the agreement for material breach by the other party. In addition, KKC may terminate the agreement for convenience; for certain safety reasons or if certain primary endpoints under an

applicable development plan are not met despite KKC's commercially reasonable efforts and KKC reasonably determines that it cannot obtain regulatory approval. We may terminate the 2017 KKC Agreement if KKC challenges any patents licensed to KKC under the agreement.

Research Collaboration with KKC

In November 2019, we entered into a Research Collaboration and Option Agreement "(the 2019 KKC Research Agreement") which expanded our strategic partnership with KKC. In the KKC Research Agreement, we established a two-year research collaboration, under which we are executing a research plan, with KKC participation, to advance two research programs focused on identification and design of compounds to two undisclosed targets. KKC agreed to pay us $10.0 million ($5.0 million per year, for a period of two years) to support the ongoing research. As of December 31, 2020, we have received the full $10.0 million. Following the end of the research period, KKC will have the option to license any candidates nominated by the companies for further development and commercialization in certain specified territories, with additional commitments payable to us of up to $10.5 million in upfront payments and up to $500.0 million in development and sales milestones.

License Agreement with Fosun

In December 2017, we entered into a license agreement ("the Fosun License Agreement") with Fosun Pharma under which we granted Fosun Pharma an exclusive license to develop and commercialize tenapanor in China for the treatment, diagnosis or prevention of irritable bowel syndrome with constipation and chronic idiopathic constipation, hyperphosphatemia related to chronic kidney disease, and other diseases or conditions for which we obtain marketing approval in either the US or China (collectively, "the Fosun Field"). The Fosun Field excludes the treatment of cancer. We retained the rights to tenapanor outside of China, and also retained the rights to tenapanor in China for indications other than those in the Fosun Field. Pursuant to the terms of the Fosun License Agreement, Fosun Pharma is responsible for all development and commercialization costs for tenapanor in the Fosun Field in China.

Under the terms of the Fosun License Agreement, we are responsible for supplying the tenapanor drug product for Fosun Pharma's use in development and during commercialization until Fosun Pharma has assumed such responsibility. Additionally, we are responsible for supplying the tenapanor drug substance for Fosun Pharma's use in development and commercialization throughout the term of the Fosun License Agreement.

Under the terms of the Fosun License Agreement, we received an upfront payment of $12.0 million and are eligible to receive additional milestones of up to $113.0 million in the aggregate, of which we have recognized and received $3.0 million to date, as well as tiered royalty payments on aggregate net sales ranging from the mid-teens percent to twenty percent, subject to certain reductions under certain circumstances, as described in the Fosun License Agreement.

The Fosun License Agreement will continue until all of Fosun Pharma's applicable payment obligations under the License Agreement have been performed or have expired, or the agreement is earlier terminated. Under the terms of the Fosun License Agreement, we and Fosun Pharma each have the right to terminate the agreement for material breach by the other party or in the event of insolvency by the other party. In addition, Fosun Pharma may terminate the agreement for convenience, and we may terminate the agreement if Fosun Pharma challenges any patents licensed to it under the agreement.

License Agreement with Knight Therapeutics

In March 2018, we entered into a license agreement with Knight ("the Knight License Agreement") that provides Knight with exclusive rights to commercialize tenapanor in Canada. Under the terms of the Knight License Agreement, Ardelyx is eligible to receive up to CAD 25 million in total payments, worth up to $19.6 million at the currency exchange rate on December 31, 2020, including an upfront payment and development and sales milestones, as well as tiered royalties on net sales ranging from the mid-single digits to the low twenties. As of December 31, 2020, we have recognized and

received $3.1 million to date under the Knight License Agreement. Knight has the exclusive rights to market and sell tenapanor in Canada.

CORPORATE DEVELOPMENT

In July 2020, we filed a Form S-3 registration statement, which became effective in August 2020, containing (i) a base prospectus for the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $250.0 million of the Company's common stock, preferred stock, debt securities, warrants and/or units, from time to time in one or more offerings; and (ii) a prospectus supplement for the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $100.0 million of our common stock that may be issued and sold, from time to time, under an Open Market Sales Agreement with Jefferies LLC, as sales agent, deemed to be "at the market offerings." As of December 31, 2020, we had sold 3.3 million shares of our common stock for aggregate gross proceeds of $21.7 million at a weighted average price of $6.65 per share under the Open Market Sales Agreement. From the period of January 2, 2021 through February 28, 2021, we sold an additional 4.9 million shares of our common stock for aggregate gross proceeds of $35.0 million at a weighted average price of $7.09 per share. In aggregate during the life of the Open Market Sales Agreement, we have sold 8.2 million shares of our common stock for aggregate gross proceeds of $56.7 million at a weighted average sales price of approximately $6.91 per share. Pursuant to the Open Market Sales Agreement, Jefferies, as sales agent, receives a commission of up to 3.0% of the gross sales price for shares of common stock sold under the Open Market Sales Agreement.

In December 2019, we completed an underwritten public offering of 23.0 million shares of common stock, resulting in the receipt of aggregate gross proceeds of approximately $143.8 million, less underwriting discounts, commissions and offering expenses totaling approximately $8.9 million, which resulted in net proceeds of approximately $134.9 million.

In November 2019, we enhanced our strategic partnership with KKC by entering into a Stock Purchase Agreement, pursuant to which we sold to KKC an aggregate of 2.9 million shares of our common stock for aggregate gross proceeds of approximately $20.0 million.

As of December 31, 2020, we had cash, cash equivalents and investments totaling $188.6 million.

INTELLECTUAL PROPERTY

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, manufacturing and process discoveries, and other know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our intellectual property by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology and inventions that are important to the development and operation of our business. We also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of our issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties. If third parties prepare and file patent applications in the United States that also claim technology or therapeutics to which we have rights, we may have to participate in interference proceedings in the U.S. Patent and Trademark Office (the "USPTO") to determine priority of invention, which would result in substantial costs to us even if the eventual outcome is favorable to us.

The term of individual patents depends upon the legal term of the patents in countries in which they are obtained. In most countries, including the United States, the patent term is generally 20 years from the earliest date of filing a non-provisional patent application in the applicable country. In the U.S., a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date.

In addition, in the United States, the Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of a U.S. patent as partial compensation for the patent term lost during the FDA regulatory review process occurring while the patent is in force. A patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in the European Union and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

We may rely, in some circumstances, on trade secrets to protect our technology. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaboration partners, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning the business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during the normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property.

Tenapanor Patents

Our tenapanor patent portfolio is wholly owned by us. This portfolio includes five issued U.S. patents, three issued Israeli patents, two issued patents in each of Japan, Korea, Hong Kong and Mexico and one issued patent in each of the following territories: Australia, Brazil, India, China, and the European Patent Organization countries. These issued patents cover the composition and certain methods of using tenapanor and are predicted, without extension or adjustment, to expire in December 2029. The portfolio further includes patents covering the use of tenapanor for the control of serum phosphorus that has issued in the U.S., Europe, Japan, China, Australia, Gulf Co-op countries, Hong Kong, Russia and Taiwan and is pending in other countries. These patents are predicted, without extension or adjustment, to expire in April 2034.

Additional U.S. and international patent applications are pending covering additional methods of treatment with tenapanor, and composition of matter and methods of using compounds that we believe may be follow on compounds to tenapanor.

Other Program Patents

We have patent applications pending in the U.S. and internationally that cover the compositions and methods of using compounds in our RDX013 program.

MANUFACTURING

To date, we have relied upon third-party contract manufacturing organizations ("CMOs") to manufacture both the active pharmaceutical ingredient and final drug product dosage forms of our potential drug candidates used as clinical trial material. We expect that we will continue to rely upon CMOs for the manufacture of our clinical trial materials and for

our commercial product requirements, when and if regulatory approval is received. Our license agreements with KKC, Knigh, and Fosun Pharma require us to supply final drug product dosage forms of tenapanor and/or active pharmaceutical ingredient for their use in the development of tenapanor in each of their respective territories, and we are further obligated to continue to supply active pharmaceutical ingredient to support their commercialization of tenapanor in each of their territories. We expect that we will use CMOs to satisfy our supply obligations to our collaboration partners.

GOVERNMENT REGULATION

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

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act (the "FFDCA") and the FDA's implementing regulations. If we fail to comply with applicable FDA or other requirements at any time during the drug development process, the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on us. FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States.

The process required by the FDA before a drug may be marketed in the United States generally involves:

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies, some performed in accordance with the FDA's current Good Laboratory Practice ("GLP") regulations;
- submission to the FDA of an Investigational New Drug ("IND") application which must become effective before human clinical trials in the United States may begin;
- approval by an independent institutional review board, ("IRB") or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice, or GCP, regulations to establish the safety and efficacy of the drug candidate for each proposed indication;
- submission to the FDA of a new drug application ("NDA");
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice ("cGMP") regulations;
- satisfactory completion of a potential review by an FDA advisory committee, if applicable; and
- FDA review and approval of the NDA prior to any commercial marketing, sale or commercial shipment of the drug.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Nonclinical tests include laboratory evaluation of product chemistry, formulation, stability and toxicity, as well as animal studies to

assess the characteristics and potential safety and efficacy of the product. The results of preclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. Additional preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises concerns or questions relating to the IND and places the clinical trial on a clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be used. Each protocol must be submitted to the FDA as part of the IND.

An independent IRB or ethics committee for each medical center proposing to conduct a clinical trial must also review and approve a plan for any clinical trial before it can begin at that center and the IRB must monitor the clinical trial until it is completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP requirements, including the requirements for informed consent.

All clinical research performed in the United States in support of an NDA must be submitted in advance by the FDA under the IND regulations and procedures described above. However, a sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA so long as the clinical trial is conducted in compliance with GCP and if the FDA is able to validate the data from the study through an onsite inspection, if necessary. GCP includes review and approval by an independent ethics committee, such as an IRB, and obtaining and documenting the freely given informed consent of the subject before study initiation. If the applicant seeks approval of an NDA solely on the basis of foreign data, the FDA will only accept such data if they are applicable to the U.S. population and U.S. medical practice, the studies have been performed by clinical investigators of recognized competence, and the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or through other appropriate means.

Clinical Trials

The clinical investigation of a new drug is typically conducted in three or four phases, which may overlap or be combined, and generally proceed as follows.

- *Phase 1*: Clinical trials are initially conducted in a limited population of subjects to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients with severe problems or life-threatening diseases to gain an early indication of its effectiveness.

- *Phase 2*: Clinical trials are generally conducted in a limited patient population to evaluate dosage tolerance and appropriate dosage, identify possible adverse effects and safety risks, and evaluate preliminarily the efficacy of the drug for specific targeted indications in patients with the disease or condition under study.

- *Phase 3*: Clinical trials are typically conducted when Phase 2 clinical trials demonstrate that a dose range of the product candidate is effective and has an acceptable safety profile. Phase 3 clinical trials are commonly referred to as “pivotal” studies, which typically denotes a study which presents the data that the FDA or other relevant regulatory agency will use to determine whether or not to approve a drug. Phase 3 clinical trials are generally undertaken with large numbers of patients, such as groups of several hundred to several thousand, to further

evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically-dispersed clinical trial sites.

- *Phase 4*: In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials after NDA approval. In other cases, a sponsor may voluntarily conduct additional clinical trials post approval to gain more information about the drug. Such post approval trials are typically referred to as Phase 4 clinical trials.

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

The FDA, the IRB or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

New Drug Applications

The results of preclinical studies and of the clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. The FDA reviews an NDA to determine, among other things, whether a drug is safe and effective for its intended use.

Under the Prescription Drug User Fee Act, the FDA has a goal of responding to standard review NDAs of new molecular entities within ten months after the 60-day filing review period, or six months after the 60-day filing review period for priority review NDAs, but this timeframe is often extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an application, the FDA may inspect the facility or the facilities at which the finished drug product, and sometimes the active pharmaceutical ingredient ("API") is manufactured, and will not approve the drug unless cGMP compliance is satisfactory. The FDA may also inspect the sites at which the clinical trials were conducted to assess their compliance and will not approve the drug unless compliance with cGCP requirements is satisfactory.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its API will be produced, if deemed necessary, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategy ("REMS") to mitigate risks, which could include medication guides, physician communication plans, or elements to assure

safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. The FDA has the authority to prevent or limit further marketing of a drug based on the results of these post-marketing programs. Once the FDA approves an NDA, or supplement thereto, the FDA may withdraw the approval if ongoing regulatory requirements are not met or if safety problems are identified after the drug reaches the market.

Drugs may be marketed only for the FDA approved indications and in accordance with the provisions of the approved labeling. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the applicant to develop additional data or conduct additional preclinical studies and clinical trials.

The testing and approval processes require substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. Even if we believe a clinical trial has demonstrated safety and efficacy of one of our drug candidates for the proposed indication, the results may not be satisfactory to the FDA. Nonclinical and clinical data may be interpreted by the FDA in different ways, which could delay, limit or prevent regulatory approval. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals which could delay or preclude us from marketing drugs. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the drugs. After approval, certain changes to the approved drug, such as adding new indications, manufacturing changes, or additional labeling claims are subject to further FDA review and approval. Depending on the nature of the change proposed, an NDA supplement must be filed and approved before the change may be implemented.

Other Regulatory Requirements

Any drugs manufactured or distributed by us or our collaboration partners pursuant to FDA approvals would be subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic announced and unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning or untitled letters, suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may, among other things, halt our clinical trials, require us to recall a drug from distribution or withdraw approval of the NDA for that drug.

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

Hatch-Waxman Act

Section 505 of the FFDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application ("ANDA"). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include nonclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The Hatch-Waxman Act establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept) an ANDA or 505(b)(2) application that relies on the branded reference drug. For example, the holder of an NDA, including a 505(b)(2) NDA, may obtain five years of exclusivity upon approval of a new drug containing new chemical entities ("NCE") that have not been previously approved by the FDA. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains

the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the condition of the new drug's approval. As a general matter, the three-year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Fraud and Abuse Laws

In the U.S. the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services ("CMS") other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other state and local government agencies. These laws include but are not limited to, the Anti-Kickback Statute, the federal False Claims Act, the federal Physician Payments Sunshine Act, and other state and federal laws and regulations.

The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs. As well, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the federal False Claims Act.

In addition to the laws described above, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively known as the Affordable Care Act, also imposed new reporting requirements on drug manufacturers for payments made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by such physicians

and their immediate family members. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives. Failure to submit required information may result in significant civil monetary penalties, and additional penalties for knowing failures, for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Manufacturers must submit reports by the 90th day of each subsequent calendar year.

Many states have also adopted laws similar to the federal laws discussed above. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. There has also been a recent trend of increased regulation of payments made to physicians and other healthcare providers. Certain states mandate implementation of compliance programs, impose restrictions on drug manufacturers' marketing practices and/or require the tracking and reporting of pricing and marketing information as well as gifts, compensation and other remuneration to physicians. Many of these laws contain ambiguities as to what is required to comply with such laws, which may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and perhaps federal, authorities.

Violations of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, reporting obligations and integrity oversight, exclusion from participation in federal and state healthcare programs and imprisonment.

Third-Party Coverage and Reimbursement

Sales of pharmaceutical products depend in significant part on the availability of coverage and adequate reimbursement by third-party payors, such as state and federal governments, including Medicare and Medicaid, and commercial managed care providers. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for our product candidates, if approved, will be made on a payor by payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved and have a material adverse effect on our future sales, results of operations and financial condition. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

There is increased uncertainty related to insurance coverage and reimbursement for certain drugs, like tenapanor, which, if approved, will be marketed for the control of serum phosphorus in CKD patients on dialysis. In January 2011, CMS implemented a new prospective payment system for dialysis treatment. Under the ESRD prospective payment system, CMS generally makes a single bundled payment to the dialysis facility for each dialysis treatment that covers all items and services routinely required for dialysis treatments furnished to Medicare beneficiaries in Medicare-certified ESRD facilities or at their home, including the cost of certain routine drugs. The inclusion of oral medications without injectable or intravenous equivalents in the bundled payment was initially delayed until January 1, 2014 and through several subsequent legislative actions was delayed until January 1, 2025. As a result, absent further legislation or regulation on this matter, beginning in 2025, oral ESRD-related drugs without injectable or intravenous equivalents may be included in the ESRD bundle and separate Medicare payment for these drugs will no longer be available, as is the case today under Medicare Part D. While it is too early to project the full impact that bundling may have on tenapanor and our business should tenapanor be brought into the bundle in 2025, or at any time, we may be unable to sell tenapanor, if approved, to

dialysis providers on a profitable basis if third-party payors reduce their current levels of payment, or if our costs of production are higher than levels necessary for an appropriate gross margin after payment of all discounts, rebates and chargebacks.

Healthcare Reform

In March 2010, Congress passed the Patient Protection and Affordable Care Act, a healthcare reform measure (the "ACA"). The ACA was signed into law and substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry.

The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, which have impacted existing government healthcare programs and have resulted in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Additionally, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded access to commercial health insurance coverage through new state-based health insurance marketplaces, or exchanges;
- required manufacturers to participate in a coverage gap discount program, under which they must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, individual states have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and to encourage importation from other countries and bulk purchasing. Recently, there has also been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship

between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. These new laws and the regulations and policies implementing them, as well as other healthcare reform measures that may be adopted in the future, may have a material adverse effect on our industry generally and on our ability to successfully develop and commercialize our products.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including the Health Insurance Portability and Accountability Act of 1996, as amended, and regulations promulgated thereunder (collectively "HIPAA"), and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain state laws, such as the California Consumer Privacy Act ("CCPA") and the California Privacy Rights Act ("CPRA") govern the privacy and security of personal data, including health-related data in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

IMPACT OF COVID-19

The global COVID-19 pandemic has impacted the operational decisions of companies worldwide. It also has created and may continue to create significant uncertainty in the global economy. We have undertaken measures to protect our employees, partners, collaborators, and vendors, some of which impact our normal operations. To date, we have been able to continue our operations with our workforce, most of whom are working remotely, and our pre-existing infrastructure that supports secure access to our internal systems. If, however, the COVID-19 pandemic has a substantial impact on the productivity of our employees, our ability to successfully prepare for the commercial launch of tenapanor for the control of serum phosphorous in CKD patients on dialysis, including our ability to hire and successfully integrate into the company the new personnel required to prepare for such launch, or our ability to progress our research and development efforts, the results of our operations and overall financial performance may be adversely impacted. The extent of the impact from the COVID-19 pandemic on our business will depend largely on future developments that are highly uncertain and cannot be predicted. For a discussion of risks of COVID-19 relating to our business, see "Item 1A. - Risk Factors- Risks Related to Our Business- The ongoing COVID-19 pandemic, or any other outbreak of epidemic diseases, or the perception of their effects, could have a material adverse effect on our business, financial condition, results of operations or cash flows. " As of the date of issuance of this financial report, we are not aware of any specific event or circumstance that would require updates to our estimates and judgments or revisions to the carrying value of our assets or liabilities. These estimates may change as new events occur and additional information is obtained.

HUMAN CAPITAL

The future success of our company depends on our ability to attract, retain, and further develop top talent. The PDUFA date for our NDA for tenapanor for the control of serum phosphorus in CKD patients on dialysis is set for April 29, 2021, and if approved, we expect to commercialize our first product in 2021. As a result, we are focused on building an

experienced commercial team and expanding our internal resources to support a commercial organization. During this ongoing transition and expansion our workforce, we remain steadfastly committed to our core values, including our goal to develop and maintain an inclusive, diverse, and safe workplace with opportunities for our employees to grow and develop in their careers, supported by strong compensation and benefits.

At December 31, 2020, we had approximately 129 full-time employees, 78 of whom were engaged directly in research and development, and 51 in marketing, sales and administrative activities. During 2020, we increased our employee base by approximately 41, or 47%.

Inclusion and Diversity

Our culture is supported by an unwavering commitment to inclusion and diversity. As of December 31, 2020, approximately 63.5% of our workforce was female; 37% of our executive leadership team was female and 23% of our employees in managerial roles were female. As of December 31, 2020, minorities represented approximately 59% of our workforce, of which 19% of our employees in managerial roles were minorities. We strive to foster a culture where mutual respect, inclusive behavior, and dignity are core to our individual expectations.

We believe that our success will be significantly impacted by our ability to create and maintain a safe inclusive environment where everyone is empowered to do their best work—regardless of race, color, national origin, religion, sex, sexual orientation, gender identity and expression, age, or disability. We are united by our desire to serve our patients, and we are proud financial sponsors of the California Life Sciences Association Racial and Social Equity Initiative, a first step in a unified effort for the life sciences industry in California to do more for the under-served and under-represented, focusing on the most critical need to address the inequality for Black, Hispanic, Native American and Pacific Islander populations in California.

Core Values

Fostering and maintaining a strong, healthy culture is a key strategic focus. Our core values reflect who we are and the way our employees interact with one another, our partners and our stockholders. We are dedicated to our core values, recognizing that this dedication will foster an environment where we will be able to realize our vision of creating a healthier tomorrow for patients with kidney and cardiovascular disease. We are Passionate, aware that with integrity and determination, we make a difference for patients. We are Fearless, aware that by challenging convention, we truly innovate. We are Dedicated, aware that working tirelessly together, we are greater than the sum of our parts. We are Inclusive, aware that with respect, grace and humor, we are family. We encourage our employees to live out our core values and to discuss our core values with potential candidates looking to join our team. We believe that this is an important step in helping our culture stay strong and unique.

Health, Safety, and Wellness

The health, safety, and wellness of our employees is a priority in which we have always invested, and will continue to do so. These investments and the prioritization of employee health, safety, and wellness took on particular significance in 2020 in light of COVID-19. In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees, as well as the communities in which we operate, in compliance with government regulations. This includes having the vast majority of our employees work from home, with a return to our facility for a very limited number of lab-based employees and those needed to support them. To protect and support our team members returning to our facility, we have implemented health and safety measures that included maximizing personal workspaces, changing shift schedules, providing personal protective equipment (“PPE”), and instituting mandatory screening before accessing buildings. We created a task force to monitor our efforts and the needs of our employees.

Compensation and Benefits

We recognize that we operate within an industry where there is significant competition for top talent, and we endeavor to provide not only a strong healthy culture, but also important compensation and benefits programs to help meet the needs of our employees. In addition to base compensation, these programs, include annual bonuses, stock awards, an Employee Stock Purchase Plan, 401(k), healthcare and insurance benefits, health savings (funded by the Company) and flexible spending accounts, family leave, family care resources, and flexible work schedules, among many others. As a response to the COVID-19 pandemic, we implemented payments to assist employees in paying for expenses incurred in working from home.

Ensuring fair and equitable pay is integral to our commitment to our employees. Our executive team and Board of Directors strongly support this commitment. We conduct pay equity reviews annually to help us understand whether our compensation structure is appropriate and to identify what improvements can be made.

CORPORATE INFORMATION

We were incorporated in Delaware on October 17, 2007, under the name Nteryx and changed our name to Ardelyx, Inc. in June 2008. We operate in one business segment, which is the research and development of biopharmaceutical products. Our principal offices are located at 34175 Ardenwood Blvd., Fremont, CA 94555 and 400 Fifth Avenue, Suite 210, Waltham, Massachusetts 02415. Our telephone number is (510) 745-1700 and our website address is www.ardelyx.com.

We file electronically with the Securities and Exchange Commission ("SEC") our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. We make available on our website at www.ardelyx.com, free of charge, copies of these reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov.

ITEM 1A. RISK FACTORS

Our business involves significant risks, some of which are described below. You should carefully consider these risks, as well as other information in this Annual Report on Form 10-K, including our financial statements and the notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, cash flows, the trading price of our common stock and our growth prospects. Many of the following risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Summary of Principal Risks Related to Our Business

- We are substantially dependent on the success of our lead product candidate, tenapanor, which may not receive regulatory approval for the control of serum phosphorus in CKD patients on dialysis or, if approved, may not be successfully commercialized for such indication.

- Even if we are successful in obtaining regulatory approval for tenapanor for the control of serum phosphorus, and tenapanor is ultimately commercialized for any approved indications, tenapanor may never achieve market acceptance, sufficient third-party coverage or reimbursement, or commercial success, which will depend, in part, upon the degree of acceptance among physicians, patients, patient advocacy groups, health care payors and the medical community. Additionally, if the number of patients in the market for tenapanor or the price that the market can bear is not as significant as we estimate, or if we are not able to secure adequate coverage and reimbursement for tenapanor, we may not generate sufficient revenue from sales of tenapanor for the control of serum phosphorus.

- Third-party payor coverage and reimbursement status of newly-approved products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for tenapanor, if approved, could limit our ability to market tenapanor for the control of serum phosphorus in CKD patients on dialysis and decrease our ability to generate revenue. For example, certain policies of the Biden administration with respect to drug pricing or reimbursement may impact our business and industry. While there is significant uncertainty related to the insurance coverage and reimbursement of newly approved products in general in the United States, there is additional uncertainty related to insurance coverage and reimbursement for drugs, like tenapanor, which, if approved, will be marketed for the control of serum phosphorus in CKD patients on dialysis. If we are successful in obtaining regulatory approval to market tenapanor for the control of serum phosphorus in CKD patients on dialysis, our ability to generate and sustain future revenues from sales of tenapanor for such indication, may be dependent upon whether and when tenapanor, along with other oral end-stage renal disease ("ESRD") related drugs without an injectable or intravenous equivalent , are bundled into the ESRD prospective payment system, and the manner in which such introduction into the ESRD prospective payment system may occur.

- We have not fully established our sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to commercialize tenapanor or any of our other product candidates.

- We rely completely on third parties to manufacture tenapanor and our other product candidates. If they are unable to comply with applicable regulatory requirements, unable to source sufficient raw materials, experience manufacturing or distribution difficulties or are otherwise unable to manufacture sufficient quantities to meet demand, our commercialization of tenapanor, if approved, and our development efforts for tenapanor, RDX013 and our other product candidates may be materially harmed.

- We have a limited operating history, have incurred significant losses since our inception and will incur losses in the future, which makes it difficult for us to assess our future viability.

- We have never generated any revenue from product sales and may never be profitable. Our ability to generate future revenue from product sales or pursuant to milestone payments is dependent upon many factors, including, but not limited to, obtaining regulatory approvals for tenapanor for the control of serum phosphorus, and establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate supply of product to support the market demand for tenapanor; and obtaining market acceptance of tenapanor as a viable treatment option for the indications for which it is approved and commercialized.

- We will require substantial additional financing to achieve our goals, and the inability to access this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our pre-commercialization efforts for tenapanor and our other product development and platform development activities

- We may not be successful in our efforts to develop RDX013 or expand our pipeline of product candidates, as a result of numerous factors, which may include the inability to access capital necessary to fund such efforts on acceptable terms.

- We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources.

- The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic may impact our business, manufacturing, preclinical development activities, preclinical studies and planned and ongoing clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as, the duration of the pandemic, travel restrictions and actions to contain the pandemic or treat its impact, such as social distancing, quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Specifically, while our Phase 3 clinical development of tenapanor for the control of serum phosphorus in CKD patients on dialysis is complete, we have ongoing and planned clinical trials for tenapanor that may be delayed as a result of the restrictions placed on access to dialysis centers during the COVID-19 pandemic. Other potential impacts of the COVID-19 pandemic on our various clinical trials, including our ongoing Phase 2 clinical trial for RDX013, include delays or difficulties in any planned clinical site initiation, including difficulties in obtaining Institutional Review Board approvals, recruiting clinical site investigators and clinical site staff, delays or difficulties in enrolling patients, interruption of planned key clinical trial activities, such as clinical trial site data monitoring due to diversion of resources at clinical sites or limitation on travel imposed by federal or state governments.

- Our operating activities may be restricted as a result of covenants related to the indebtedness under our loan and security agreement and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.

- Our products or product candidates may cause undesirable side effects or have other properties that could delay our clinical trials, or delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval that is achieved. If we or others identify undesirable side effects caused by any product candidate following receipt of marketing approval, the ability for us or a collaboration partner to achieve or maintain market acceptance of the approved product could be materially affected and could result in the loss of significant revenue to us, which would materially and adversely affect our results of operations and business.

- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. Even if we receive regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, any product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Principal Risks Related to Our Business

We are substantially dependent on the success of our lead product candidate, tenapanor, which may not receive regulatory approval for the control of serum phosphorus or be successfully commercialized for hyperphosphatemia or IBS-C.

To date, we have invested a significant amount of our efforts and financial resources in the research and development of tenapanor, which is currently our lead product candidate. The commercial success of tenapanor will depend on a number of factors, including the following:

- whether tenapanor's safety and efficacy profile is satisfactory to the FDA and foreign regulatory authorities to gain marketing approval for the control of serum phosphorus;

- the ability of the third-party manufacturers we contract with to provide an adequate (in amount and quality) supply of product to support the market demand for tenapanor for the treatment of IBS-C, and/or if approved, tenapanor

for the control of serum phosphorus in adult CKD patients on dialysis, particularly in light of the effects of the COVID-19 pandemic;

- whether or not the content of the label approved by the FDA or foreign regulatory authorities may materially and adversely impact our ability the ability of our collaboration partners to commercialize the product for the approved indication, or for any other indication;
- whether we will be required to conduct clinical trials in addition to those anticipated to obtain adequate commercial pricing;
- the prevalence and severity of adverse side effects of tenapanor;
- the timely receipt of necessary marketing approvals from the FDA and foreign regulatory authorities;
- our ability, either alone, or with a collaboration partner, to successfully commercialize tenapanor, if approved for marketing and sale by the FDA or foreign regulatory authorities, including educating physicians and patients about the benefits, administration and use of tenapanor;
- achieving and maintaining compliance with all regulatory requirements applicable to tenapanor;
- acceptance of tenapanor as safe, effective and well-tolerated by patients and the medical community;
- our ability, alone or with collaboration partners, to manage the complex pricing and reimbursement negotiations associated with marketing the same product at different doses for separate indications for tenapanor for the treatment of IBS-C, and, if approved, for the control of serum phosphorus in CKD patients on dialysis;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of tenapanor compared to alternative and competing treatments;
- obtaining and sustaining an adequate level of coverage and reimbursement for tenapanor by third-party payors;
- enforcing intellectual property rights in and to tenapanor;
- avoiding third-party interference, opposition, derivation or similar proceedings with respect to our patent rights, and avoiding other challenges to our patent rights and patent infringement claims; and
- a continued acceptable safety and tolerability profile of tenapanor following approval.
- As tenapanor is a first-in-class drug, there is a higher likelihood that approval may not be attained as compared to a class of drugs with approved products. Although tenapanor met the primary endpoints in all of the three Phase 3 clinical trials evaluating tenapanor for the control of serum phosphorus in CKD patients on dialysis, there can be no assurances that we will receive regulatory approval to market tenapanor for the control of serum phosphorus in CKD patients on dialysis. Further, it may not be possible or practicable to demonstrate, or if approved, to market tenapanor on the basis of certain of the benefits we believe tenapanor possesses. If the number of patients in the market for tenapanor or the price that the market can bear is not as significant as we estimate, or if we are not able to secure adequate coverage and reimbursement for tenapanor, we may not generate sufficient revenue from sales of tenapanor for the control of serum phosphorus, if approved, or for IBS-C if commercialized. There can be no assurance that tenapanor will ever be successfully commercialized or that we will ever generate income from sales of tenapanor. If we are not successful in obtaining approval for tenapanor for the control of serum phosphorus, or we are not successful in commercializing tenapanor, or are significantly delayed in doing so, our business will be materially harmed.

Even if we are successful in obtaining regulatory approval for tenapanor for the control of serum phosphorus, and tenapanor is ultimately commercialized for any approved indications, tenapanor may never achieve market acceptance, sufficient third-party coverage or reimbursement, or commercial success, which will depend, in part, upon the degree of acceptance among physicians, patients, patient advocacy groups, health care payors and the medical community.

Market acceptance of tenapanor for IBS-C and, in the event that marketing approval is obtained, for the control of serum phosphorus, depends on a number of factors, including:

- the efficacy demonstrated in our clinical trials;
- with respect to tenapanor for the control of serum phosphorus, whether tenapanor, along with other oral only medications, are included in the bundled prospective payment system for the treatment of ESRD patients, and the time and manner in which such transition is achieved;
- the prevalence and severity of any side effects and overall safety and tolerability profile of the product;
- the clinical indications for which it is approved;
- advantages over new or traditional or existing therapies, including recently approved therapies or therapies that the physician community anticipate will be approved;
- acceptance by physicians, major operators of clinics and patients of tenapanor as a safe, effective and well-tolerated treatment;
- relative convenience and ease of administration of tenapanor;
- the potential and perceived advantages of tenapanor over current treatment options or alternative treatments, including future alternative treatments;
- the cost of treatment in relation to alternative treatments and the willingness to pay for tenapanor, if approved, on the part of physicians and patients;
- the availability of alternative products and their ability to meet market demand; and
- the quality of our relationships with patient advocacy groups.
- Any failure of tenapanor to achieve market acceptance, sufficient third-party coverage or reimbursement, or commercial success for any approved indications would adversely affect our results of operations.

We do not have a fully established sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to commercialize tenapanor or any of our other product candidates.

We currently plan to commercialize tenapanor for the control of serum phosphorus in CKD patients on dialysis, if approved, on our own. In order to do so, we will need to complete the establishment of an appropriate sales organization with technical expertise, as well as supporting distribution capabilities. This will continue to be expensive and time consuming. As a company, we have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to secure the capital necessary to fund such efforts on acceptable terms, hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, comply with regulatory requirements applicable to the marketing and sale of drug products and effectively manage a geographically dispersed sales and marketing team.

If we fail or are delayed in the development of our internal sales, marketing and distribution capabilities, we may need to delay the commercialization tenapanor for the control of serum phosphorus, if approved, or such commercialization could be adversely impacted.

Third-party payor coverage and reimbursement status of newly-approved products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our products, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The pricing, coverage and reimbursement of our product candidates, if approved, must be adequate to support a commercial infrastructure. The availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to be able to afford treatments such as ours, assuming approval. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid for by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government authorities, private health insurers, and other third-party payors. If coverage and reimbursement are not available, or are available only to limited levels, we, or our collaboration partners, may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by the Centers for Medicare & Medicaid Services (“CMS”), an agency within the United States Department of Health and Human Services responsible for administering the Medicare program, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for products such as ours.

There is increased uncertainty related to insurance coverage and reimbursement for drugs, like tenapanor, which, if approved, will be marketed for the control of serum phosphorus in CKD patients on dialysis. In January 2011, CMS implemented a new prospective payment system for dialysis treatment. Under the ESRD prospective payment system, CMS generally makes a single bundled payment to the dialysis facility for each dialysis treatment that covers all items and services routinely required for dialysis treatments furnished to Medicare beneficiaries in Medicare-certified ESRD facilities or at their home, including the cost of certain routine drugs. The inclusion of oral medications without injectable or intravenous equivalents in the bundled payment was initially delayed until January 1, 2014 and through several subsequent legislative actions was delayed until January 1, 2025. As a result, absent further legislation or regulation on this matter, beginning in 2025, oral ESRD-related drugs without injectable or intravenous equivalents may be included in the ESRD bundle and separate Medicare payment for these drugs will no longer be available, as is the case today under Medicare Part D. While it is too early to project the full impact that bundling may have on tenapanor and our business should tenapanor be brought into the bundle in 2025, or at any time, we may be unable to sell tenapanor, if approved, to dialysis providers on a profitable basis if third-party payors reduce their current levels of payment, or if our costs of production are higher than levels necessary for an appropriate gross margin after payment of all discounts, rebates and chargebacks.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, Japan, China and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medicinal products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved

products and, as a result, these caps may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

We rely completely on third parties to manufacture tenapanor and our other product candidates. If they are unable to comply with applicable regulatory requirements, unable to source sufficient raw materials, experience manufacturing or distribution difficulties or are otherwise unable to manufacture sufficient quantities to meet demand, our commercialization of tenapanor, if approved, and our development efforts for tenapanor, RDX013 and our other product candidates may be materially harmed.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture tenapanor or any of other our product candidates on a commercial scale, or to manufacture our drug supplies for use in the conduct of our nonclinical and clinical studies. The facilities used by our contract manufacturers to manufacture our drug supply are subject to inspection by the FDA. Our ability to control the manufacturing process of our product candidates is limited to the contractual requirements and obligations we impose on our contract manufacturer. Although they are contractually required to so do, we are completely dependent on our contract manufacturing partners for compliance with the regulatory requirements, known as current Good Manufacturing Practice requirements ("cGMPs"), for manufacture of both active drug substances and finished drug products.

The manufacture of pharmaceutical products requires significant expertise and capital investment. Manufacturers of pharmaceutical products often encounter difficulties in commercial production. These problems may include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, and shortages of qualified personnel, as well as compliance with federal, state and foreign regulations and the challenges associated with complex supply chain management. Even if our contract manufacturers do not experience problems and commercial manufacturing is achieved, their maximum or available manufacturing capacities may be insufficient to meet commercial demand. Finding alternative manufacturers or adding additional manufacturers requires a significant amount of time and involves significant expense. New manufacturers would need to develop and implement the necessary production techniques and processes, which along with their facilities, would need to be inspected and approved by the regulatory authorities in each applicable territory. In addition, the raw materials necessary to make API for our products are acquired from a limited number of sources. Any delay or disruption in the availability of these raw materials could result in production disruptions, delays or higher costs with consequent adverse effects on us.

If our contract manufacturers fail to adhere to applicable GMP or other regulatory requirements, experience delays or disruptions in the availability of raw materials or experience manufacturing or distribution problems, we may suffer significant consequences, including the inability to meet our product requirements for our clinical development programs, and if tenapanor is approved for marketing for the control of serum phosphorus in CKD patients on dialysis, such events could result in product seizures or recalls, loss of product approval, fines and sanctions, reputational damage, shipment delays, inventory shortages, inventory write-offs and other product-related charges and increased manufacturing costs. As a result, or if maximum or available manufacturing capacities are insufficient to meet demand, our development or our commercialization efforts for tenapanor for the control of serum phosphorus, if approved, may be materially harmed.

Risks Related to our Financial Condition and Capital Requirements

We have a limited operating history, have incurred significant losses since our inception and we will incur losses in the future, which makes it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have focused substantially all of our efforts on our research and development activities, including developing tenapanor and developing our proprietary drug discovery and design platform. To date, we have not commercialized any products or generated any revenue from the sale of products.

We are not profitable and have incurred losses in each year since our inception in October 2007, and we do not know whether or when we will become profitable. We continue to incur significant research, development and other expenses related to our ongoing operations. As of December 31, 2020, we had an accumulated deficit of $554.8 million.

We expect to continue to incur substantial operating losses for the foreseeable future as we prepare for the potential commercialization of, and incur manufacturing and development costs for, tenapanor for the control of serum phosphorus in CKD patients on dialysis; as we commence commercialization of tenapanor for that indication, if approved; as we incur development costs for RDX013; and as we continue our discovery and research activities.

Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

We have substantial net operating loss and tax credit carryforwards for Federal and California income tax purposes. Such net operating losses and tax credits carryforwards may be reduced as a result of certain intercompany restructuring transactions. In addition, the future utilization of such net operating loss and tax credit carryforwards and credits will be subject to limitations, pursuant to Internal Revenue Code Sections 382 and 383, as a result of ownership changes that have occurred previously and additional limitations may be applicable as a result of ownership changes that could occur in the future.

We have never generated any revenue from product sales and may never be profitable.

We received FDA approval for our New Drug Application ("NDA") for tenapanor for the treatment of IBS-C in adults in September 2019. However, we have not commercialized tenapanor for IBS-C ourselves in the United States and have not entered into a collaboration partnership for such commercialization. We have no other products approved for sale and have never generated any revenue from product sales. Our ability to generate revenue from product sales and achieve profitability depends on our ability to obtain approval of the United States Food and Drug Administration ("FDA") to commercialize tenapanor for the control of serum phosphorus in CKD patients on dialysis in the U.S. and the ability of our collaboration partners to obtain regulatory approval to market tenapanor in their respective territories. There can be no assurances that we will generate product revenue from sales of tenapanor, either on our own, or with a collaboration partner. Our ability to generate future revenue from product sales or pursuant to milestone payments depends heavily on many factors, including but not limited to:

- obtaining regulatory approvals for tenapanor for the control of serum phosphorus in adult CKD patients on dialysis, either on our own or with one or more collaboration partners;
- our ability to successfully commercialize tenapanor, which has been approved by the FDA for the treatment of IBS-C in adults, and/or tenapanor for the control of serum phosphorus in adult CKD patients on dialysis, if approved, either on our own or with one or more collaboration partners;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide an adequate (in amount and quality) supply of product to support the market demand for tenapanor for the treatment of IBS-C, and/or, if approved, tenapanor for the control of serum phosphorus in adult CKD patients on dialysis;
- obtaining market acceptance of tenapanor as a viable treatment option for the indications for which it is approved and commercialized;
- addressing any competing technological and market developments;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how, and our ability to develop, manufacture and commercialize our product candidates and products without infringing intellectual property rights of others; and

- attracting, hiring, and retaining qualified personnel.

In cases where we are successful in obtaining regulatory approvals to market tenapanor for one or more indications, our revenue will be dependent, in part, upon the size of the markets in the territories for which regulatory approval is granted, the accepted price for the product, the ability to get reimbursement at any price and whether we are commercializing the product or the product is being commercialized by a collaboration partner, and in such case, whether we have royalty and/or co-promotion rights for that territory, and whether any royalty we have a right to receive from a collaboration partner is in excess of the royalty we owe AstraZeneca as a result of the termination of our License Agreement with AstraZeneca in 2015. See Note 12, Collaboration and Licensing Agreements, in the notes to our financial statements, included in Part II, Item 8, for details on our obligations to AstraZeneca. While there is significant uncertainty related to the insurance coverage and reimbursement of newly approved products in general in the United States, there is additional uncertainty related to insurance coverage and reimbursement for drugs, like tenapanor, which, if approved, will be marketed for the control of serum phosphorus in CKD patients on dialysis. If we are successful in obtaining regulatory approval to market tenapanor for the control of serum phosphorus in CKD patients on dialysis, our ability to generate and sustain future revenues from sales of tenapanor for such indication, may be dependent upon whether and when tenapanor, along with other oral end-stage renal disease ("ESRD") related drugs without an injectable or intravenous equivalent, are bundled into the ESRD prospective payment system, and the manner in which such introduction into the ESRD prospective payment system may occur. See "*Third-party payor coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our products, if approved, could limit our ability to market those products and decrease our ability to generate revenue"* below**.** Additionally, if the number of patients suitable for tenapanor is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, coverage and reimbursement for tenapanor are not available in the manner and to the extent which we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from the sale of tenapanor, even if approved. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to generate revenue from product sales would likely depress our market value and could impair our ability to raise capital, expand our business, discover or develop other product candidates or continue our operations. A decline in the value of our common stock could cause our stockholders to lose all or part of their investment.

We will require substantial additional financing to achieve our goals, and the inability to access this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our commercialization efforts for tenapanor for the control of serum phosphorus, if approved, and our other product development and platform development activities.

Since our inception, most of our resources have been dedicated to our research and development activities, including developing our clinical product candidate tenapanor and developing our proprietary drug discovery and design platform. We believe that we will continue to expend substantial resources for the foreseeable future, including, if approved, costs associated with the commercialization of tenapanor for the control of serum phosphorus in CKD patients on dialysis, research and development, conducting preclinical studies and clinical trials for our other programs, including RDX013, obtaining regulatory approvals, scaling our manufacturing processes for our product candidates and sales and marketing. Because the outcome of any clinical trial and/or regulatory approval process is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization or co-promotion of any of our product candidates. Our future funding requirements will depend on many factors, including, but not limited to:

- the FDA's actions and decisions with respect to the NDA submitted to the FDA on June 30, 2020 to request marketing authorization for tenapanor for the control of serum phosphorus in adult CKD patients on dialysis;

- our ability to successfully commercialize tenapanor for the control of serum phosphorus in CKD patients on dialysis, if approved, either alone or with one or more collaboration partners;

- the sales price and the availability of adequate third-party reimbursement for tenapanor, if approved;

- the manufacturing costs of our product candidates, and the availability of one or more suppliers for our product candidates at reasonable costs, both for clinical and commercial supply;

- the selling and marketing costs associated with tenapanor, including the cost and timing of building our sales and marketing capabilities;

- our ability to maintain our existing collaboration partnerships and to establish additional collaboration partnerships, in-license/out-license, joint ventures or other similar arrangements and the financial terms of such agreements;

- the timing, receipt, and amount of sales of, or royalties on, tenapanor, if any;

- the cash requirements of any future acquisitions or discovery of product candidates;

- the number and scope of preclinical and discovery programs that we decide to pursue or initiate, and any clinical trials we decide to pursue for other product candidates, including RDX013;

- the time and cost necessary to respond to technological and market developments;

- the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights, including litigation costs and the outcome of such litigation, including costs of defending any claims of infringement brought by others in connection with the development, manufacture or commercialization of tenapanor or any of our product candidates; and

- the payment of interest and principal related to our loan and security agreement entered into with Solar Capital and Western Alliance Bank in May 2018, as amended in October 2020.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate our research activities, preclinical and clinical trials for our product candidates and our establishment and maintenance of sales and marketing capabilities or other activities that may be necessary to commercialize tenapanor, either alone or with collaboration partners. Additionally, our inability to access capital on a timely basis and on terms that are acceptable to us may force us to restructure certain aspects of our business or identify and complete one or more strategic collaborations or other transactions in order to fund the development or commercialization of tenapanor or certain of our product candidates through the use of alternative structures.

Our operating activities may be restricted as a result of covenants related to the indebtedness under our loan and security agreement and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.

On May 16, 2018, we entered into a loan and security agreement with Solar Capital, Ltd. and Western Alliance Bank (collectively the “Lenders”) pursuant to which the Lenders agreed to provide us a $50.0 million term loan facility with a maturity date of November 1, 2022. On October 9, 2020, we entered into an amendment to the loan and security agreement. The full amount of the loan was funded on May 16, 2018. Until we have repaid such indebtedness, the loan and security agreement subjects us to various customary covenants, including requirements as to financial reporting and insurance and restrictions on our ability to dispose of our business or property, to change our line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on our property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock, to redeem capital stock, to enter into licensing agreements, to engage in transactions with affiliates, and to encumber our intellectual property. Our business may be adversely affected by these restrictions on our ability to operate our business.

We are permitted to make interest only payments on the loan facility through December 1, 2021, unless we have not received FDA approval for our NDA for tenapanor for the control of serum phosphorus in CKD patients on dialysis on or before May 31, 2020, or the FDA issues a complete response letter in connection with such NDA. In either event, the period in which we are permitted to make interest only payments shall end on the earlier of June 1, 2021, or the first day of the month following the date that the FDA issues a CRL. However, we may be required to repay the outstanding indebtedness under the loan facility if an event of default occurs under the loan and security agreement. An event of default will occur if, among other things, we fail to make payments under the loan and security agreement; we breach any of our covenants under the loan and security agreement, subject to specified cure periods with respect to certain breaches; the Lenders determine that a material adverse change has occurred; we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings; we are unable to pay our debts as they become due; or we default on contracts with third parties which would permit the Lenders to accelerate the maturity of such indebtedness or that could have a material adverse change on us. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In this case, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others' rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. The Lenders could also exercise their rights as collateral agent to take possession of and to dispose of the collateral securing the term loans, which collateral includes substantially all of our property (excluding intellectual property, which is subject to a negative pledge). Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

Additional Risks Related to Our Business and Industry

We may not be successful in our efforts to develop RDX013 or any other product candidates that are at an early stage of development, or expand our pipeline of product candidates, as a result of numerous factors, which may include the inability to access capital necessary to fund such efforts on acceptable terms.

A key element of our strategy has been focused on the expansion of our pipeline of product candidates utilizing our proprietary drug discovery and design platform and to advance such product candidates through clinical development. Our inability to access capital in a timely manner or on acceptable terms to fund our early stage product candidates may force us to consider certain restructuring activities to enable the funding of those early assets through the use of alternative structures. In addition, of the large number of drugs in development, only a small percentage of such drugs successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to continue to fund our research and early-stage development programs, there can be no assurance that any product candidates will reach the clinic or be successfully developed or commercialized.

Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Although our research and development efforts to date have resulted in several development programs, we may not be able to develop product candidates that are safe, effective and well-tolerated. Our research programs may initially show promise in identifying potential product candidates, and we may select candidates for development, yet we may fail to advance product candidates to clinical development for many reasons, including the following:

- we may be unable to access sufficient capital on acceptable terms to fund the development of all of our assets and as a result we may be forced to delay or terminate the development of certain product candidates, or to consider restructuring efforts to secure alternate funding for those assets;
- the research methodology used and our drug discovery and design platform may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;

- the market for a product candidate may change during our program so that the continued development of that product candidate is no longer reasonable;

- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective, well-tolerated or otherwise does not meet applicable regulatory or commercial criteria;

- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and

- a product candidate may not be accepted as safe, effective and well-tolerated by patients, the medical community or third-party payors, if applicable.

Even if we are successful in continuing to expand our pipeline, through our own research and development efforts, the potential product candidates that we identify or for which we acquire rights may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize a product pipeline, we may not be able to generate revenue from product sales in future periods or ever achieve profitability.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome and the results of earlier studies and trials may not be predictive of future trial results.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical and clinical studies of our product candidates, including RDX013, may not be predictive of the results of later-stage clinical trials. An unexpected adverse event profile, or the results of drug-drug interaction studies, may present challenges for the future development and commercialization of a product candidate for a particular condition despite receipt of positive efficacy data in a clinical study. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials for similar indications that we are pursuing due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks.

Our ongoing RDX013 Phase 2 clinical trial or any of our other ongoing clinical trials may be impacted by the COVID-19 pandemic in a number of ways, including delays or difficulties in any planned clinical site initiation, difficulties in obtaining IRB approvals, recruiting clinical site investigators and clinical site staff, delays or difficulties in enrolling patients, interruption of planned key clinical trial activities, such as clinical trial site data monitoring due to diversion of resources at clinical sites or limitation on travel imposed by federal or state governments.

Furthermore, we could encounter delays if our ongoing RDX013 Phase 2 clinical trial, or any other of our clinical trials are suspended or terminated by us, by the IRBs of the institutions in which the trial is being conducted, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

In addition, identifying and qualifying patients to participate in our RDX013 Phase 2 clinical trial or any of our other clinical trials is critical to our success. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in testing our product candidates. Patients may be unwilling to participate in our clinical studies because of concerns about adverse events observed with the current standard of care, competitor products and/or other investigational agents, in each case for the same indications and/or similar patient populations. In addition, patients

currently receiving treatment with the current standard of care or a competitor product may be reluctant to participate in a clinical trial with an investigational drug, or our inclusion and exclusion criteria for our clinical trials may present challenges in identifying acceptable patients. As a result, the timeline for recruiting patients and conducting our RDX013 Phase 2 clinical trial or any of our other clinical trials may be delayed. These delays could result in increased costs, delays in advancing our development of our product candidates, or termination of the clinical studies altogether. Any of these occurrences may significantly harm our business, financial condition and prospects.

Furthermore, even though we have completed our Phase 3 clinical development program for tenapanor for the control of serum phosphorus, the results may not be sufficient to obtain the desired regulatory approval for tenapanor, or if such regulatory approval is obtained, the content of the label approved by regulatory authorities may materially and adversely impact our ability to commercialize the product for the approved indication.

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

We do not have the ability to independently conduct clinical trials and, in some cases, nonclinical studies. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as CROs, to conduct clinical trials on our product candidates. The third parties with whom we contract for execution of the clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we control only certain aspects of their activities and have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely, and will continue to rely, on these third parties to conduct some of our nonclinical studies and all of our clinical trials, we remain responsible for ensuring that each of our studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. We, and these third parties are required to comply with current GLPs for nonclinical studies, and good clinical practices ("GCPs") for clinical studies. GLPs and GCPs are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area ("EEA") and comparable foreign regulatory authorities for all of our products in nonclinical and clinical development, respectively. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our third-party contractors fail to comply with applicable regulatory requirements, including GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the European Medicines Agency ("EMA"), or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Our products or product candidates may cause undesirable side effects or have other properties that could delay our clinical trials, or delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval that is achieved. If we or others identify undesirable side effects caused by any product candidate following receipt of marketing approval, the ability to market such product candidate could be compromised.

Undesirable side effects caused by our products or product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials, result in the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities or limit the commercial profile of an approved label. To date, patients treated with tenapanor have experienced drug-related side effects including diarrhea, nausea, vomiting, flatulence, abdominal discomfort, abdominal pain, abdominal distention and changes in electrolytes. Despite our receipt of marketing approval for tenapanor for IBS-C in adults and the completion of our Phase 3 clinical program for tenapanor for the control of serum phosphorus, in the event that future trials conducted by us with tenapanor, or trials we conduct with RDX013 or our other product candidates, reveal an unacceptable severity and prevalence of these or other side effects, such trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of tenapanor, RDX013, or any such other product candidate, for any or all targeted indications. Additionally,

despite a positive efficacy profile, the prevalence and/or severity of these or other side effects could cause us to cease further development of a product candidate for a particular indication, or entirely. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, if we or others identify undesirable side effects caused by one of our products for which we have received regulatory approval, a number of potentially significant negative consequences could occur, including:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we or a collaboration partner may be required to recall the product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof, including the imposition of a Risk Evaluation and Mitigation Strategy ("REMS") which could require creation of a Medication Guide or patient package insert outlining the risks of such side effects for distribution to patients, a communication plan to educate healthcare providers of the drugs' risks, as well as other elements to assure safe use of the product, such as a patient registry and training and certification of prescribers;
- we or a collaboration partner may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us, or a collaboration partner, from achieving or maintaining market acceptance of a particular product candidate, if approved, and could result in the loss of significant revenue to us, which would materially and adversely affect our results of operations and business.

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

The biotechnology and pharmaceutical industries are highly competitive, and we face significant competition from companies in the biotechnology, pharmaceutical and other related markets that are researching and marketing products designed to address diseases that we are currently developing products to treat. If approved for marketing by the FDA or other regulatory agencies, tenapanor, as well as our other product candidates, would compete against existing treatments.

For example, tenapanor, if approved for the control of serum phosphorus in adult patients with CKD on dialysis, will compete with phosphate binders used for the same indication`. The various types of phosphate binders commercialized in the United States include the following:

- Calcium carbonate (many over-the-counter brands including Tums and Caltrate);
- Calcium acetate (several prescription brands including PhosLo and Phoslyra);
- Lanthanum carbonate (Fosrenol);

- Sevelamer hydrochloride (Renagel);
- Sevelamer carbonate (Renvela);
- Sucroferric oxyhydroxide (Velphoro); and
- Ferric citrate (Auryxia).

All of the phosphate binders listed above are available as generics in the U.S., with the exception of Velphoro and Auryxia. In addition to the currently available phosphate binders, we are aware of at least two other binders in development, including fermagate (Alpharen), an iron-based binder in Phase 3 being developed by Opko Health, Inc., and PT20, an iron-based binder in Phase 3 being developed by Shield Therapeutics.

In respect of tenapanor for the treatment of IBS-C, numerous treatments exist for constipation and the constipation component of IBS-C, many of which are over-the-counter. These include psyllium husk (such as Metamucil), methylcellulose (such as Citrucel), calcium polycarbophil (such as FiberCon), lactulose (such as Cephulac), polyethylene glycol (such as MiraLax), sennosides (such as Exlax), bisacodyl (such as Ducolax), docusate sodium (such as Colace), magnesium hydroxide (such as Milk of Magnesia), saline enemas (such as Fleet) and sorbitol. These agents are generally inexpensive and work well to temporarily relieve constipation.

We are aware of four prescription products marketed for certain patients with IBS-C, including Linzess (linaclotide), Amitiza (lubiprostone), Trulance (plecanatide) and Zelnorm (tegaserod maleate).

It is possible that our competitors will develop and market drugs or other treatments that are less expensive and more effective than our product candidates, or that will render our product candidates obsolete. It is also possible that our competitors will commercialize competing drugs or treatments before we or our collaboration partners can launch any products developed from our product candidates. We also anticipate that we will face increased competition in the future as new companies enter into our target markets.

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

We may experience difficulties in managing our current activities and growth given our level of managerial, operational, financial and other resources.

While we have continued to work to optimize our management composition, personnel and systems to support our current activities for future growth, these resources may not be adequate for this purpose. Our need to effectively execute our business strategy requires that we:

- manage any commercialization activities in which we may engage effectively;
- manage our clinical trials effectively;
- manage our internal research and development efforts effectively while carrying out our contractual obligations to licensors, contractors, collaborators, government agencies and other third parties;
- continue to improve our operational, financial and management controls, reporting systems and procedures; and

- retain and motivate our remaining employees and potentially identify, recruit, and integrate additional employees.

If we are unable to maintain or expand our managerial, operational, financial and other resources to the extent required to manage our development and commercialization activities, our business will be materially adversely affected.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize or co-promote our product candidates.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of any products we develop. Although we maintain product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

If we fail to attract, retain and motivate our executives, senior management and key personnel, our business will suffer.

Recruiting and retaining qualified scientific, clinical, medical, manufacturing, and sales and marketing personnel is critical to our success. We are highly dependent on our executives, senior management and certain other key employees. The loss of the services of our executives, senior management or other key employee could impede the achievement of our research, development and commercial objectives and seriously harm our ability to successfully implement our

business strategy. Furthermore, replacing executives, senior management and other 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 marketing approval of and commercialize products. We may be unable to hire, train or motivate these key personnel on acceptable terms given the intense competition among numerous biopharmaceutical companies for similar personnel, particularly in our geographic regions. If we are unable to continue to attract and retain high quality personnel, our ability to grow and pursue our business strategy will be limited.

Our proprietary drug discovery and design platform, and, in particular, APECCS, is a new approach to the discovery, design and development of new product candidates and may not result in any products of commercial value. Furthermore, the APECCS aspects of our drug discovery and design platform may have diminished relevance to our efforts focused on the discovery of targets and therapies for the treatment of renal diseases.

We have developed a proprietary drug discovery and design platform integrating our proprietary chemistry capabilities and our APECCs stem cell platform to enable the identification, screening, testing, design and development of new product candidates, and have developed APECCS as a component of this of this platform. We have utilized APECCS in the design of our small molecules and to identify new and potentially novel targets in the GI tract. However, there can be no assurance that APECCS will be able to identify new targets in the GI tract or that any of these potential targets or other aspects of our proprietary drug discovery and design platform will yield product candidates that could enter clinical development and, ultimately, be commercially valuable. In addition, as we focus our efforts on the discovery and design of therapies for the treatment of cardiorenal diseases, we may need to further develop our proprietary drug discovery and design platform to enhance its usefulness in the identification, screening, testing, design and development of new product candidates for the treatment of cardiorenal diseases. There can be no assurances that we will be successful in such additional development of our platform or that our platform will yield product candidates for the treatment of renal diseases.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, California enacted the California Consumer Privacy Act (CCPA) on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, the California Privacy Rights Act (CPRA) recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional

consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In Europe, the European Union General Data Protection Regulation (GDPR) went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area (EEA). Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Relatedly, following the United Kingdom's withdrawal from the European Economic Area and the European Union, and the expiry of the transition period, companies have to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which may expose us to further compliance risk.

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

We and our collaborators, CROs and other contractors and consultants depend on information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

We and our collaborators, CROs, and other contractors and consultants collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we and our collaborators, CROs and other contractors and consultants collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we and our collaborators, CROs and other contractors and consultants do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, CROs, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. As a result of the COVID-19 pandemic, we may also face

increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs, and/or of our efforts to commercialize tenapanor for the control of serum phosphorus in CKD patients on dialysis, if approved. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including HIPAA. Moreover, if a computer security breach affects our systems or those of our collaborators, CROs or other contractors, or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. Even when HIPAA does not apply, according to the Federal Trade Commission (the "FTC") failing to take appropriate steps to keep consumers' personnel information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade CommissionFTC Act (the "FTCA") 15 U.S. C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. We may also be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. For example, California recently enacted legislation, the California Consumer Privacy Act ("CCPA")theCCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents,

including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context. Further, the CPRA recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required.

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

We have previously identified a material weakness in our internal control over financial reporting. If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us and could have a material adverse effect on the price of our common stock.

In 2019, management and our independent registered public accounting firm identified a control deficiency that constituted a material weakness in our internal control over financial reporting. The material weakness was due to a failure in the design and implementation of controls over the evaluation of the terms of our clinical trial contracts for inclusion into our clinical financial model which estimates clinical trial expenses. Specifically, we had failed to properly interpret an expense in our clinical trial contracts which resulted in the over accrual of our clinical trial expenses during 2018 and the first quarter of 2019.

We developed and implemented a remediation plan for this material weakness which included modifications to the design and implementation of certain internal controls, and the material weakness was remediated as of December 31, 2019. Although we have remediated this material weakness, as attested by our independent registered public accounting firm, we can give no assurance that an additional material weakness or significant deficiency in our internal controls over financial reporting will not be identified in the future. Our failure to implement and maintain effective internal controls over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements and cause us to fail to meet our reporting obligations. If we cannot in the future favorably assess the effectiveness of our internal controls over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on the trading price of our common stock.

We have formed in the past, and may form in the future, collaboration partnerships, joint ventures and/or licensing arrangements, and we may not realize the benefits of such collaborations.

We have current collaboration partnerships for the commercialization of tenapanor in certain foreign countries, and we may form additional collaboration partnerships, create joint ventures or enter into additional licensing arrangements with third parties in the United States and abroad that we believe will complement or augment our existing business. In particular, we have formed collaboration partnerships with Kyowa Kirin Co. , Ltd. ("KKC") for certain research programs and for commercialization of tenapanor for hyperphosphatemia in Japan; with Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. ("Fosun Pharma") for commercialization of tenapanor for hyperphosphatemia and IBS-C in China and related territories; and in Canada with Knight Therapeutics, Inc. ("Knight") for commercialization of tenapanor for IBS-C and hyperphosphatemia. We face significant competition in seeking appropriate collaboration partners, and the process to identify an appropriate partner and negotiate appropriate terms is time-consuming and complex. Any delays in identifying suitable additional collaboration partners and entering into agreements to develop our product candidates could

also delay the commercialization of our product candidates, which may reduce their competitiveness even if they reach the market. There is no guarantee that our current collaboration partnerships or any such arrangements we enter into in the future will be successful, or that any collaboration partner will commit sufficient resources to the development, regulatory approval, and commercialization effort for such products, or that such alliances will result in us achieving revenues that justify such transactions.

The ongoing COVID-19 pandemic, or any other outbreak of epidemic diseases, or the perception of their effects, could have a material adverse effect on our business, financial condition, results of operations or cash flows.

Outbreaks of epidemic, pandemic, or contagious diseases, such as the current novel coronavirus ("COVID-19") pandemic or, historically, the Ebola virus, Middle East Respiratory Syndrome, Severe Acute Respiratory Syndrome, or the H1N1 virus, could disrupt our business. Business disruptions could include disruptions or restrictions on our ability to conduct our clinical trials, as planned, travel, as well as temporary closures of the facilities of our collaboration partners, suppliers or contract manufacturers. Any disruption of our clinical trial operations, collaboration partners, suppliers or contract manufacturers could adversely impact our operating results.

While the COVID-19 pandemic did not materially adversely affect our business operations in the year ended December 31, 2020, economic and health conditions in the United States and across most of the globe remain uncertain and continue to evolve. While at this point, the extent to which the coronavirus outbreak may impact our results is uncertain, it could result in delays in the manufacture of tenapanor, or in the delivery of key intermediates or raw materials required to manufacture tenapanor or delays in clinical development activities by us, or our collaboration partners. It could also materially and negatively impact our ability, either alone, or with a collaboration partner, to successfully commercialize tenapanor, if approved for marketing and sale by the FDA or foreign regulatory authorities, including our ability to educate physicians and patients about the benefits, administration and use of tenapanor.

- As a result of the COVID-19 pandemic, we may also experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- While our Phase 3 clinical development of tenapanor for the control of serum phosphorus in CKD patients on dialysis is complete, we have ongoing and planned clinical trials for tenapanor and an ongoing Phase 2 clinical trial for RDX013, any of which may be delayed as a result the COVID-19 outbreak. Other potential impacts of the COVID-19 pandemic on our various clinical trials include delays or difficulties in any planned clinical site initiation, including difficulties in obtaining Institutional Review Board approvals, recruiting clinical site investigators and clinical site staff, delays or difficulties in enrolling patients, interruption of planned key clinical trial activities, such as clinical trial site data monitoring due to diversion of resources at clinical sites or limitation on travel imposed by federal or state governments.

- We have limited the use of our offices to essential employees and requested that most of our personnel, including all of our administrative employees, work remotely. We have restricted on-site staff to only those personnel and contractors who must perform essential activities that must be completed on-site and limited the number of staff in our research laboratories. The COVID-19 pandemic could disrupt our ability to secure supplies for our facilities and to provide personal protective equipment for our employees. The safety, health and well-being of our workforce is of primary concern and we may need to enact further precautionary measures to help minimize the risk of our employees being exposed to the novel coronavirus.

- Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber-security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and important agencies and contractors.

- The FDA and comparable foreign regulatory agencies may experience operational interruptions or delays, which may impact timelines for regulatory submission, trial initiation and regulatory approval.

The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business, manufacturing, preclinical development activities, preclinical studies and planned clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of COVID-19, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

We may consider strategic transactions, such as acquisitions of companies, asset purchases, and/or in-licensing of products, product candidates or technologies. In addition, if we are unable to access capital on a timely basis and on terms that are acceptable to us, we may be forced to restructure certain aspects of our business or identify and complete one or more strategic collaborations or other transactions in order to fund the development or commercialization of tenapanor and/or the development of RDX013 or certain of our other product candidates through the use of alternative structures. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, spin outs, collaboration partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- up-front, milestone and royalty payments, equity investments and financial support of new research and development candidates including increase of personnel, all of which may be substantial;
- exposure to unknown liabilities;
- disruption of our business and diversion of our management’s time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities;
- higher-than-expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and could have a material adverse effect on our business, results of operations, financial condition and prospects.

If we seek and obtain approval to commercialize our product candidates outside of the United States, manufacture our product candidates outside of the United States, or otherwise engage in business outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

We or our collaboration partners may decide to seek marketing approval for certain of our product candidates outside the United States or otherwise engage in business outside the United States, including entering into contractual agreements with third-parties. We currently utilize contract manufacturing organizations located outside of the United States to manufacture our active drug substance for tenapanor. We are subject to additional risks related to entering these international business markets and relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing United States and foreign drug import and export rules;
- reduced protection for intellectual property rights in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems, and different competitive drugs;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- 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;
- potential liability resulting from development work conducted by these distributors; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

Our business involves the use of hazardous materials and we and third-parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and manufacturers and suppliers with whom we may contract 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. We cannot guarantee that the safety procedures utilized by third-party manufacturers and suppliers with whom we may contract will comply with the standards prescribed by laws and regulations or will eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could

exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

We may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

We have dual headquarters and one of our facilities is located in the San Francisco Bay Area, which in the past has experienced severe earthquakes. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our California facility, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Risks Related to Government Regulation

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor any of our collaboration partners is permitted to market any drug product in the United States until we receive marketing approval from the FDA. Obtaining regulatory approval of a NDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable United States and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

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

Prior to obtaining approval to commercialize a drug candidate in the United States or abroad, we or our collaboration partners must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or other foreign regulatory agencies, that such drug candidates are safe and effective for their intended uses. The number of nonclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our drug candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering drug candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory authorities denying approval of a drug candidate for any or all targeted indications.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical studies and depends upon numerous factors. The FDA and comparable foreign authorities have substantial discretion in the approval process and we may encounter matters with the FDA or such comparable authorities that requires us to expend additional time and resources and delay or prevent the approval of our product candidates. For example, the FDA may require us to conduct additional studies for a drug product either prior to or post-approval, such as additional drug-drug interaction studies or safety or efficacy studies, or it may object to elements of our clinical development program such as the number of subjects in our current clinical trials from the United States. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or result in a decision not to approve an application for regulatory approval. Despite the time and expense exerted, failure can occur at any stage.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

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

This lengthy approval process, as well as the unpredictability of the results of clinical studies, may result in our failure and/or that of our collaboration partners to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. Additionally, if the FDA requires that we conduct additional clinical studies, places limitations in our label, delays approval to market our product candidates or limits the use of our products, our business and results of operations may be harmed.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if we receive regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, any product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Even if a drug is approved by the FDA or foreign regulatory authorities, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP regulations for any clinical trials that we conduct post-approval. As such, we and our third-party contract manufacturers will be subject to continual review and periodic inspections to assess compliance with regulatory requirements. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. Regulatory authorities may also impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing studies. Furthermore, any new legislation addressing drug safety issues could result in delays or increased costs to assure compliance.

We will also be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have FDA approval.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- warning or untitled letters, fines or holds on clinical trials;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- injunctions or the imposition of civil or criminal penalties;
- suspension or revocation of existing regulatory approvals;
- suspension of any of our ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications submitted by us;
- restrictions on our or our contract manufacturers' operations; or
- product seizure or detention, or refusal to permit the import or export of products.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

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

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, the results of the 2020 President election may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these Executive Orders will be implemented, or whether they will be rescinded or replaced under a Biden Administration. The policies and priorities of an incoming administration are unknown, and could materially impact the regulatory framework governing our products.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

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

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

Separately, in response to the global COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.

All entities involved in the preparation of product candidates for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP regulations. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA or comparable regulatory filing on a timely basis and must adhere to cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection programs. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent suspension of production or closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product, withdrawal of an approval, or suspension of production. As a result, our business, financial condition, and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA, a supplemental NDA or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical studies, regulatory submissions, required approvals, or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

If we fail to comply or are found to have failed to comply with FDA and other regulations related to the promotion of our products for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other government agencies. If tenapanor or our other product candidates receive marketing

approval, we and our collaboration partners, if any, will be restricted from marketing the product outside of its approved labeling, also referred to as off-label promotion. However, physicians may nevertheless prescribe an approved product to their patients in a manner that is inconsistent with the approved label, which is an off-label use. We are implementing compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations regarding off-label promotion. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of our product candidates for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

Over the past several years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the FFDCA, the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "qui tam" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a qui tam suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

Tenapanor, which has been approved by the FDA for the treatment of IBS-C in adults, and/or RDX013, and our other product candidates, if approved, may cause or contribute to adverse medical events that we are required to report to regulatory agencies and if we fail to do so we could be subject to sanctions that would materially harm our business.

Some participants in clinical studies of tenapanor have reported adverse effects after being treated with tenapanor, including diarrhea, nausea, flatulence, abdominal discomfort, abdominal pain, abdominal distention and changes in electrolytes. If we are successful in commercializing any products, FDA and foreign regulatory agency regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or a foreign regulatory agency could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

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

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, collaboration partners, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate any of the following:

FDA regulations, including those laws that require the reporting of true, complete and accurate financial and other information to the FDA; manufacturing standards; or federal and state healthcare fraud and abuse laws and regulations. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These activities also include the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

In order to market any product in the EEA (which is composed of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein), and many other foreign jurisdictions, separate regulatory approvals are required. In the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization ("MA"). Before the MA is granted, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

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

We and our collaboration partners may be subject to healthcare laws, regulation and enforcement; our failure or the failure of any such collaboration partners to comply with these laws could have a material adverse effect on our results of operations and financial conditions.

Although we do not currently have any products on the market, once we begin commercializing our products, we and our collaboration partners may be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate as a commercial organization include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;

- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;

- the federal physician sunshine requirements under the ACA, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to CMS information related to payments and other transfers of value to physicians, certain other healthcare providers beginning in 2022, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers;

- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;

- state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or pricing information and marketing expenditures; and

- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to market our products and adversely impact our financial results.

Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates and to produce, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways

that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recall, replacement, or discontinuance of one or more of our products; and
- additional record keeping.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition and results of operations.

In addition, the full impact of recent healthcare reform and other changes in the healthcare industry and in healthcare spending is currently unknown, and may adversely affect our business model. In the United States, the ACA was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. By way of example, the Tax Cuts and Jobs Act of 2017 included a provision repealing, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal, or replace the ACA will impact the ACA or our business. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability, and the level of taxes that we are required to pay.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These new laws, among other things, included aggregate reductions of Medicare payments of 2% per fiscal year to providers that will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional action is taken by Congress, additional specific reductions in Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, individual states have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and to encourage importation from other countries and bulk purchasing. Recently, there has also been heightened governmental

scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

Risks Related to Intellectual Property

We may become subject to claims alleging infringement of third parties' patents or proprietary rights and/or claims seeking to invalidate our patents, which would be costly, time consuming and, if successfully asserted against us, delay or prevent the development and commercialization of tenapanor or our other product candidates, or prevent or delay the continued use of our drug discovery and development platform, including APECCS.

There have been many lawsuits and other proceedings asserting infringement or misappropriation of patents and other intellectual property rights in the pharmaceutical and biotechnology industries. There can be no assurances that we will not be subject to claims alleging that the manufacture, use or sale of tenapanor or any other product candidates, or that the use of our drug discovery and development platform, including APECCS, infringes existing or future third-party patents, or that such claims, if any, will not be successful. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of tenapanor or other product candidates or by the use of APECCS. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. We may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of tenapanor or our other product candidates, or by the use of APECCS.

We may be subject to third-party patent infringement claims in the future against us or our that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third party's patents. We may be required to indemnify future collaboration partners against such claims. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If a patent infringement suit were brought against us we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. In addition, if a patent infringement suit were brought against us regarding the use of aspects of our drug discovery and development platform, we could be forced to stop our use of APECCS or of other aspects of our platform, or we could be forced to modify our processes to avoid infringement, which may not be possible at a reasonable cost, if at all, and which could result in substantial delay in our use of our platform for the discovery of new product candidates or potential targets. As a result of patent infringement claims, or in order to avoid potential claims, we may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, we may be unable to maintain such licenses and the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to redesign it, or to cease our use of APECCS or some other aspect of our drug discovery and development platform or our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms, or unable to maintain such licenses when granted. Even if we are successful in defending against such claims, such litigation can be expensive and time consuming to litigate and would divert management's attention from our core business. Any of these events could harm our business significantly.

In addition to infringement claims against us, if third parties prepare and file patent applications in the United States that also claim technology similar or identical to ours, we may have to participate in interference or derivation proceedings in the United States Patent and Trademark Office (the "USPTO") to determine which party is entitled to a patent on the disputed invention. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates.

If our intellectual property related to our product candidates is not adequate or if we are not able to protect our trade secrets or our confidential information, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates, our drug discovery and development platform and our development programs. Any disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

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 license may fail to result in issued patents in the United States or in foreign countries. Additionally, our research and development efforts may result in product candidates for which patent protection is limited or not available. Even if patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. For example, U.S. patents can be challenged by any person before the new USPTO Patent Trial and Appeals Board at any time before one year after that person is served an infringement complaint based on the patents. Patents granted by the European Patent Office may be similarly opposed by any person within nine months from the publication of the grant. Similar proceedings are available in other jurisdictions, and in the United States, Europe and other jurisdictions third parties can raise questions of validity with a patent office even before a patent has granted. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. For example, a third party may develop a competitive product that provides therapeutic benefits similar to one or more of our product candidates but has a sufficiently different composition to fall outside the scope of our patent protection. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is successfully challenged, then our ability to commercialize such product candidates could be negatively affected, and we may face unexpected competition that could have a material adverse impact on our business. Further, if we encounter delays in our clinical trials, the period of time during which we or our collaboration partners could market tenapanor or other product candidates under patent protection would be reduced.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering the product candidate, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including 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. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability against our intellectual property related to a product candidate, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business. Moreover, our competitors could counterclaim that we infringe their intellectual property, and some of our competitors have substantially greater intellectual property portfolios than we do.

We also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain and/or enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, to assign their inventions to us, and endeavor to execute confidentiality agreements with all such parties, we cannot be certain that we have executed such agreements with all parties who may have helped to develop our intellectual property or who had access to our proprietary information, nor can we be certain that our agreements will not be breached by such consultants, advisors or third parties, or by our former employees. The breach of such agreements by individuals or entities who are actively involved in the discovery and design of our potential drug candidates, or in the development of our discovery and design platform, including APECCS, could require us to

pursue legal action to protect our trade secrets and confidential information, which would be expensive, and the outcome of which would be unpredictable. If we are not successful in prohibiting the continued breach of such agreements, our business could be negatively impacted. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be materially harmed.

Following the approval by the FDA for our NDA to market tenapanor for IBS-C, we became eligible to seek and sought patent term restoration under the Hatch-Waxman Act for one of the U.S. patents covering our approved product or the use thereof. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Despite seeking patent term extension for tenapanor or other product candidates, we may not be granted patent term extension either in the United States or in any foreign country 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 term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority 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, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

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

The USPTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions to maintain patent applications and issued patents. Noncompliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain

similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our technology.

We may be subject to claims that we or our employees have misappropriated the intellectual property, including know-how or trade secrets, of a third party, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants and contractors were previously employed at or engaged by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and contractors do not use the intellectual property and other proprietary information or know-how or trade secrets of others in their work for us, and do not perform work for us that is in conflict with their obligations to another employer or any other entity, we may be subject to claims that we or these employees, consultants and contractors have used or disclosed such intellectual property, including know-how, trade secrets or other proprietary information. In addition, an employee, advisor or consultant who performs work for us may have obligations to a third party that are in conflict with their obligations to us, and as a result such third party may claim an ownership interest in the intellectual property arising out of work performed for us. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, or access to consultants and contractors. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants 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 develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Risks Related to Our Common Stock

Our stock price may be volatile and our stockholders may not be able to resell shares of our common stock at or above the price they paid.

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this “Risk Factors” section and others such as:

- announcements of regulatory decisions regarding our NDA seeking marketing approval for tenapanor for the control of serum phosphorus in CKD patients on dialysis;
- results of regulatory inspections of our facilities or those of our contract manufacturing organizations, or specific label restrictions or patient populations for tenapanor’s use, or changes or delays in the regulatory review process;
- announcements regarding whether tenapanor, alone or with other oral only medications, will be included in the bundled prospective payment system for the treatment of ESRD patients, and the time and manner in which such transition is achieved;
- results from, or any delays in, our RDX013 Phase 2 clinical trial;
- announcements relating to our current or future collaboration partnerships;

- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our product label, our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our approved products or our product candidates;
- the success of our testing and clinical trials;
- failure to meet any of our projected timelines or goals with regard to the clinical development and commercialization of any of our product candidates;
- the success of our efforts to acquire or license or discover additional product candidates;
- any intellectual property infringement actions in which we may become involved;
- the success of our efforts to obtain adequate intellectual property protection for our product candidates;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry or other healthcare reform measures in the United States;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of our common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future;
- sales of debt securities and sales or licensing of assets;
- general economic and market conditions and overall fluctuations in the United States equity markets; and
- the loss of any of our key scientific or management personnel.

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

Our principal stockholders own a significant percentage of our stock and, together with our management, will be able to exert significant control over matters subject to stockholder approval.

Based on the number of shares outstanding as of December 31, 2020, our officers, directors and stockholders who hold at least 5% of our stock together beneficially own approximately 43.1% of our outstanding common stock. If these officers, directors, and principal stockholders or a group of our principal stockholders act together, they will be able to exert a significant degree of influence over our management and affairs and control matters requiring stockholder approval, including the election of directors, amendments to our organizational documents, and approval of any merger, sale of assets or other business combination transactions. The interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. For instance, officers, directors and principal stockholders, acting together, could cause us to enter into transactions or agreements that we would not otherwise consider. Similarly, this concentration of ownership may have the effect of delaying or preventing a change in control of our company otherwise favored by our other stockholders.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of December 31, 2020, we had approximately 93.6 million shares of common stock outstanding. Of those shares, approximately 37.8 million were held by current directors, executive officers and stockholders owning 5% or more of our outstanding common stock.

As of December 31, 2020, 0.2 million shares of common stock issuable upon vesting of outstanding restricted stock units and approximately 9.8 million shares of common stock issuable upon exercise of outstanding options were eligible for sale in the public market to the extent permitted by the provisions of the applicable vesting schedules, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are issued and sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

General Risk Factors

We incur significant costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and regulations regarding corporate governance practices. The listing requirements of The Nasdaq Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure

associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002 ("Section 404") and the related rules of the Securities and Exchange Commission ("SEC") which require, among other things, our management to report on the effectiveness of our internal control over financial reporting. Our compliance with Section 404 requires that we incur substantial expense and expend significant management efforts.

During the course of our review and testing of our internal controls, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Market or other adverse consequences that would materially harm our business.

We may be adversely affected by the global economic environment.

Our ability to attract and retain collaboration partners or customers, invest in and grow our business and meet our financial obligations depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the United States, presidential elections, other political influences and inflationary pressures. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The 2008 global financial crisis caused extreme volatility and disruptions in the capital and credit markets. We cannot anticipate all the ways in which the global economic climate and global financial market conditions could adversely impact our business in the future.

We are exposed to risks associated with reduced profitability and the potential financial instability of our collaboration partners or customers, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, our collaboration partners or customers may experience reductions in revenues, profitability and/or cash flow that could lead them to reduce their support of our programs or financing activities. If collaboration partners or customers are not successful in generating sufficient revenue or are precluded from securing financing, they may not be able to pay, or may delay payment of, accounts receivable that are owed to us. In addition, volatility in the financial markets could cause significant fluctuations in the interest rate and currency markets. We currently do not hedge for these risks. The foregoing events, in turn, could adversely affect our financial condition and liquidity. In addition, if economic challenges in the United States result in widespread and prolonged unemployment, either regionally or on a national basis, or if certain provisions of the Patient Protection and ACA, as amended by the Health Care and Education Reconciliation Act, collectively known as the ACA, are repealed, a substantial number of people may become uninsured or underinsured. To the extent economic challenges result in fewer individuals pursuing or being able to afford our product candidates once commercialized, our business, results of operations, financial condition and cash flows could be adversely affected.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquirer or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least two-thirds of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

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

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

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.

- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

We do not currently intend to pay dividends on our common stock, and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Additionally, the terms of our loan and security agreements could restrict our ability to pay dividends. Therefore, our stockholders are not likely to receive any dividends on our common stock for the foreseeable future. Since we do not intend to pay dividends, our stockholders' ability to receive a return on their investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

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

Following a national referendum and enactment of legislation by the government of the United Kingdom, the United Kingdom formally withdrew from the European Union and ratified a trade and cooperation agreement governing its future relationship with the European Union. The agreement, which is being applied provisionally from January 1, 2021 until it is ratified by the European Parliament and the Council of the European Union, addresses trade, economic arrangements, law enforcement, judicial cooperation and a governance framework including procedures for dispute resolution, among other things. Because the agreement merely sets forth a framework in many respects and will require complex additional

bilateral negotiations between the United Kingdom and the European Union as both parties continue to work on the rules for implementation, significant political and economic uncertainty remains about how the precise terms of the relationship between the parties will differ from the terms before withdrawal.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our headquarters is currently co-located in Fremont, California and Waltham, Massachusetts. The Fremont headquarters consists of 72,500 square feet of leased office and laboratory space under a lease that expires in September 2021. During December 2020, we entered into a new lease agreement that currently expires in June 2026 for 12,864 square feet of office space in Waltham, Massachusetts which will serve as our east coast headquarters. In addition, we lease 3,520 square feet of additional office space at a different location in Waltham, Massachusetts, under a lease that currently expires in September 2021, as well as 4,768 square feet of office space in Milwaukee, Wisconsin, under a lease that expires in February 2026. We have not renewed the lease at our current Fremont headquarters location and expect to enter into a new facility lease in Fremont, California during the first quarter of 2021.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. We believe that as of December 31, 2020, there is no litigation pending that would reasonably be expected to have a material adverse effect on our results of operations and financial condition, and no contingent liabilities were accrued as of December 31, 2020.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Common Stock

On June 19, 2014, our common stock commenced trading on The Nasdaq Global Market under the symbol "ARDX". Prior to that date, there was no public trading market for our common stock. As of December 31, 2020, there were 33 holders of record of our common stock.

Dividends

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the growth and development of our business.

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Not applicable.

Issuer Purchases of Equity Securities

Not applicable.

ITEM 6. SELECTED FINANCIAL DATA

The data set forth below is not necessarily indicative of the results of future operations and should be read in conjunction with the financial statements and the notes thereto in Item 8 of Part II, "Financial Statements and Supplementary Data," and the information contained in Item 7 of Part II, "Management's Discussion and Analysis of Financial Condition and Results of Operations." Historical results are not necessarily indicative of future results.

	Year Ended December 31,				
Statement of Operations Data:	**2020**	**2019**	**2018**	**2017**	**2016**
	(in thousands, except share and per share amounts)				
Revenues:					
Collaborative development revenue	$ 5,364	$ 459	$ —	$ 42,000	$ —
Product supply revenue	1,501	322	287	—	—
Licensing revenue	706	4,500	2,320	—	—
Total revenues	7,571	5,281	2,607	42,000	—
Operating expenses:					
Cost of revenue	145	600	466	8,400	—
Research and development	65,053	71,677	69,373	75,484	94,161
General and administrative	33,153	24,267	23,715	23,231	18,734
Total operating expenses	98,351	96,544	93,554	107,115	112,895
Loss from operations	(90,780)	(91,263)	(90,947)	(65,115)	(112,895)
Interest expense	(5,099)	(5,726)	(3,534)	—	—
Other income, net	1,568	2,352	3,187	1,955	508
Loss before provision for income taxes	(94,311)	(94,637)	(91,294)	(63,160)	(112,387)
Provision for income taxes	2	303	4	1,179	—
Net loss	$ (94,313)	$ (94,940)	$ (91,298)	$ (64,339)	$ (112,387)
Net loss per common share, basic and diluted	$ (1.05)	$ (1.47)	$ (1.62)	$ (1.36)	$ (2.80)
Shares used in computing net loss per share - basic and diluted	89,582,138	64,478,066	56,219,919	47,435,331	40,118,522

	As of December 31,				
Balance Sheet Data:	**2020**	**2019**	**2018**	**2017**	**2016**
			(in thousands)		
Cash and investments	$ 188,598	$ 247,512	$ 168,089	$ 133,976	$ 200,823
Total assets	201,562	259,782	183,332	157,903	213,131
Loan payable, current and non-current	50,788	50,014	49,209	—	—
Accumulated deficit	(554,765)	(460,452)	(365,512)	(278,214)	(213,875)
Total stockholders' equity	126,112	186,655	115,813	139,312	193,151

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the section of this report entitled "Selected Financial Data" and our financial statements and related notes included elsewhere in this report. This discussion and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "Risk Factors. " These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason. Unless the context requires otherwise, the terms "Ardelyx", "Company", "we", "us", and "our" refer to Ardelyx, Inc.

OVERVIEW

We are a specialized biopharmaceutical company focused on developing first-in-class medicines to improve treatment for people with kidney and cardiorenal diseases. This includes patients with chronic kidney disease ("CKD") on dialysis suffering from elevated serum phosphorus, or hyperphosphatemia; and CKD patients and/or heart failure patients with elevated serum potassium, or hyperkalemia. Our lead product candidate, tenapanor, is a first-in-class medicine for which we submitted a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") in June 2020 for the control of serum phosphorus in adult patients with CKD on dialysis. In September 2020 the FDA accepted the filing of our NDA and set a Prescription Drug User Fee Act ("PDUFA") date of April 29, 2021. Tenapanor has a unique mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3, or NHE3. This results in the tightening of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption.

OUR PRODUCT PIPELINE

Tenapanor: A New Approach for The Control of Serum Phosphorus in CKD Patients on Dialysis

Our portfolio is led by the development of tenapanor, a first-in-class medicine for the control of serum phosphorus in adult patients with CKD on dialysis. Tenapanor for the control of serum phosphorus has a unique mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3 ("NHE3"). This results in the tightening of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption. In September 2020 we announced that the FDA accepted the filing of our NDA for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis. The acceptance of our NDA represents the next critical step toward bringing to market a completely new approach to the management of hyperphosphatemia. The FDA has set a PDUFA date of April 29, 2021. We continue to advance our commercial preparations for the launch of tenapanor. The NDA is supported by three successful Phase 3 trials involving over 1,000 patients that evaluated the use of tenapanor for the control of serum phosphorus in CKD patients on dialysis, with two trials evaluating tenapanor as monotherapy and one trial evaluating tenapanor as part of a dual mechanism approach with binders.

We have established agreements with Kyowa Kirin Co., Ltd. ("KKC") in Japan, Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. ("Fosun Pharma") in China and Knight Therapeutics, Inc. ("Knight") in Canada for the development and commercialization of tenapanor for certain indications in their respective territories.

In December 2019, we reported statistically significant topline efficacy results from our second monotherapy Phase 3 clinical trial, the PHREEDOM trial, which evaluated tenapanor for the control of serum phosphorus in CKD patients on dialysis. The PHREEDOM trial followed a successful monotherapy Phase 3 clinical trial completed in 2017, the BLOCK trial, which achieved statistical significance for the primary endpoint. The only adverse event reported in these Phase 3 trials in less than 5% of patients was diarrhea, with an incidence rate of 52% in the PHREEDOM trial and 39% in the BLOCK trial, with most incidences in each trial being mild to moderate in nature. PHREEDOM is a one-year study with a 26-week open-label treatment period and a 12-week double-blind, placebo-controlled randomized withdrawal period

followed by a 14-week open-label safety extension period. An active safety control group, for safety analysis only, received sevelamer, open-label, for the entire 52-week study period. Patients completing the PHREEDOM trial from both the tenapanor arm and the sevelamer active safety control arm had the option to participate in NORMALIZE, an ongoing open-label 18-month extension study.

In June 2020, we announced positive results from a planned interim data analysis from our ongoing NORMALIZE extension study evaluating tenapanor, as monotherapy or in combination with sevelamer, to achieve serum phosphorus levels in the normal range (2.5 – 4.5 mg/dL) in patients with CKD on dialysis. The NORMALIZE extension study allowed patients from our PHREEDOM study to continue therapy with tenapanor and enabled those patients in the PHREEDOM safety control arm receiving sevelamer carbonate to transition to tenapanor. The data from the planned interim analysis demonstrated that the foundational use of tenapanor as monotherapy or in combination with sevelamer carbonate produces a significant phosphorus-lowering effect with a mean serum phosphorous reduction of 2. 33 mg/dL, from a mean baseline phosphorus of 7. 27 mg/dL at the beginning of the PHREEDOM trial to a mean of 4. 94 mg/dL at the time of this analysis. Of the 171 patients in this interim analysis who completed up to 9 months of treatment in this extension study, up to 47. 4% achieved a normal serum phosphorus level, and of those, the majority were on tenapanor alone or tenapanor with low dose sevelamer of three or fewer sevelamer tablets per day. These data represent a 58% improvement in the rate of patients who achieve a normal serum phosphorus level, as compared to current treatment practice data as reported in the April 2020 Dialysis Outcomes Practice Patterns Study (“DOPPS”) Practice Monitor. The DOPPS data demonstrate that, with currently available treatments, only 30% of patients have serum phosphorous levels less than 4.6 mg/dL. The only adverse event reported in greater than 5% of patients in NORMALIZE was diarrhea, with an incidence rate of 23.3%.

In September 2019, we reported positive results from the AMPLIFY trial, a Phase 3 study evaluating tenapanor in patients with CKD on dialysis who had uncontrolled hyperphosphatemia despite phosphate binder treatment. In this trial, approximately twice the number of patients achieved the serum phosphorus treatment goal of less than 5.5 mg/dL with tenapanor and phosphate binders versus phosphate binders alone. The only adverse event with a placebo-adjusted rate greater than 3% was diarrhea, with an incidence rate of 43%, with most being mild to moderate in nature.

In June 2020, our partner Kyowa Kirin Co., Ltd., a Japan-based global specialty pharmaceutical company exclusively developing tenapanor in Japan, presented results from a Phase 2 trial of tenapanor at the European Renal Association-European Dialysis and Transplant Association annual meeting (“ERA-EDTA 2020”). The trial was designed to evaluate if, with tenapanor, patients with hyperphosphatemia undergoing hemodialysis could achieve at least a 30% decrease in mean pill burden while maintaining their serum phosphorus level. The study results were statistically significant, with 71.6% ($p<0.001$) of patients achieving at least a 30% reduction in mean pill burden. The overall mean reduction in phosphate binder usage was 80% (reduction from 14.7 to 3.0 pills per day), while maintaining serum phosphorus control. The mean phosphorus level of patients entering the study on treatment with binders was 5.2 mg/dL at baseline and 4.7 mg/dL at the end of the 26-week study.

Tenapanor, if approved, would be the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake. It is not a phosphate binder. Tenapanor is a novel, potent, small molecule, that has been shown in phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach.

IBSRELA® (tenapanor) for Irritable Bowel Syndrome with Constipation (IBS-C)

In addition to the development of tenapanor for hyperphosphatemia, we have developed tenapanor for the treatment of patients with irritable bowel syndrome with constipation (“IBS-C”). In September 2019, we received FDA approval of IBSRELA® (tenapanor) for the treatment of IBS-C in adults. IBS-C is a burdensome gastrointestinal (“GI”) disorder. It is characterized by significant abdominal pain, constipation, straining during bowel movements, bloating and/or gas.

RDX013 Program: Small Molecule for Treating Hyperkalemia

We are also advancing a small molecule potassium secretagogue program, RDX013, for the potential treatment of hyperkalemia. Hyperkalemia is a common problem in patients with heart and kidney disease, particularly in patients taking common blood pressure medications known as renin-angiotensin-aldosterone system (“RAAS”) inhibitors. Similar to what we have done with tenapanor in developing a non-binder approach for the treatment of elevated serum phosphate levels,

RDX013 is designed to target the underlying biological mechanisms of potassium secretion to lower elevated potassium. While currently available therapies are all ion exchange agents, RDX013 is a first in class approach that exerts its effects by amplifying the underlying pathways of potassium secretion in the colon.

Since commencing operations in October 2007, substantially all our efforts have been dedicated to our research and development ("R&D") activities, including developing our clinical product candidate tenapanor and developing our proprietary drug discovery and design platform. We have not generated any revenues from product sales. As of December 31, 2020, we had an accumulated deficit of $554.8 million.

We expect to continue to incur substantial operating losses for the foreseeable future as a result of costs associated with the following activities: our continued development of tenapanor for the control of serum phosphorus in CKD patients on dialysis; our preparations for, and if approved, the commercialization of tenapanor in the United States for the control of serum phosphorus in CKD patients on dialysis, including significantly increased personnel costs associated with our commercial team; the performance of certain activities required as a result of our NDA approval of tenapanor for IBS-C; the continued development of RDX013 and the advancement of our research programs into the preclinical stage. To date, we have funded our operations from the sale and issuance of common stock and convertible preferred stock, funds from our collaboration partnerships, which includes license fees, milestones and product supply revenue, as well as funds from our Loan Agreement with Solar Capital Ltd. and Western Alliance Bank.

RDX020 Program: Small molecule for Treating Metabolic Acidosis

We have an ongoing discovery program targeting the inhibition of bicarbonate exchange inhibitor for the treatment of metabolic acidosis, a highly prevalent comorbidity in CKD patients that is strongly correlated with disease progression and adverse outcomes. We have identified lead compounds that are potent, selective and proprietary inhibitors of bicarbonate secretion.

FINANCIAL OPERATIONS OVERVIEW

Revenue

Our revenue to date has been generated primarily through license, research and development collaborative agreements with various collaboration partners. We have not generated any revenue from commercial product sales. In the future, we may generate revenue from a combination of our own product sales, if regulatory approval is received, and payments in connection with our current or future collaborative partnerships, including license fees, other upfront payments, milestone payments, royalties and payments for drug product and/or drug substance. We expect that any revenue we generate will fluctuate in future periods as a result of, among other factors: whether we receive regulatory approval for tenapanor for the control of serum phosphorus in CDK patients on dialysis, and if such approval is received, the timing of such approval and the extent to which we are successful in our efforts to commercialize tenapanor for such indication; the timing and progress of goods and services provided pursuant to our current or future collaborative partnerships; our or our collaborators' achievement of preclinical, clinical, regulatory or commercialization milestones, to the extent achieved; the timing and amount of any payments to us relating to the aforementioned milestones; and the extent to which any of our product candidates are approved and successfully commercialized by a collaboration partner. If we, our current collaboration partners or any future collaboration partners fail to obtain regulatory approval for tenapanor, our ability to generate future revenue from our product sales or from our collaborative arrangements, and our results of operations and financial position, would be materially and adversely affected. Our past revenue performance is not necessarily indicative of results to be expected in future periods. See Note 2, Summary of Significant Accounting Policies, in the notes to our financial statements, included in Part II, Item 8, of this Annual Report on Form 10-K, for further details.

Cost of Revenue

Cost of revenue currently represents payments due to AstraZeneca, which under the terms of a termination agreement entered into in 2015 is entitled to (i) future royalties at a rate of 10% of net sales of tenapanor or other NHE3 products by us or our licensees, and (ii) 20% of non-royalty revenue received from our collaboration partners to which we provide

rights to develop and commercialize tenapanor or certain other NHE3 inhibitors. We have agreed to pay AstraZeneca up to a maximum of $75.0 million in the aggregate for (i) and (ii). We recognize these expenses as cost of revenue when we recognize the corresponding revenue that gives rise to payments due to AstraZeneca. To date, we recognized an aggregate of $10.6 million as cost of revenue under the AZ Termination Agreement since 2017. See details in Note 12, Collaboration and Licensing Agreements, under AstraZeneca, in the notes to our financial statements, included in Part II, Item 8, of this Annual Report on Form 10-K.

Research and Development

We recognize all research and development expenses as they are incurred to support the discovery, research, development and manufacturing of our product candidates. Research and development expenses include, but are not limited to, the following:

- external research and development expenses incurred under agreements with consultants, third-party contract research organizations (“CROs”) and investigative sites where a substantial portion of our clinical studies are conducted, and with contract manufacturing organizations where our clinical supplies are produced;
- expenses associated with supplies and materials consumed in connection with our research operations;
- expenses associated with producing tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis prior to FDA approval;
- other costs associated with research, clinical development and regulatory activities; and
- employee-related expenses, which include salaries, bonuses, benefits, travel and stock-based compensation;
- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization expense, information technology expense and other supplies.

We expect to continue to make substantial investments in research and development activities as we further progress the development of tenapanor, RDX013 and our other product candidates as we advance our research programs into the preclinical stage and as we continue our early stage research. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time-consuming. We may not succeed in achieving marketing approval for our product candidates, including tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis. The probability of success of each of the product candidates may be affected by numerous factors, including preclinical data, clinical data, the regulatory process, market acceptance, sufficient third-party coverage or reimbursement, our ability to access capital on acceptable terms, competition, manufacturing capability and commercial viability.

We anticipate that we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, ongoing assessment as to each product candidate’s commercial potential, and our ability to access capital on acceptable terms. We will need to raise additional capital to complete the development and commercialization of tenapanor. If we are unable to access capital on a timely basis and on terms that are acceptable to us, we may be forced to restructure certain aspects of our business or identify and complete one or more strategic collaborations or other transactions in order to fund the development or commercialization of tenapanor, the development of RDX013 or certain of our product candidates through the use of alternative structures.

General and Administrative

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, for certain of our executives, our board members, and our finance, legal, business development, market development, commercial and support staff. Other general and administrative expenses include facility related costs and

professional fees for legal, accounting and audit, investor relations, other consulting services and allocated facility related costs not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future primarily because of increased pre-commercial and commercial activities, personnel costs and professional fees for services to support the potential launch and commercialization of tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis.

Interest Expense

Interest expense represents the interest paid on our loan payable.

Other Income, net

Other income, net consists of interest income earned on our cash and cash equivalents and held-to-maturity investments, the periodic revaluation of the exit fee related to our loan and currency exchange gains and losses.

Provision for Income Taxes

Our provision for income taxes includes current and deferred tax, including foreign withholding taxes paid on payments received from certain collaboration partners. Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Our deferred tax assets continue to be fully offset by a valuation allowance, including deferred tax assets related to our net operating loss carryforwards, which may be subject to annual limitations as a result of ownership changes that may have occurred or could occur in the future.

CRITICAL ACCOUNTING POLICES AND ESTIMATES

A detailed discussion of our significant accounting policies can be found in Note 2, Summary of Significant Accounting Policies, in the notes to our financial statements, included in Part II, Item 8, of this Annual Report on Form 10-K. Critical accounting policies are those that require significant judgment and/or estimates by management at the time that financial statements are prepared such that materially different results might have been reported if other assumptions had been made. These estimates form the basis for making judgments about the carrying values of assets and liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates.

We consider certain accounting policies related to revenue recognition, accrued research and development expenses and stock-based compensation to be critical policies to understanding the judgments and estimates applied in our reported financial results.

Revenue Recognition

We generate revenue primarily from research and collaboration and license agreements with customers. Goods and services in the agreements may include the grant of licenses for the use of our technology, the provision of services associated with the research and development of product candidates, manufacturing services, and participation in joint steering committees. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, up-front license fees; research, development, regulatory and commercial milestone payments; reimbursement of research and development services; option payments; reimbursement of certain costs; payments for manufacturing supply services; and future royalties on net sales of licensed products.

When two or more contracts are entered into with the same customer at or near the same time, we evaluate the contracts to determine whether the contracts should be accounted for as a single arrangement. Contracts are combined and accounted for as a single arrangement if one or more of the following criteria are met: (i) the contracts are negotiated as a package

with a single commercial objective; (ii) the amount of consideration to be paid in one contract depends on the price or performance of the other contract; or (iii) the goods or services promised in the contracts (or some goods or services promised in each of the contracts) are a single performance obligation.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of our agreements, management performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including any constraints on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. As part of the accounting for contracts with customers, we develop assumptions that require judgment to determine whether promised goods and services represent distinct performance obligations and the standalone selling price for each performance obligation identified in the contract. This evaluation is subjective and requires us to make judgments about the promised goods and services and whether those goods and services are separable from other aspects of the contract. Further, determining the standalone selling price for performance obligations requires significant judgment, and when an observable price of a promised good or service is not readily available, we consider relevant assumptions to estimate the standalone selling price, including, as applicable, market conditions, development timelines, probabilities of technical and regulatory success, reimbursement rates for personnel costs, forecasted revenues, potential limitations to the selling price of the product and discount rates.

We apply judgment in determining whether a combined performance obligation is satisfied at a point in time or over time, and, if over time, concluding upon the appropriate method of measuring progress to be applied for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, as estimates related to the measure of progress change, related revenue recognition is adjusted accordingly. Changes in our estimated measure of progress are accounted for prospectively as a change in accounting estimate. We recognize collaboration revenue by measuring the progress toward complete satisfaction of the performance obligation using an input measure. In order to recognize revenue over the research and development period, we measure actual costs incurred to date compared to the overall total expected costs to satisfy the performance obligation. Revenues are recognized as the program costs are incurred. We will re-evaluate the estimate of expected costs to satisfy the performance obligation each reporting period and make adjustments for any significant changes. Amounts received prior to satisfying the revenue recognition criteria are recorded as contract liabilities in our balance sheets. If the related performance obligation is expected to be satisfied within the next twelve months, this will be classified in current liabilities. Amounts recognized as revenue prior to receipt are recorded as contract assets in our balance sheets. If we expect to have an unconditional right to receive the consideration in the next twelve months, this will be classified in current assets. A net contract asset or liability is presented for each contract with a customer.

Milestone Payments: At the inception of each arrangement that includes research and development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. Milestone payments that are not within the control of us or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraints, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect earnings in the period of adjustment.

Manufacturing supply services: Arrangements that include a promise for the future supply of drug substance or drug product for either clinical development or commercial supply at the customer’s discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If we are entitled to additional payments when the customer exercises these options, any payments are recorded in product supply revenues when the customer obtains control of the goods, which is upon delivery.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and where the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our licensing arrangements.

Licenses of intellectual property: If a license granted to a customer to use our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from consideration allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we apply judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, to conclude upon the appropriate method of measuring progress for purposes of recognizing revenue related to consideration allocated to the performance obligation.

Options: Customer options, such as options granted to allow a licensee to choose to research, develop and commercialize licensed compounds are evaluated at contract inception in order to determine whether those options provide a material right (i. e. , an optional good or service offered for free or at a discount) to the customer. If the customer options represent a material right, the material right is treated as a separate performance obligation at the outset of the arrangement. We allocate the transaction price to material rights based on the standalone selling price, and revenue is recognized when or as the future goods or services are transferred or when the option expires. Customer options that are not material rights do not give rise to a separate performance obligation, and as such, the additional consideration that would result from a customer exercising an option in the future is not included in the transaction price for the current contract. Instead, the option is deemed a marketing offer, and additional option fee payments are recognized or being recognized as revenue when the licensee exercises the option. The exercise of an option that does not represent a material right is treated as a separate contract for accounting purposes.

Contract modifications: Contract modifications, defined as changes in the scope or price (or both) of a contract that are approved by the parties to the contract, such as a contract amendment, exist when the parties to a contract approve a modification that either creates new or changes existing enforceable rights and obligations of the parties to the contract. Depending on facts and circumstances, we account for a contract modification as one of the following: (i) a separate contract; (ii) a termination of the existing contract and a creation of a new contract; or (iii) a combination of the preceding treatments. A contract modification is accounted for as a separate contract if the scope of the contract increases because of the addition of promised goods or services that are distinct and the price of the contract increases by an amount of consideration that reflects our standalone selling prices of the additional promised goods or services. When a contract modification is not considered a separate contract and the remaining goods or services are distinct from the goods or services transferred on or before the date of the contract modification, we account for the contract modification as a termination of the existing contract and a creation of a new contract. When a contract modification is not considered a separate contract and the remaining goods or services are not distinct, we account for the contract modification as an add-on to the existing contract and as an adjustment to revenue on a cumulative catch-up basis.

We receive payments from our licensees as established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements. Where applicable, amounts are recorded as unbilled revenue when our right to consideration is unconditional. We do not assess whether a contract with a customer has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service

providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with clinical studies;
- investigative sites in connection with clinical studies;
- vendors related to contract manufacturing, development and distribution of clinical supplies;
- collaborator entities in connection with our collaboration agreements; and
- vendors in connection with preclinical development activities.

We record expenses related to clinical studies and manufacturing development activities based on our estimates of the services received and efforts expended pursuant to contracts with our CROs and manufacturing vendors that conduct and manage these activities on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which each component of a service will be performed, and estimate, with vendor input if appropriate, the resulting level of completion of each component of the service, with such estimates often involving drivers that provide a surrogate measurement of completion such as number of enrolled subjects and/or number of sites activated in the calculation of clinical trial fee accruals. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrued or prepaid expense balance accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period.

Stock-Based Compensation

We estimate the fair value of stock options and Employee Stock Purchase Plan (“the ESPP”) shares using the Black-Scholes valuation model. The Black-Scholes model requires the input of highly subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

Expected Term—We have limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for our stock-option grants. As such, the expected term is estimated using the simplified method whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option.

Expected Volatility— Since January 1, 2017, we have used the historic volatility of our own stock over the retrospective period corresponding to the expected remaining term of the options, or the period since our shares were first quoted on The Nasdaq Global Market, if that is shorter, to compute our expected stock price volatility.

Risk-Free Interest Rate—The risk-free interest rate assumption is based on zero-coupon U.S. Treasury instruments on the date of grant with a maturity date consistent with the expected term of our stock option grants.

Expected Dividend— To date, we have not declared or paid any cash dividends and do not have any plans to do so in the future. Therefore, we use an expected dividend yield of zero.

As required, we review our valuation assumptions at each grant date and, as a result, we are likely to change our valuation assumptions used to value employee stock-based awards granted in future periods. Employee and director stock-

based compensation costs are to be recognized over the vesting period of the award, and we have elected to use the straight-line attribution method. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimate forfeitures based on historical experience.

Restricted stock units, or RSUs, are measured at the fair value of our common stock on the date of grant and expensed over the period of vesting using the straight-line attribution approach.

Performance-based RSUs, or PRSUs, are valued at grant-date fair market value. The vesting of the PRSUs is based on performance conditions. Performance conditions include: (i) a specific performance criteria and (ii) the employee's continuous employment by the company for a stated period of time in order to earn the right to the related PRSUs to vest. The Company recognizes compensation cost with respect to the vesting of the PRSUs on a ratable basis over the requisite service period, upon the performance conditions being deemed probable of achievement.

RESULTS OF OPERATIONS

Comparison of the Years Ended December 31, 2020 and 2019

Revenue

Below is a summary of our total revenue (dollars in thousands):

	Year Ended December 31,			
	2020	2019	$ Change	% Change
Collaborative development revenue	$ 5,364	$ 459	$ 4,905	1,068.6 %
Product supply revenue	1,501	322	1,179	366.1 %
Licensing revenue	706	4,500	(3,794)	(84.3)%
Total revenues	$ 7,571	$ 5,281	$ 2,290	43.4 %

The increase in our revenue was primarily attributable to $4.9 million higher collaborative development revenue recognized in connection with the 2019 KKC Agreement, which was entered into in November 2019, a $0.7 million licensing revenue recognized upon Knight's achievement of a development milestone pursuant to the Knight Agreement and a $1.4 million increase in manufacturing supply of tenapanor and other materials sold to KKC in accordance with the 2017 KKC Agreement, partially offset by $3.0 million revenue related to achievement of a milestone pursuant to the Fosun agreement during the year ended December 31, 2019.

Operating Expenses

Below is a summary of our operating expenses (dollars in thousands):

	Year Ended December 31,			
	2020	2019	$ Change	% Change
Cost of revenue	$ 145	$ 600	$ (455)	(75.8) %
Research and development	65,053	71,677	(6,624)	(9.2) %
General administrative	33,153	24,267	8,886	36.6 %
Total	$ 98,351	$ 96,544	$ 1,807	1.9 %

Cost of Revenue

Cost of revenue was $0.1 million for the year ended December 31, 2020, a decrease of $0.5 million, or 75.8%, compared to $0.6 million for the year ended December 31, 2019. Cost of revenue in both periods is the portion of tenapanor-related upfront and milestone payment from our collaboration partners that we are required to make to AstraZeneca under the AstraZeneca Termination Agreement.

Research and Development

Below is a summary of our research and development expenses (dollars in thousands):

	Year Ended December 31,			
	2020	2019	$ Change	% Change
External R&D expenses	$ 37,624	$ 45,989	$ (8,365)	(18.2)%
Employee-related expenses	20,911	19,466	1,445	7.4 %
Facilities, equipment and depreciation expense	5,738	5,934	(196)	(3.3)%
Other	780	288	492	170.8 %
Total	$ 65,053	$ 71,677	$ (6,624)	(9.2)%

The decrease in our external R&D expenses for the year ended December 31, 2020 primarily includes a $9.7 million decrease in our tenapanor-related expenses, partially offset by $3.0 million of higher expenses attributable to KKC Research Agreement-related research and general R&D expenses. Of the overall tenapanor-related decrease, approximately $11.0 million relates to lower clinical study costs due to the winding down of expenses associated with our Phase 3 program for tenapanor for the control of hyperphosphatemia, offset by an out-of-period adjustment recorded during 2019 that reduced clinical trial expenses by $3.6 million related to our tenapanor clinical trials for the nine months ended September 30, 2019; and approximately $2.9 million relates to lower manufacturing expenses due to reduced validation related expenses for tenapanor in 2020 as compared to 2019; offset by an increase of $3.1 million related to regulatory expenses that includes $2.9 million paid to the FDA for the filing of a NDA for tenapanor for the control of serum phosphorus in CKD patients on dialysis in June 2020.

General and Administrative

The increase in general and administrative expenses for the year ended December 31, 2020 was primarily due to an increase in costs associated with building and staffing our commercial infrastructure and teams as we prepare for the anticipated U.S. launch of tenapanor for the control of serum phosphorus in CKD patients on dialysis. The increase consisted of headcount and related personnel costs and an increase in external spending for disease awareness initiatives, commercial infrastructure and strategy.

Other Income (Expense), net

Below is a summary of our other income (expense), net (dollars in thousands):

	Year Ended December 31,			
	2020	2019	$ Change	% Change
Interest expense	$ (5,099)	$ (5,726)	$ 627	(11.0) %
Other income, net	1,568	2,352	(784)	(33.3) %
Total	$ (3,531)	$ (3,374)	$ (157)	4.7 %

The decrease in interest expense for the year ended December 31, 2020 was primarily due to lower interest rates on our variable-rate term loan.

The decrease in other income, net for the year ended December 31, 2020 was primarily due to a decrease in investment income, a lower exit fee revaluation adjustment related to our loan agreement and a decrease in currency exchange losses.

Comparison of the Years Ended December 31, 2019 and 2018

Revenue

Below is a summary of our operating expenses (dollars in thousands):

	Year Ended December 31,			
	2019	2018	$ Change	% Change
Collaborative development revenue	$ 459	$ —	$ 459	n/m
Product supply revenue	322	287	35	12.2 %
Licensing revenue	4,500	2,320	2,180	94.0 %
Total revenues	$ 5,281	$ 2,607	$ 2,674	102.6 %

Total revenues for the year ended December 31, 2019 were $5.3 million, which represents an increase of $2.7 million, or 102.6%, as compared to total revenues of $2.6 million for the year ended December 31, 2018. The licensing revenue of $4.5 million is attributable to the achievement of a milestone, which amounted to $3.0 million, pursuant to our exclusive license agreement with Fosun Pharma, entered into in December 2017 for the development, commercialization and distribution of tenapanor in China for both hyperphosphatemia and IBS-C, and the full recognition of the $1.5 million license fee related to the XuanZhu Agreement, as discussed in Note 12, Collaboration and Licensing Agreements, to our financial statements, included in Part II, Item 8 of this Annual Report on Form 10-K.

The increase in collaborative development revenue is attributed to revenue recognized during the fourth quarter of 2019 related to the 2019 KKC Agreement. We expect to recognize the remaining $9.5 million of the initial transaction price over the research and development period of the program, which we currently expect to extend through the end of 2021. We will revisit our current estimates and timing of performance at the end of each future reporting period and adjust as necessary.

Product supply revenue of $0.3 million relates to the manufacturing supply of tenapanor and other materials sold to KKC in connection with that collaboration partner's product development and clinical trials in Japan.

Operating Expenses

Below is a summary of our operating expenses (dollars in thousands):

	Year Ended December 31,			
	2019	2018	$ Change	% Change
Cost of revenue	$ 600	$ 466	$ 134	28.8 %
Research and development	71,677	69,373	2,304	3.3 %
General administrative	24,267	23,715	552	2.3 %
Total	$ 96,544	$ 93,554	$ 2,990	3.2 %

Cost of Revenue

Cost of revenue was $0.6 million for the year ended December 31, 2019, an increase of $0.1 million, or 28.8%, compared to $0.5 million for the year ended December 31, 2018. Cost of revenue in both periods is the portion of tenapanor-related up front and milestone payment from our collaboration partners that we are required to make to AstraZeneca under the AstraZeneca Termination Agreement.

Research and Development

Below is a summary of our research and development expenses (dollars in thousands):

	Year Ended December 31,			
	2019	2018	$ Change	% Change
External R&D expenses	$ 45,989	$ 47,060	$ (1,071)	(2.3) %
Employee-related expenses	19,466	16,666	2,800	16.8 %
Facilities, equipment and depreciation expenses	5,934	5,360	574	10.7 %
Other expenses	288	287	1	0.3 %
Total	$ 71,677	$ 69,373	$ 2,304	3.3 %

Research and development expenses were $71.7 million for the year ended December 31, 2019, an increase of $2.3 million, or 3.3%, compared to $69.4 million for the year ended December 31, 2018. The increase consisted of a $3.7 million increase to advance our internal pipeline programs and a $1.4 million decrease in our collaboration program costs.

The increase in our internal costs of $3.7 million was primarily due to an increase in headcount and related personnel costs and an increase in stock-based compensation expenses.

The decrease in our external program costs of $1.4 million included a $4.6 million decrease in expenses primarily related to manufacturing of tenapanor and regulatory expenses related to our IBS-C NDA in 2018, partially offset by $2.5 million increase in clinical development expenses related to our RDX013 program and a $0.7 million increase primarily related to our tenapanor clinical trial expenses that includes an out-of-period adjustment recorded during the second quarter of 2019 that reduced clinical trial expenses by $3.6 million related to our tenapanor clinical trials.

General and Administrative

General and administrative expenses were $24.3 million for the year ended December 31, 2019, an increase of $0.6 million, or 2.3%, compared to $23.7 million for the year ended December 31, 2018. The increase was primarily due to an increase in personnel costs, stock-based compensation expense, audit expenses and recruiting expenses, partially offset by a decrease in other professional services.

Other Income (Expense), net

Below is a summary of our other income (expense), net (dollars in thousands):

	Year Ended December 31,			
	2019	2018	$ Change	% Change
Interest expense	$ (5,726)	$ (3,534)	$ (2,192)	62.0 %
Other income, net	2,352	3,187	(835)	(26.2) %
Total	$ (3,374)	$ (347)	$ (3,027)	872.3 %

Interest expense, net was $5.7 million for the year ended December 31, 2019, an increase of $2.2 million, or 62.0%, compared to $3.5 million for the year ended December 31, 2018. The increase in interest expense in 2019 compared to 2018 was because the interest expense during 2018 represents only part of the year related to the loan agreement entered in May 2018, as compared with a full year of interest expense in 2019.

Other income, net, was $2.4 million for the year ended December 31, 2019, which represents a decrease of $0.8 million, or 26.2%, compared to $3.2 million for the year ended December 31, 2018. The decrease was primarily due to a decrease in treasury-related income and revaluation adjustments related to our loan agreement.

LIQUIDITY AND CAPITAL RESOURCES

Below is a summary of our cash, cash equivalents and marketable securities (in thousands):

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 91,032	$ 181,133
Marketable securities - current	95,452	66,379
Marketable securities - non-current	2,114	—
Total liquid funds	$ 188,598	$ 247,512

As of December 31, 2020, we had cash, cash equivalents and marketable securities totaling $188.6 million compared to $247.5 million as of December 31, 2019.

In July 2020, we filed a Form S-3 registration statement, which became effective in August 2020, containing (i) a base prospectus for the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $250.0 million of the Company's common stock, preferred stock, debt securities, warrants and/or units, from time to time in one or more offerings; and (ii) a prospectus supplement for the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $100.0 million of our common stock that may be issued and sold, from time to time, under a sales agreement with Jefferies LLC, deemed to be "at the market offerings." As of December 31, 2020, we have received net proceeds of $21.2 million through the sale of approximately 3.3 million shares pursuant to this sales agreement.

On December 9, 2019, we completed an underwritten public offering of 20.0 million shares of common stock at a price of $6.25 per share before underwriting discounts and commissions ("the 2019 Offering"). In connection with the 2019 Offering, we entered into an underwriting agreement ("the 2019 Underwriting Agreement") with Citigroup Global Markets Inc., Cowen and Company LLC, SVB Leerink LLC and Piper Jaffray & Co., collectively "the 2019 Underwriters") pursuant to which we granted to the 2019 Underwriters a 30-day option to purchase up to an additional 3.0 million shares of our common stock ("the 2019 Overallotment"). We completed the sale of 23.0 million shares, inclusive of the 2019 Overallotment, and that sale resulted in our receipt of aggregate gross proceeds of approximately $143.8 million, less underwriting discounts, commissions and offering expenses totaling approximately $8.9 million, which resulted in net proceeds of approximately $134.9 million.

On November 22, 2019, we and KKC entered into a stock purchase agreement, pursuant to which we sold an aggregate of 2.9 million shares of our common stock at $6.96 per share for aggregate net proceeds of approximately $20.0 million, or the Private Placement. The Private Placement closed on November 25, 2019.

On May 25, 2018, we completed an underwritten public offering of 12.5 million shares of common stock at a price of $4.00 per share before underwriting discounts and commissions ("the 2018 Offering"). In connection with the 2018 Offering, we entered into an underwriting agreement ("the 2018 Underwriting Agreement") with Jefferies LLC and SVB Leerink (formerly known as Leerink Partners LLC), or together the 2018 Underwriters, pursuant to which we granted to the 2018 Underwriters a 30-day option to purchase up to an additional 1.9 million shares of our common stock ("the 2018 Overallotment"). We completed the sale of 14.4 million, inclusive of the 2018 Overallotment, to the 2018 Underwriters. That sale resulted in our receipt of aggregate gross proceeds of approximately $57.5 million, less underwriting discounts, commissions and offering expenses totaling approximately $3.7 million, which resulted in net proceeds of approximately $53.8 million.

On May 16, 2018, we entered into a loan and security agreement ("the Loan Agreement") with Solar Capital Ltd. and Western Alliance Bank ("the Lenders"). The Loan Agreement provides for a $50.0 million term loan facility with a maturity date of November 1, 2022. The full amount of the loan was funded on May 16, 2018. We received net proceeds from the loan of $49.3 million, after deducting the closing fee, legal expenses and issuance cost. On October 9, 2020, we and the Lenders entered into an amendment to the Loan Agreement, as defined and discussed in Note 6, Borrowings, to extend the date through which we are permitted to make interest-only payments on the Term Loan from December 1, 2020 to December 1, 2021. See Note 6, Borrowings, in the notes to our financial statements, included in Part II, Item 8, for details on our Loan Agreement.

Our primary sources of cash have been from the sale and issuance of common stock (in both public offerings and private placements) and private placements of convertible preferred stock, funds from our collaboration partnerships and funds from our loan agreement. Our primary uses of cash are to fund operating expenses, primarily research and development expenditures and pre-commercial expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We believe that our existing capital resources as of December 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months following our financial statement issuance date. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. In particular, our operating plan can change, and we may require significant additional capital to fund our operations, including to support the development, commercialization and manufacturing efforts for tenapanor. We may seek to obtain such additional capital through debt financings, credit facilities, additional equity offerings and/or strategic collaborations. We currently have no unutilized credit facility or committed sources of capital, and there can be no assurances that such sources of capital will be available to us when needed or on acceptable terms. There are numerous risks and uncertainties associated with research, development and commercialization initiatives, and actual results could vary materially as a result of a number of factors, many of which are outside of our control. Our future capital requirements are difficult to forecast and will depend on many factors, including:

- the FDA's actions and decisions with respect to the NDA submitted to the FDA on June 30, 2020 to request marketing authorization for tenapanor for the control of serum phosphorus in adult CKD patients on dialysis;
- our ability to successfully commercialize tenapanor in the U.S. for the control of serum phosphorus in CKD patients on dialysis, if approved;
- the sales price and the availability of adequate third-party reimbursement for tenapanor, if approved;
- the manufacturing costs of our product candidates, and the availability of one or more suppliers for our product candidates at reasonable costs, both for clinical and commercial supply;
- the selling and marketing costs associated with tenapanor, including the cost and timing of building our sales and marketing capabilities;
- our ability to maintain our existing collaboration partnerships and to establish additional collaboration partnerships, in-license/out-license, joint ventures or other similar arrangements and the financial terms of such agreements;
- the timing, receipt, and amount of sales of, or royalties on, tenapanor, if any;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the number and scope of preclinical and discovery programs that we decide to pursue or initiate, and any clinical trials we decide to pursue for other product candidates, including RDX013;
- the time and cost necessary to respond to technological and market developments;
- the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights, including litigation costs and the outcome of such litigation, including costs of defending any claims of infringement brought by others in connection with the development, manufacture or commercialization of tenapanor or any of our product candidates; and
- the payment of interest and principal related to our loan and security agreement entered into with Solar Capital and Western Alliance Bank in May 2018, as amended on October 9, 2020.

CASH FLOW ACTIVITIES

The following table summarizes our cash flows for the periods indicated (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Cash used in operating activities	$ (81,435)	$ (76,484)	$ (70,274)
Cash (used in) provided by investing activities	(31,442)	23,373	(29,894)
Cash provided by financing activities	22,776	155,476	103,553
Net (decrease) increase in cash and cash equivalents	$ (90,101)	$ 102,365	$ 3,385

Cash Flows from Operating Activities

2020 compared to 2019

Net cash used in operating activities during the year ended December 31, 2020 was $81.4 million, as compared to $76.5 million for the year ended December 31, 2019. The most significant factors that contributed to the $5.0 million increase in net cash used in operating activities for the year ended December 31, 2020, as compared to 2019 was primarily a $6.2 million decrease to changes in operating assets and liabilities, primarily driven by cash received in 2019 and reported as deferred revenue for the KKC Research Agreement that was recognized as revenue in 2020, offset by a $0.6 million increase in non-cash charges and $0.6 million decrease to the net loss.

2019 compared to 2018

Net cash used in operating activities during the year ended December 31, 2019, was $76.5 million, as compared to $70.3 million of net cash used in operating activities during the year ended December 31, 2018. The $6.2 million increase in net cash used in operating activities is predominantly attributable toa $1.9 million decrease in payments made to AstraZeneca during 2019 in connection with the AZ Termination Agreement, as compared to payments made in 2018; a $0.4 million increase in cash R&D expenses (excluding working capital-related fluctuations) in 2019, as compared to 2018;

- a $0.4 million decrease in cash G&A expenses (excluding working capital-related fluctuations) in 2019, as compared to 2018;
- a $2.1 million increase in net cash interest payments in 2019, as compared to 2018;
- a $0.9 million decrease in cash paid for income taxes in 2019, as compared to 2018; and
- a $6.5 million net increase in cash used related to fluctuations in components of our non-revenue-related working capital in 2019, as compared to 2018, which was comprised of a $7.8 million decrease, a $1.9 million decrease and a $0.4 million decrease in cash provided by fluctuations in our non-payroll-related accruals and other current liabilities, lease liability and prepaid expenses and other current assets, respectively, partially offset by a $2.2 million increase and a $1.4 million increase of cash provided by fluctuations in our accrued compensation and benefits and accounts payable, respectively.

Cash Flows from Investing Activities

2020 compared to 2019

Net cash provided by investing activities decreased by $54.8 million during the year ended December 31, 2020, as compared to the year ended December 31, 2019. This decrease was attributable to a $48.2 million increase in purchases of available-for-sale investments and a decrease in proceeds from maturities and redemptions of short-term investments of $6.6 million.

2019 compared to 2018

Net cash provided by investing activities increased by $53.3 million during the year ended December 31, 2019, as compared to the year ended December 31, 2018. This increase was attributable to a $66.3 million decrease in purchases of short-term available-for-sale investments and a $1.2 million increase in sales and redemptions of investments, partially offset by a decrease in proceeds from maturities and redemptions of short-term investments of $13.1 million.

Cash Flows from Financing Activities

2020 compared to 2019

Net cash provided by financing activities decreased by $132.7 million during the year ended December 31, 2020, as compared to the year ended December 31, 2019. This decrease was predominantly attributable to $134.9 million in net proceeds received in connection with underwritten public offering initiatives that was received in 2019 but did not recur in 2020. This decrease was partially offset by $2.4 million net additional proceeds received in 2020 as compared to 2019 from sales of our common stock pursuant to our at-the-market sales agreement with Jefferies LLC, employee stock plan purchases and option exercises, and the 2019 sale of common stock in the Private Placement with KKC..

2019 compared to 2018

Net cash provided by financing activities increased by $51.9 million during the year ended December 31, 2019, as compared to the year ended December 31, 2018. This increase was predominantly attributable to an $81.2 million increase in net proceeds received in connection with underwritten public offering initiatives and a $20.0 million increase in net proceeds received in connection with the Private Placement, partially offset by a net $49.3 million decrease in proceeds received in connection with a long-term loan borrowing.

OFF-BALANCE SHEET ARRANGEMENTS

As of December 31, 2020 and 2019, respectively, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K as promulgated by the SEC.

SMALLER REPORTING COMPANY AND NON-ACCELERATED FILER STATUS

On June 28, 2018, the SEC adopted amendments that raise the thresholds in the smaller reporting company, or SRC, definition, whereby we were determined to qualify as an SRC. We elected to reflect that determination and avail ourselves with most of the SRC scaled disclosure accommodations in our filings subsequent to the adoption. On March 12, 2020, the SEC amended its rules to allow SRCs that have less than $100.0 million in annual revenue and a public float of less than $700.0 million to qualify as a non-accelerated filer. As a non-accelerated filer, we are not required to obtain an opinion of our independent auditors with respect to our internal controls over financial reporting for the period ended December 31, 2020.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We are subject to market risks, including interest rate fluctuation exposure through our investments, in the ordinary course of our business. However, the goals of our investment policy are the preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. To achieve our goal of maximizing income without assuming significant market risk, we maintain our excess cash and cash equivalents in money market funds and short-term debt securities. Because of the short-term maturities of our cash equivalents, we do not believe that a decrease in interest rates would have any material negative impact on the fair value of our cash equivalents.

As of December 31, 2020, we had cash, cash equivalents and marketable securities of $188.6 million, which consist of bank deposits and money market funds, as well as high quality fixed income instruments including corporate bonds, commercial paper, and asset-backed securities collateralized by non-mortgage consumer receivables. The credit rating of our short-term investments must be rated A-1/P-1, or better by Standard and Poor's and Moody's Investors Service. Asset-backed securities must be rated AAA/Aaa. Money Market funds must be rated AAAm/Aaa. Such interest-earning instruments carry a degree of interest rate risk. However, because our investments are high quality and short-term in duration, we believe that our exposure to interest rate risk is not significant and that a 10% movement in market interest rates would not have a significant impact on the total value of our portfolio, as noted above. We do not enter into investments for trading or speculative purposes.

We are subject to interest rate fluctuation exposure through our borrowings under the Loan Agreement and our investment in money market accounts which bear a variable interest rate. Borrowings under the Loan Agreement bear interest at a rate equal to one-month London Interbank Offered Rate, or LIBOR, plus 7.45% per annum. A hypothetical increase in one-month LIBOR of 100 basis points above the current one-month LIBOR rates would have increased our interest expense by approximately $0.5 million for the year ended December 31, 2020. As of December 31, 2020, we had an aggregate principal amount of $50.0 million outstanding pursuant to our Loan Agreement.

Foreign Currency Exchange Risk

The majority of our transactions are denominated in U.S. dollars. However, we do have certain transactions that are denominated in currencies other than the U.S. dollar, primarily Swiss francs and the euro, and we therefore are subject to foreign exchange risk. The fluctuation in the value of the U.S. dollar against other currencies affects the reported amounts of expenses, assets and liabilities associated with a limited number of manufacturing activities.

We do not use derivative financial instruments for speculative trading purposes, nor do we hedge foreign currency exchange rate exposure in a manner that entirely offsets the earnings effects of changes in foreign currency exchange rates. The counterparties to our forward foreign currency exchange contracts are creditworthy commercial banks, which minimizes the risk of counterparty nonperformance.

As of December 31, 2020, we had no open forward foreign currency exchange contracts.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ARDELYX, INC.
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

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

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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

Accrued clinical and contract manufacturing expenses

Description of the Matter

During 2020, the Company incurred $65.1 million of research and development expenses and accrued $2.2 million of clinical expenses and $1.8 million of contract manufacturing expenses as of December 31, 2020. As described in Note 2 to the Financial Statements, the Company estimates the accruals for its contracts with third party service providers including contract research organizations ("CROs"), investigative sites, vendors related to contract manufacturing, development and distribution of clinical supplies, and vendors in connection with preclinical development activities, which comprise a significant component of the Company's research and development activities. External costs are accrued and expensed based on estimates of the services received and efforts expended pursuant to contracts with multiple CROs, investigative sites, contract manufacturing vendors, and preclinical development vendors. The timing and the amount of payments required under each individual arrangement are often different from the pattern of costs actually incurred. The Company accrues the cost of the services under its contracts with third party service providers based on the extent of activities completed by vendors over the estimated service period, number of subjects enrolled, and number of sites activated.

Auditing management's accounting for accrued clinical and contract manufacturing expenses is especially challenging because the evaluation is dependent on a high volume of data exchanged between third-party service providers, internal clinical and manufacturing personnel as well as the company's finance team. Determining the accrued amounts is based on an evaluation of the unique terms and conditions set in each respective CRO, investigative site, contract manufacturing, and pre-clinical development agreement. Additionally, due to the duration of clinical-related development activities and the timing of invoices received from third parties, the determination of the accrual for services incurred requires application of judgment by management.

How We Addressed the Matter in Our Audit

To test accrued clinical and contract manufacturing expenses, our audit procedures included, among others, testing the accuracy and completeness of the inputs used in management's analysis to determine costs incurred. We also inspected terms and conditions for material vendor contracts and change orders and compared these to the cost models management used in tracking progress of service agreements. We met with internal legal personnel to understand material unique contract terms and conditions that require special consideration in estimating the accrued research and development expenses. We met with internal clinical and manufacturing personnel to understand the status of significant clinical and contract manufacturing activities. We evaluated estimated services incurred by third parties by understanding the terms and timeline of significant projects, evaluating management's estimate of work performed, subjects enrolled and sites activated and costs incurred, and obtaining external confirmation of contracts and change orders executed with the Company for a sample of vendors as well as key terms and conditions of those contracts. Further, we inspected material invoices received from third parties after the balance sheet date and evaluated whether services performed prior to the balance sheet date had been properly included in the accrual.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2009.

Redwood City, California
March 8, 2021

ARDELYX, INC.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 91,032	$ 181,133
Short-term investments	95,452	66,379
Unbilled revenue	—	750
Prepaid expenses and other current assets	8,202	3,800
Total current assets	194,686	252,062
Property and equipment, net	1,936	3,436
Long-term investments	2,114	—
Right-of-use assets	2,274	3,970
Other assets	552	314
Total assets	$ 201,562	$ 259,782
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,626	$ 2,187
Accrued compensation and benefits	5,672	4,453
Current portion of operating lease liability	2,117	2,608
Loan payable, current portion	4,167	1,183
Deferred revenue	4,177	4,541
Accrued expenses and other current liabilities	6,657	7,248
Total current liabilities	28,416	22,220
Operating lease liability, net of current portion	413	2,076
Loan payable, net of current portion	46,621	48,831
Total liabilities	75,450	73,127
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized; no shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively.	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized; 93,599,975 and 88,817,741 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively.	9	9
Additional paid-in capital	680,872	647,078
Accumulated deficit	(554,765)	(460,452)
Accumulated other comprehensive income	(4)	20
Total stockholders' equity	126,112	186,655
Total liabilities and stockholders' equity	$ 201,562	$ 259,782

The accompanying notes are an integral part of these financial statements.

ARDELYX, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2020	2019	2018
Revenues:			
Collaborative development revenue	$ 5,364	$ 459	$ —
Product supply revenue	1,501	322	287
Licensing revenue	706	4,500	2,320
Total revenues	7,571	5,281	2,607
Operating expenses:			
Cost of revenue	145	600	466
Research and development	65,053	71,677	69,373
General and administrative	33,153	24,267	23,715
Total operating expenses	98,351	96,544	93,554
Loss from operations	(90,780)	(91,263)	(90,947)
Interest expense	(5,099)	(5,726)	(3,534)
Other income, net	1,568	2,352	3,187
Loss before provision for income taxes	(94,311)	(94,637)	(91,294)
Provision for income taxes	2	303	4
Net loss	$ (94,313)	$ (94,940)	$ (91,298)
Net loss per common share, basic and diluted	$ (1.05)	$ (1.47)	$ (1.62)
Shares used in computing net loss per share - basic and diluted	89,582,138	64,478,066	56,219,919
Comprehensive loss:			
Net loss	$ (94,313)	$ (94,940)	$ (91,298)
Unrealized (losses) gains on available-for-sale securities	(24)	58	9
Comprehensive loss	$ (94,337)	$ (94,882)	$ (91,289)

The accompanying notes are an integral part of these financial statements.

ARDELYX, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2017	47,534,979	$ 5	$ 417,568	$ (278,214)	$ (47)	$ 139,312
Adoption of ASU No. 2014-09 on January 1, 2018	—	—	—	4,000	—	4,000
Issuance of common stock under employee stock purchase plan	120,959	—	491	—	—	491
Issuance of common stock for services	75,183	—	303	—	—	303
Issuance of common stock upon exercise of options	—	—	—	—	—	—
Issuance of common stock upon vesting of restricted stock units	410,506	—	—	—	—	—
Stock-based compensation	—	—	9,226	—	—	9,226
Unrealized gains on available-for-sale securities	—	—	—	—	9	9
Issuance of common stock upon underwritten public offering, net of issuance costs	14,375,000	1	53,769	—	—	53,770
Net loss	—	—	—	(91,298)	—	(91,298)
Balance as of December 31, 2018	62,516,627	$ 6	$ 481,357	$ (365,512)	$ (38)	$ 115,813
Issuance of common stock under employee stock purchase plan	160,744	—	396	—	—	396
Issuance of common stock for services	113,136	—	312	—	—	312
Issuance of common stock upon exercise of options	68,062	—	178	—	—	178
Stock-based compensation	—	—	9,936	—	—	9,936
Unrealized gains on available-for-sale securities	—	—	—	—	58	58
Issuance of common stock upon underwritten public offering, net of issuance costs	23,000,000	3	134,924	—	—	134,927
Issuance of common stock upon private placement, net of issuance costs	2,873,563	—	19,975	—	—	19,975
Net loss	—	—	—	(94,940)	—	(94,940)
Balance as of December 31, 2019	88,817,741	$ 9	$ 647,078	$ (460,452)	$ 20	$ 186,655
Issuance of common stock under employee stock purchase plan	169,931	—	834	—	—	834
Issuance of common stock for services	42,403	—	310	—	—	310
Issuance of common stock upon exercise of options	445,942	—	1,020	—	—	1,020
Issuance of common stock upon vesting of restricted stock units	866,528	—	—	—	—	—
Stock-based compensation	—	—	10,583	—	—	10,583
Unrealized gains on available-for-sale securities	—	—	—	—	(24)	(24)
Issuance of common stock in At-the-market offering	3,257,430	—	21,047	—	—	21,047
Net loss	—	—	—	(94,313)	—	(94,313)
Balance as of December 31, 2020	93,599,975	$ 9	$ 680,872	$ (554,765)	$ (4)	$ 126,112

The accompanying notes are an integral part of these financial statements.

ARDELYX, INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	2020	2019	2018
Operating activities			
Net loss	$ (94,313)	$ (94,940)	$ (91,298)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	1,824	2,501	2,678
Amortization of deferred financing costs	496	670	236
Amortization of deferred compensation for services	313	309	253
Amortization of premium on investment securities	(92)	(698)	(1,136)
Non-cash lease expense	2,147	1,839	—
Stock-based compensation	10,583	9,936	9,226
Change in derivative liabilities	407	436	111
Non-cash interest associated with debt discount accretion	413	478	303
Changes in operating assets and liabilities:			
Unbilled revenue	750	4,250	—
Accounts receivable	—	85	10,711
Prepaid expenses and other assets	(4,653)	93	525
Accounts payable	3,439	39	(2,730)
Accrued compensation and benefits	1,219	1,730	(506)
Lease liabilities	(2,604)	(1,892)	—
Accrued and other liabilities	(1,000)	(5,861)	1,353
Deferred revenue	(364)	4,541	—
Net cash used in operating activities	(81,435)	(76,484)	(70,274)
Investing activities			
Proceeds from maturities and redemptions of investments	119,734	126,369	139,450
Purchases of investments	(150,852)	(102,671)	(169,033)
Purchases of property and equipment	(324)	(325)	(311)
Net cash (used in) provided by investing activities	(31,442)	23,373	(29,894)
Financing activities			
Proceeds from underwritten public offering, net of issuance costs	—	134,927	53,770
Proceeds from issuance of common stock upon private placement, net of issuance costs	—	19,975	—
Proceeds from issuance of common stock in At-the-market offering, net of issuance costs	21,047	—	—
Proceeds from issuance of common stock under equity incentive and stock purchase plans	1,854	574	491
Proceeds from (payments for) loan payable, net of issuance costs	(125)	—	49,292
Net cash provided by financing activities	22,776	155,476	103,553
Net (decrease) increase in cash and cash equivalents	(90,101)	102,365	3,385
Cash and cash equivalents at beginning of period	181,133	78,768	75,383
Cash and cash equivalents at end of period	$ 91,032	$ 181,133	$ 78,768
Supplementary disclosure of cash flow information:			
Cash paid for interest	$ 4,200	$ 4,920	$ 3,071
Cash paid for income taxes	$ 1	$ 2	$ 4
Supplementary disclosure of non-cash activities:			
Right-of-use assets obtained in exchange for lease obligations	$ 450	$ 5,810	$ —
Issuance of common stock for services	$ 310	$ 312	$ 303
Issuance of derivative in connection with issuance of loan payable	$ —	$ —	$ 546

The accompanying notes are an integral part of these financial statements.

ARDELYX, INC.
NOTES TO FINANCIAL STATEMENTS

1. ORGANIZATION AND BASIS OF PRESENTATION

Ardelyx, Inc. (the "Company," "we," "us" or "our") is a specialized biopharmaceutical company focused on developing first-in-class medicines to improve treatment choices for people with kidney and cardiorenal diseases. The Company operates in one business segment, which is the research and development of biopharmaceutical products.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Prior Period Errors

In connection with our review of our financial statements as of and for the six months ended June 30, 2019, we corrected errors related to the accounting for clinical trial accruals that had resulted in an overstatement of research and development expenses during the year ended December 31, 2018. Specifically, management concluded that the Company's research and development expenses recorded during the year ended December 31, 2018 had been overstated by $3.6 million and that the Company's accrued expenses and other current liabilities as of December 31, 2018 had been overstated by the same amount. Management analyzed the potential impact of these errors in accordance with the U.S. Securities and Exchange Commission's ("SEC") Staff Accounting Bulletin No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements, and concluded that while the errors were significant to the Company's financial statements as of and for the six months ended June 30, 2019, a correction of the errors would not have been material to the full year results for 2019 and 2018 nor affect the trend of financial results. Accordingly, the Company reduced accrued and other liabilities by $3.6 million and recorded a cumulative adjustment of $3.6 million in the statement of operations and comprehensive loss to reduce research and development expenses in 2019.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to recognition of revenue, clinical trial accruals, contract manufacturing accruals, fair value of assets and liabilities, income taxes and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could materially differ from those estimates.

Liquidity

As of December 31, 2020, the Company had cash and investments of approximately $188.6 million, which include net proceeds of approximately $21.0 million from the 2020 At-the-Market Offerings, $134.9 million from the 2019 Offering, and $20.0 million received in connection with the 2019 Private Placement, respectively, as defined and discussed in Note 7. We believe our current available cash and investments will be sufficient to fund our planned expenditures and meet the Company's obligations for at least 12 months following March 8, 2021, which is the date that the financial statements are being issued.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity date of 90 days or less on the date of purchase to be cash equivalents.

Short-Term Investments

Short-term investments consist of debt securities classified as available-for-sale and have maturities greater than 90 days, but less than one year, from the date of acquisition. Short-term investments are carried at fair value based upon quoted market prices. Unrealized gains and losses on available-for-sale securities are excluded from earnings and are reported as a component of accumulated other comprehensive loss. The cost of available-for-sale securities sold is based on the specific-identification method.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. The Company is exposed to credit risks in the event of default by the counterparties to the extent of the amount recorded in its balance sheet. Cash, cash equivalents and short-term investments are invested through banks and other financial institutions in the U.S.

Foreign Currency and Forward Contracts

The Company manages its foreign currency exposures with the use of foreign currency purchases as well as currency spot and forward contracts. The Company primarily conducts its business in U.S. dollars; however, a portion of the Company’s expense and capital activities are transacted in foreign currencies which are subject to exchange rate fluctuations that can affect cash or earnings. The Company has been in a loss position and therefore its primary objective is to conserve and manage cash. There are generally two methods by which the Company manages the cash flow risk of foreign exchange fluctuations when a contract is signed (i) it can purchase the foreign funds, in full or in part, upon the execution of the contract, or (ii) it can obtain the right to purchase such funds, in full or in part, at the execution of the contract, i.e., obtain a forward contract from an appropriate bank, that can be exercised to obtain the currency of interest at a particular point in time. The derivative instruments that the Company uses to hedge the exposure shall generally not be designated as cash flow hedges, and as a result, changes in their fair value will be recorded in other income (expense), net, in the Company's statements of operations and comprehensive loss. The fair values of forward foreign currency exchange contracts are estimated using current exchange rates and interest rates and the current creditworthiness of the counterparties is taken into consideration.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, with ranges generally from three to five years. Leasehold improvements are amortized over the lesser of the estimated useful lives or the related remaining lease term.

Impairment of Long-Lived Assets

The carrying value of long-lived assets, including property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the asset may not be recoverable. An impairment loss is recognized when the total of estimated future undiscounted cash flows, expected to result from the use of the asset and its eventual disposition, are less than the asset’s carrying amount. Impairment, if any, would be assessed using discounted cash flows or other appropriate measures of fair value. For the years ending December 31, 2020, 2019 and 2018 there have been no impairment losses.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

Revenue Recognition

On January 1, 2018 the Company adopted the Financial Accounting Standards Board's ("FASB") Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606) and related amendments* ("ASC 606"), on a modified retrospective basis, which resulted in an adjustment to the opening accumulated deficit balance on the adoption date. As a result of the adoption of the new standard, on January 1, 2018, the Company recorded the following: (i) unbilled revenue under current assets of $5.0 million representing a future receivable related to the first milestone under the Company's license agreement with Kyowa Kirin Co., Ltd. (formerly known as Kyowa Hakko Kirin Co., Ltd, or KHK) ("KKC"), which was subsequently achieved by KKC and collected in February 2019, thereby reducing the unbilled revenue balance to zero, (ii) uncharged license fees under current liabilities of $1.0 million representing the corresponding future payable related to AstraZeneca AB, or AstraZeneca, in accordance with the Company's termination agreement with AstraZeneca, which, upon KKC achieving the milestone, was reclassified to accounts payable and subsequently paid to AstraZeneca during the second quarter of 2019, and (iii) a related decrease in accumulated deficit of approximately $4.0 million as the new standard permitted revenue from milestones that possess certain criteria to be recognized earlier and also contained different recognition criteria related to milestones than under the previous accounting standard.

The Company generates revenue primarily from research and collaboration and license agreements with customers. Goods and services in the agreements may include the grant of licenses for the use of the Company's technology, the provision of services associated with the research and development of product candidates, manufacturing services, and participation in joint steering committees. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; research, development, regulatory and commercial milestone payments; reimbursement of research and development services; option payments; reimbursement of certain costs; payments for manufacturing supply services; and future royalties on net sales of licensed products.

When two or more contracts are entered into with the same customer at or near the same time, the Company evaluates the contracts to determine whether the contracts should be accounted for as a single arrangement. Contracts are combined and accounted for as a single arrangement if one or more of the following criteria are met: (i) the contracts are negotiated as a package with a single commercial objective; (ii) the amount of consideration to be paid in one contract depends on the price or performance of the other contract; or (iii) the goods or services promised in the contracts (or some goods or services promised in each of the contracts) are a single performance obligation.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its agreements, management performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraints on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for contracts with customers, the Company develops assumptions that require judgment to determine whether promised goods and services represent distinct performance obligations and the standalone selling price for each performance obligation identified in the contract. This evaluation is subjective and requires the Company to make judgments about the promised goods and services and whether those goods and services are separable from other aspects of the contract. Further, determining the standalone selling price for performance obligations requires significant judgment, and when an observable price of a promised good or service is not readily available, the Company considers relevant assumptions to estimate the standalone selling price, including, as applicable, market conditions, development timelines, probabilities of technical and regulatory success, reimbursement rates for personnel costs, forecasted revenues, potential limitations to the selling price of the product and discount rates.

The Company applies judgment in determining whether a combined performance obligation is satisfied at a point in time or over time, and, if over time, concluding upon the appropriate method of measuring progress to be applied for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, as estimates related to the measure of progress change, related revenue recognition is adjusted accordingly. Changes in the Company's estimated measure of progress are accounted for prospectively as a change in accounting estimate. The Company recognizes collaboration revenue by measuring the progress toward complete satisfaction of the performance obligation using an input measure. In order to recognize revenue over the research and development period, the Company measures actual costs incurred to date compared to the overall total expected costs to satisfy the performance obligation. Revenues are recognized as the program costs are incurred. The Company will re-evaluate the estimate of expected costs to satisfy the performance obligation each reporting period and make adjustments for any significant changes.

Amounts received prior to satisfying the revenue recognition criteria are recorded as contract liabilities in the Company's balance sheets. If the related performance obligation is expected to be satisfied within the next twelve months this will be classified in current liabilities. Amounts recognized as revenue prior to receipt are recorded as contract assets in the Company's balance sheets. If the Company expects to have an unconditional right to receive the consideration in the next twelve months, this will be classified in current assets. A net contract asset or liability is presented for each contract with a customer.

Milestone Payments: At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraints, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect earnings in the period of adjustment.

Manufacturing supply services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered as options. The Company assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the customer exercises these options, any payments are recorded in product supply revenue when the customer obtains control of the goods, which is upon delivery.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and where the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

Licenses of intellectual property: If a license granted to a customer to use the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from consideration allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company applies judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, to conclude upon the appropriate method of measuring progress for purposes of recognizing revenue related to consideration allocated to the performance obligation.

Options: Customer options, such as options granted to allow a licensee to choose to research, develop and commercialize licensed compounds are evaluated at contract inception in order to determine whether those options provide

a material right (i.e., an optional good or service offered for free or at a discount) to the customer. If the customer options represent a material right, the material right is treated as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the standalone selling price, and revenue is recognized when or as the future goods or services are transferred or when the option expires. Customer options that are not material rights do not give rise to a separate performance obligation, and as such, the additional consideration that would result from a customer exercising an option in the future is not included in the transaction price for the current contract. Instead, the option is deemed a marketing offer, and additional option fee payments are recognized or being recognized as revenue when the licensee exercises the option. The exercise of an option that does not represent a material right is treated as a separate contract for accounting purposes.

Contract modifications: Contract modifications, defined as changes in the scope or price (or both) of a contract that are approved by the parties to the contract, such as a contract amendment, exist when the parties to a contract approve a modification that either creates new or changes existing enforceable rights and obligations of the parties to the contract. Depending on facts and circumstances, the Company accounts for a contract modification as one of the following: (i) a separate contract; (ii) a termination of the existing contract and a creation of a new contract; or (iii) a combination of the preceding treatments. A contract modification is accounted for as a separate contract if the scope of the contract increases because of the addition of promised goods or services that are distinct and the price of the contract increases by an amount of consideration that reflects the Company's standalone selling prices of the additional promised goods or services. When a contract modification is not considered a separate contract and the remaining goods or services are distinct from the goods or services transferred on or before the date of the contract modification, the Company accounts for the contract modification as a termination of the existing contract and a creation of a new contract. When a contract modification is not considered a separate contract and the remaining goods or services are not distinct, the Company accounts for the contract modification as an add-on to the existing contract and as an adjustment to revenue on a cumulative catch-up basis.

The Company receives payments from its licensees as established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Where applicable, amounts are recorded as unbilled revenue when the Company's right to consideration is unconditional. The Company does not assess whether a contract with a customer has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

Research and Development Costs

Research and development costs are charged to expense as incurred and consist of costs incurred to further the Company's research and development activities and include salaries and related employee benefits, costs associated with clinical trials, costs related to pre-commercialization manufacturing activities such as manufacturing process validation activities and the manufacturing of clinical drug supply, nonclinical research and development activities, regulatory activities, research-related overhead expenses and fees paid to external service providers and contract research and manufacturing organizations that conduct certain research and development activities on behalf of the Company.

Accrued Research and Development Expenses

The Company is required to estimate its accrued expenses at the end of each reporting period. This process involves reviewing open contracts and purchase orders, communicating with Company personnel to identify services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual costs. The majority of the Company's service providers submit invoices in arrears for services performed or when contractual milestones are met. The Company makes estimates of its accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to the Company at that time. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- contract research organizations, or CROs, in connection with clinical studies;

- investigative sites in connection with clinical studies;
- vendors related to product manufacturing, development and distribution of clinical supplies; and
- vendors in connection with preclinical development activities.

The Company records expenses related to clinical studies and manufacturing development activities based on its estimates of the services received and efforts expended pursuant to contracts with multiple CROs and manufacturing vendors that conduct and manage these activities on the Company's behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which services will be performed, enrollment of subjects, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the Company's estimate, the Company will adjust the accrued or prepaid expense balance accordingly.

Stock-Based Compensation

The Company recognizes compensation expense for all stock-based payment awards made to employees, nonemployees and directors based on estimated fair values. For employee and nonemployee stock options, the Company determines the grant date fair value of the awards using the Black-Scholes option-pricing model and generally recognizes the fair value as stock-based compensation expense on a straight-line basis over the vesting period of the respective awards. For restricted stock and performance-based restricted stock, to the extent they are probable, the compensation cost for these awards is based on the closing price of the Company's common stock on the date of grant and recognized as compensation expense on a straight-line basis over the requisite service period. Stock-based compensation expense is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, the Company's stock-based compensation is reduced for the estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Derivatives and Hedging Activities

The Company accounts for its derivative instruments as either assets or liabilities on the balance sheet and measures them at fair value. Derivatives are adjusted to fair value through other income (expense), net in the statements of operations and comprehensive loss.

Leases

The Company determines if an arrangement is a lease at the inception of the arrangement. Operating leases are included in right-of-use assets, current portion of operating lease liability, and operating lease liability, net of current portion in our balance sheets. Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date. The operating lease right-of-use assets also include any lease payments made and exclude lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term. The Company has elected not to separate lease and non-lease components, such as common area maintenance charges, and instead it accounts for these as a single lease component.

Comprehensive Loss

Comprehensive loss is composed of two components: net loss and other comprehensive income (loss). Other comprehensive income (loss) refers to gains and losses that are recorded as an element of stockholders' equity but are excluded from net loss.

Net Loss per Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of potential common shares. Diluted net loss per common share in the periods presented is the same as basic net loss per common share, since the effects of potentially dilutive securities are antidilutive due to the net loss for all periods presented.

Recent Accounting Pronouncements

New Accounting Pronouncements - Recently Adopted

In December 2019, as part of its initiative to reduce complexity in the accounting standards, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. ASU 2019-12 also clarifies and simplifies other aspects of the accounting for income taxes. The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company early adopted ASU 2019-12 on April 1, 2020 and this adoption had no material impact on the Company's financial position or results of operations.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* ("ASU 2018-18"), which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under the FASB's Accounting Standards Codification ("ASC") No. 606, *Revenue from Contracts with Customers* ("ASC 606") when the collaborative arrangement participant is a customer. The Company adopted ASU 2018-18 on January 1, 2020, and the adoption of this standard did not have a material impact on the Company's financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which considers cost and benefits and removes, modifies and adds disclosure requirements in Topic 820. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements and the narrative description of measurement uncertainty is to be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments were to be applied retrospectively to all periods presented. The Company adopted ASU 2018-13 on January 1, 2020, and the adoption of this standard did not have a material impact on the Company's financial statements.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles (Topic 350): *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. The amendments in this Update align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). This ASU requires a customer in a cloud computing arrangement (i.e. hosting arrangement) that is a service contract to follow the internal-use software guidance in ASC 350-40 to determine which implementation costs to capitalize as assets or expense as incurred. ASC 350-40 requires that certain costs incurred during the application development stage be capitalized and other costs incurred during the preliminary project and post-implementation stages be expensed as incurred. We adopted this ASU on January 1, 2020 and the adoption of this standard did not have a material impact on our financial statements.

In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, which provides temporary optional guidance to companies impacted by the transition away from the London Interbank Offered Rate ("LIBOR"). The guidance provides certain expedients and exceptions to applying GAAP in order to lessen the potential accounting burden when contracts, hedging relationships, and other transactions that reference LIBOR as a benchmark rate are modified. This guidance was effective upon issuance and expires on December 31, 2022. The Company adopted ASU 2020-04 on April 1, 2020, and the adoption of this standard did not have a material impact on the Company's financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, an amendment which modifies the measurement and recognition of credit losses for most financial assets and certain other instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. Accordingly, these financial assets will be presented at the net amount expected to be collected. The amendment also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. For smaller reporting companies the guidance is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. Management is currently assessing the impact of this standard on the Company's financial statements.

3. CASH AND INVESTMENTS

Securities classified as cash and investments as of December 31, 2020 and December 31, 2019 are summarized below (in thousands). Estimated fair value is based on quoted market prices for these investments.

	December 31, 2020			
		Gross Unrealized		
	Amortized Cost	Gains	Losses	Fair Value
Cash and cash equivalents:				
Money market funds	$ 88,151	$ —	$ —	$ 88,151
Commercial paper	2,100	—	—	2,100
Cash	781	—	—	781
Total cash and cash equivalents	91,032	—	—	91,032
Short-term investments:				
Commercial paper	$ 60,631	$ 2	$ (4)	$ 60,629
Corporate bonds	24,547	3	(6)	24,544
U.S. government-sponsored agency bonds	9,277	2	—	9,279
U.S. treasury notes	1,000	—	—	1,000
Total short-term investments	95,455	7	(10)	95,452
Long-term investments:				
Corporate bonds	$ 2,115	$ —	$ (1)	$ 2,114
Total cash equivalents and investments	$ 188,602	$ 7	$ (11)	$ 188,598

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Money market funds	$ 147,208	$ —	$ —	$ 147,208
Commercial paper	19,357	3	—	19,360
Corporate bonds	11,441	—	—	11,441
Cash	3,124	—	—	3,124
Total cash and cash equivalents	181,130	3	—	181,133
Short-term investments				
Commercial paper	$ 36,667	$ 14	$ —	$ 36,681
Corporate bonds	21,690	6	(3)	21,693
Asset-backed securities	8,005	—	—	8,005
Total short-term investments	66,362	20	(3)	66,379
Total cash equivalents and short-term investments	$ 247,492	$ 23	$ (3)	$ 247,512

Cash equivalents consist of money market funds and other debt securities with original maturities of three months or less at the time of purchase, and the carrying amount is a reasonable approximation of fair value. The Company invests its cash in high quality securities of financial and commercial institutions. These securities are carried at fair value, which is based on readily available market information, with unrealized gains and losses included in accumulated other comprehensive income (loss) within stockholders' equity on the Company's balance sheets. The Company uses the specific identification method to determine the amount of realized gains or losses on sales of marketable securities. Realized gains or losses have been insignificant and are included in other income (expense), net, in the statement of operations.

As of December 31, 2020, the Company held both short- and long-term investments. All short-term available-for-sale securities held as of December 31, 2020 and 2019, had contractual maturities of less than one year. The long-term securities held as of December 31, 2020 had contractual maturities greater than one year. The Company's available-for-sale securities are subject to a periodic impairment review. The Company considers a debt security to be impaired when its fair value is less than its carrying cost, in which case the Company would further review the investment to determine whether it is other-than-temporarily impaired. When the Company evaluates an investment for other-than-temporary impairment, the Company reviews factors such as the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and any changes thereto, intent to sell, and whether it is more likely than not the Company will be required to sell the investment before the recovery of its cost basis. If an investment is other-than-temporarily impaired, the Company writes it down through the statement of operations to its fair value and establishes that value as a new cost basis for the investment. The Company did not identify any of its available-for-sale securities as other-than-temporarily impaired in any of the periods presented. As of December 31, 2020 and 2019, no investment was in a continuous unrealized loss position for more than one year and the Company believes that it is more likely than not that the investments will be held until maturity or a forecasted recovery of fair value.

As of December 31, 2020, the amortized cost and estimated fair value of available-for-sale debt securities by contractual maturity were as follows (in thousands):

	Amortized Cost	Fair Value
Due in one year or less	$ 95,455	$ 95,452
Due in one to two years	2,115	2,114
Total	$ 97,570	$ 97,566

4. FAIR VALUE MEASUREMENTS

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market

participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.
The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

Level 1 – Valuations are based on quoted prices in active markets for identical assets or liabilities and readily accessible by the Company at the reporting date. Examples of assets and liabilities utilizing Level 1 inputs are certain money market funds, U.S. treasuries and trading securities with quoted prices on active markets.

Level 2 – Valuations based on inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Examples of assets and liabilities utilizing Level 2 inputs are corporate bonds, commercial paper, certificates of deposit and over-the-counter derivatives.

Level 3 – Valuations based on unobservable inputs in which there is little or no market data, which require the Company to develop its own assumptions.

The following table sets forth the fair value of the Company's financial assets and liabilities measured on a recurring basis by level within the fair value hierarchy (in thousands):

	December 31, 2020			
	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 88,151	$ 88,151	$ —	$ —
Commercial paper	62,729	—	62,729	—
Corporate bonds	26,658	—	26,658	—
U.S. government-sponsored agency bonds	9,279	—	9,279	
U.S. treasury notes	1,000	—	1,000	—
Total	$ 187,817	$ 88,151	$ 99,666	$ —
Liabilities:				
Derivative liability for Exit Fee	$ 1,376	$ —	$ —	$ 1,376
Total	$ 1,376	$ —	$ —	$ 1,376

	December 31, 2019			
	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 147,208	$ 147,208	$ —	$ —
Commercial paper	56,041	—	56,041	—
Corporate bonds	33,134	—	33,134	—
Asset-backed securities	8,005	—	8,005	—
Total	$ 244,388	$ 147,208	$ 97,180	$ —
Liabilities:				
Derivative liability for Exit Fee	$ 969	$ —	$ —	$ 969
Total	$ 969	$ —	$ —	$ 969

Where quoted prices are available in an active market, securities are classified as Level 1. The Company classifies money market funds, U.S. treasury securities and U.S. treasury notes as Level 1. When quoted market prices are not available for the specific security, the Company estimates fair value by using benchmark yields, reported trades, broker/dealer quotes and issuer spreads. The Company classifies corporate bonds, commercial paper, asset-backed

securities and foreign currency derivative contracts as Level 2. In certain cases, where there is limited activity or less transparency around inputs to valuation, securities or derivative liabilities such as the Exit Fee, as defined and discussed in Note 6, are classified as Level 3.

The carrying amounts reflected in the balance sheets for cash equivalents, short-term investments, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values at both December 31, 2020 and December 31, 2019, due to their short-term nature.

Fair Value of Debt

The interest rate of the Company's term loan facility approximates the rate at which the Company could obtain alternative financing. Therefore, the carrying amount of the term loan facility approximated its fair value at December 31, 2020 and 2019.

5. DERIVATIVE LIABILITY

Exit Fee

In May 2018, in connection with entering into the Loan Agreement, as defined and discussed in Note 6, the Company entered into an agreement pursuant to which the Company agreed to pay $1.5 million in cash, or the Exit Fee, upon any change of control transaction in respect of the Company or if the Company obtains both (i) FDA approval of tenapanor for the treatment of hyperphosphatemia in CKD patients on dialysis and (ii) FDA approval of tenapanor for the treatment of patients with irritable bowel syndrome with constipation, or IBS-C, which was obtained on September 12, 2019 when the FDA approved IBSRELA® (tenapanor), a 50 mg, twice daily oral pill for the treatment of IBS-C, in adults (the "Exit Fee Agreement"). Notwithstanding the prepayment or termination of the Term Loan, the Company's obligation to pay the Exit Fee will expire on May 16, 2028. The Company concluded that the Exit Fee is a freestanding derivative which should be accounted for at fair value on a recurring basis. The estimated fair value of the Exit Fee is recorded as a derivative liability and included in accrued expense and other current liabilities on the accompanying balance sheets.

The fair value of the derivative liability was determined using a discounted cash flow analysis and is classified as a Level 3 measurement within the fair value hierarchy since the Company's valuation utilized significant unobservable inputs. Specifically, the key assumptions included in the calculation of the estimated fair value of the derivative instrument include: i) the Company's estimates of both the probability and timing of a potential $1.5 million payment to Solar Capital Ltd. and Western Alliance Bank as a result of the FDA approvals, and ii) a discount rate which was derived from the Company's estimated cost of debt, adjusted with current LIBOR. Generally, increases or decreases in the probability of occurrence would result in a directionally similar impact in the fair value measurement of the derivative instrument and it is estimated that a 10% increase (decrease), not to exceed 100%, in the probability of occurrence would result in a fair value fluctuation of no more than $0.1 million.

Changes in the fair value of recurring measurements included in Level 3 of the fair value hierarchy are presented as other income (expense), net in the Company's statements of operations and were as follows for the years ended December 31, 2020, 2019 and 2018 (in thousands):

	2020	2019	2018
Fair value of Exit Fee derivative liability at January 1	$ 969	$ 533	—
Change in estimated fair value of derivative liability	407	436	533
Fair value of Exit Fee derivative liability at December 31	$ 1,376	$ 969	$ 533

6. BORROWINGS

Solar Capital and Western Alliance Bank Loan Agreement

On May 16, 2018, the Company entered into a loan and security agreement, or the Loan Agreement, with Solar Capital Ltd. and Western Alliance Bank ("the Lenders"). The Loan Agreement provides for a $50.0 million term loan facility with

a maturity date of November 1, 2022 (”the Term Loan”). The full amount of the Tern Loan was funded on May 16, 2018. The Company received net proceeds from the loan of approximately $49.3 million, after deducting the closing fee, legal expenses and issuance costs. On October 9, 2020, the Company and the Lenders entered into an amendment to the Loan Agreement (“the 2020 Amendment”) to extend the date through which the Company is permitted to make interest-only payments on the Term Loan by twelve months to December 1, 2021 subject to the repayment terms noted below.

Borrowings under the Term Loan bear interest at a floating per annum rate equal to 7.45% plus the one-month London Inter-bank Offered Rate, or LIBOR. The Company was permitted to make interest-only payments on the Term Loan through June 1, 2020, until it achieved its primary endpoint in the Phase 3 study of tenapanor for the treatment of hyperphosphatemia in end-stage renal disease patients on dialysis, prior to June 1, 2020, in which case the Company would have been permitted to make interest-only payments on the Term Loan through December 1, 2020. On December 3, 2019, the Company reported positive topline results for PHREEDOM, a long-term Phase 3 study evaluating the efficacy and safety of tenapanor as monotherapy for the treatment of hyperphosphatemia in patients with CKD on dialysis. The Lenders were in agreement that these positive data from the Phase 3 PHREEDOM study achieve the “Phase 3 Endpoint” required by the Term Loan to extend the interest only period by six months to December 1, 2020. Subsequent to the 2020 Amendment, the interest only period was extended an additional twelve months to December 1, 2021. Accordingly, beginning on December 1, 2021 through the maturity date, the Company will be required to make monthly payments of interest plus repayment of the Term Loan in consecutive equal monthly installments of principal. If however, either the FDA does not approve the Company’s New Drug Application for tenapanor for control of serum phosphorus in adult CKD on dialysis on or before May 31, 2021 or the FDA issues a complete response letter (“CRL”) for tenapanor for the control of serum phosphorus in adult CKD on dialysis, then the Company is to begin principal payments on the earlier of June 1, 2021 or the first day of the month immediately following the date that the FDA issues a CRL to the Company. The Company paid a closing fee of $0.5 million, upon the closing of the Term Loan and $0.1 million upon closing of the 2020 Amendment. Under the Term Loan, the Company was obligated to pay a final fee equal to 3.95% of the Term Loan upon the earliest to occur of the maturity date, the acceleration of the Term Loan, the prepayment or repayment of the Term Loan or the termination of the Loan Agreement. Under the 2020 Amendment, the final fee was increased to 4.95% of the Term Loan. The Company may voluntarily prepay the outstanding Term Loan, subject to a prepayment premium of (i) 3% of the principal amount of the Term Loan if prepaid prior to or on the first anniversary of the Closing Date, (ii) 2% of the principal amount of the Term Loan if prepaid after the first anniversary of the Closing Date through and including the second anniversary of the Closing Date, or (iii) 1% of the principal amount of the Term Loan if prepaid after the second anniversary of the Closing Date and prior to the maturity date. The Term Loan is secured by substantially all the Company’s assets, except for the Company’s intellectual property and certain other customary exclusions. Additionally, in connection with the Term Loan, the Company entered into the Exit Fee Agreement, as discussed in Note 4.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including restrictions on payment of dividends for our common stock. As of December 31, 2020, the Company was in compliance with all of the covenants set forth in the Loan Agreement.

In addition, the Loan Agreement contains customary events of default that entitle the Lender to cause the Company’s indebtedness under the Loan Agreement to become immediately due and payable, and to exercise remedies against the Company and the collateral securing the Term Loan, including its cash. Upon the occurrence and for the duration of an event of default, an additional default interest rate equal to 4.0% per annum will apply to all obligations owed under the Loan Agreement. As of December 31, 2020, to the Company’s knowledge, there were no facts or circumstances in existence that would give rise to an event of default.

As of December 31, 2020, the Company's future debt payment obligations towards the Term Loan principal and final fee, excluding interest payments and the Exit Fee are as follows (in thousands):

2021	$ 4,167
2022	48,308
Total repayment obligations	$ 52,475
Less: Unamortized discount and debt issuance costs	(518)
Less: Unaccreted value of final fee	(1,169)
Loan payable	50,788
Less: Loan payable, current portion	(4,167)
Loan payable, net of current portion	$ 46,621

7. STOCKHOLDERS' EQUITY

In July 2020, the Company filed a Form S-3 registration statement, which became effective in August 2020, containing (i) a base prospectus for the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $250.0 million of the Company's common stock, preferred stock, debt securities, warrants and/or units, from time to time in one or more offerings; and (ii) a prospectus supplement for the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $100.0 million of its common stock that may be issued and sold, from time to time, under an Open Market Sales Agreement with Jefferies LLC, as sales agent, deemed to be "at the market offerings." As of December 31, 2020, we had sold 3.3 million shares of our common stock for aggregate gross proceeds of $21.7 million at a weighted average price of $6.65 per share under the Open Market Sales Agreement. From the period of January 2, 2021 through February 28, 2021, we sold an additional 4.9 million shares of our common stock for aggregate gross proceeds of $35.0 million at a weighted average price of $7.09 per share. In aggregate during the life of the Open Market Sales Agreement, we have sold 8.2 million shares of our common stock for aggregate gross proceeds of $56.7 million at a weighted average sales price of approximately $6.91 per share. Pursuant to the Open Market Sales Agreement, Jefferies, as sales agent, receives a commission of up to 3.0% of the gross sales price for shares of common stock sold under the Open Market Sales Agreement.

On December 9, 2019, the Company completed an underwritten public offering of 20.0 million shares of common stock at a price of $6.25 per share before underwriting discounts and commissions, or the 2019 Offering. In connection with the 2019 Offering, the Company entered into an underwriting agreement, or the 2019 Underwriting Agreement, with Citigroup Global Markets Inc., Cowen and Company LLC, SVB Leerink LLC and Piper Jaffray & Co., or collectively the 2019 Underwriters, pursuant to which the Company granted to the 2019 Underwriters a 30-day option to purchase up to an additional 3.0 million shares of the Company's common stock, or the 2019 Overallotment. The Company completed the sale of 23.0 million shares, inclusive of the 2019 Overallotment, to the 2019 Underwriters and that sale resulted in the receipt by the Company of aggregate gross proceeds of approximately $143.8 million, less underwriting discounts, commissions and offering expenses totaling approximately $8.9 million, which resulted in net proceeds of approximately $134.9 million.

On November 22, 2019, the Company and KKC entered into a stock purchase agreement, pursuant to which the Company sold an aggregate of approximately 2.9 million shares of its common stock at $6.96 per share for net proceeds of approximately $20.0 million, or the Private Placement. The Private Placement closed on November 25, 2019.

On May 25, 2018, the Company completed an underwritten public offering of 12.5 million shares of common stock at a price of $4.00 per share before underwriting discounts and commissions, or the 2018 Offering. In connection with the 2018 Offering, the Company entered into an underwriting agreement, or the 2018 Underwriting Agreement, with Jefferies LLC and SVB Leerink (formerly known as Leerink Partners LLC) (together the "2018 Underwriters") pursuant to which the Company granted to the 2018 Underwriters a 30-day option to purchase up to an additional 1.9 million shares of the Company's common stock, or the 2018 Overallotment. The Company completed the sale of 14.4 million shares, inclusive of the 2018 Overallotment, to the 2018 Underwriters, and that sale resulted in the receipt by the Company of aggregate gross proceeds of approximately $57.5 million, less underwriting discounts, commissions and offering expenses totaling approximately $3.7 million, which resulted in net proceeds of approximately $53.8 million.

In June 2015, the Company sold and issued warrants to purchase 2.2 million shares of common stock. The purchase price for the warrants was $0.125 per warrant. The warrants were exercisable for an exercise price of $13.91 per share at any time prior to the earlier of (i) 5 years from the date of issuance or (ii) certain changes in control of the Company. In June 2020, the warrants expired with none of the warrants exercised.

8. EQUITY INCENTIVE PLANS

2008 Plan

The Company granted options under its 2008 Stock Incentive Plan (the "2008 Plan") until June 2014 when it was terminated as to future awards, although it continues to govern the terms of options that remain outstanding under the 2008 Plan. The 2008 Plan provided for the granting of incentive and non-qualified stock options, and stock purchase rights to employees, directors and consultants at the discretion of the Board of Directors. Stock options granted generally vest over a period of four years from the date of grant. In connection with the Board of Directors and stockholders' approval of the 2014 Plan, all remaining shares available for future award under the 2008 Plan were transferred to 2014 Plan, and the 2008 Plan was terminated.

2014 Plan

The 2014 Equity Incentive Award Plan (the "2014 Plan") became effective on June 18, 2014. Under the 2014 Plan, 1,419,328 shares of common stock were initially reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, or SARs, restricted stock awards, service-based restricted stock unit ("RSU") awards, performance-based restricted stock unit ("PRSU") awards, deferred stock awards, deferred stock unit awards, dividend equivalent awards, stock payment awards and performance awards. In addition, 35 thousand shares that had been available for future awards under the 2008 Plan as of June 18, 2014, were added to the initial reserve available under the 2014 Plan, bringing the total reserve upon the effective date of the 2014 Plan to 1.5 million shares. The number of shares initially reserved for issuance or transfer pursuant to awards under the 2014 Plan will be increased by (i) the number of shares represented by awards outstanding under 2008 Plan on June 18, 2014, that are either forfeited or lapse unexercised or that are repurchased for the original purchase price thereof, up to a maximum of 1.2 million shares, and (ii) if approved by the Administrator of the 2014 Plan, an annual increase on the first day of each fiscal year ending in 2024 equal to the lesser of (A) four percent (4.0%) of the shares of stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (B) such smaller number of shares of stock as determined by our board of directors; provided, however, that no more than 10.7 million shares of stock may be issued upon the exercise of incentive stock options.

2016 Plan

In November 2016, the Company's board of directors approved the 2016 Employment Commencement Incentive Plan (the "Inducement Plan") under which 1.0 million shares were reserved. As of December 31, 2020, 0.4 million shares of the Company's common stock were subject to inducement grants that were issued pursuant to the Inducement Plan.

Stock Plan Activity

The following table summarizes activity under the 2008 Plan and the 2014 Plan, including grants issued to nonemployees, in the year ended December 31, 2020:

	Shares Available for Grant	Options Issued and Outstanding			Weighted Average Remaining Contractual Term (in Years)		Aggregate Intrinsic Value (in thousands)
		Number of Shares		Weighted-Average Exercise Price per Share			
Balance at December 31, 2019	1,196,746	7,272,768	$	6.55			
Options authorized	3,552,709	—	$	—			
Options granted	(3,727,947)	3,727,947	$	6.89			
Options exercised	—	(445,942)	$	2.29			
Options canceled	764,724	(764,724)	$	8.03			
Issuance of common stock for services	(42,403)	—		—			
Forfeitures of PRSUs granted in prior years	13,229	—		—			
Balance at December 31, 2020	1,757,058	9,790,049	$	6.76	7.44	$	12,797
Vested and expected to vest at December 31, 2020		9,790,049	$	6.76	7.44	$	12,797
Exercisable at December 31, 2020		5,230,640	$	7.53	6.23	$	7,765

The aggregate intrinsic value represents the difference between the total pre-tax value (i.e., the difference between the Company's stock price and the exercise price) of stock options outstanding as of December 31, 2020, based on the Company's common stock closing price of $6.47 per share, which would have been received by the option holders had all their in-the-money options been exercised as of that date.

The intrinsic value of options exercised during the years ended December 31, 2020, 2019 and 2018, was $2.7 million, $0.4 million, and zero, respectively.

The weighted-average grant-date estimated fair value of options granted during the years ended December 31, 2020, 2019 and 2018 was $4.82, $1.79 and $4.29 per share, respectively. The estimated grant date fair value of employee stock options was calculated using the Black-Scholes option-pricing model, based on the following weighted-average assumptions:

	Year Ended December 31, 2020
Expected term (years)	6.00
Expected volatility	83 %
Risk-free interest rate	1.07 %
Dividend yield	— %

Expected Term—The Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock-option grants. As such, the expected term was estimated using the simplified method whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option.

Expected Volatility—Since January 1, 2017, the Company has used the historic volatility of its own stock over the retrospective period corresponding to the expected remaining term of the options, or the period since its shares were first quoted on The Nasdaq Global Market, if that is shorter, to compute its expected stock price volatility.

Risk-Free Interest Rate—The risk-free interest rate assumption is based on the zero-coupon U.S. treasury instruments on the date of grant with a maturity date consistent with the expected term of the Company's stock option grants.

Dividend Yield—To date, the Company has not declared or paid any cash dividends and does not have any plans to do so in the future. Therefore, the Company used an expected dividend yield of zero.

Restricted Stock Units

The following table summarizes restricted stock unit activity under the 2014 Plan in the year ended December 31, 2020, and includes restricted stock units with time or service-based vesting and those restricted stock units with performance-based vesting:

	Number of RSUs	Weighted-Average Grant Date Fair Value Per Share	Number of PRSUs	Weighted-Average Grant Date Fair Value Per Share
Non-vested restricted stock units at December 31, 2019	—	$ —	849,757	$ 4.30
Granted	158,626	$ 5.64	30,000	$ 7.58
Vested	—	$ —	(866,528)	$ 4.41
Forfeited	—	$ —	(13,229)	$ 4.30
Non-vested restricted stock units at December 31, 2020	158,626	$ 5.64	—	$ —

In July 2018, the Company granted 0.9 million PRSUs to its employees that vest upon the achievement of certain performance conditions, subject to the employees' continued service relationship with the Company through the achievement date. During 2020, the Company granted an additional 30 thousand PRSUs subject to the same performance conditions. All 0.9 million of these PRSUs vested in September 2020. None of these PRSUs vested during the years ended December 31, 2019 or 2018. The Company recognized $1.2 million and zero of related expense during the year ended December 31, 2020 and 2019, respectively.

The Company recognized $30 thousand, $0.3 million and $0.9 million of RSU related expense during the year ended December 31, 2020, 2019 and 2018, respectively. The total estimated fair value of RSUs vested during the years ended December 31, 2020, 2019 and 2018 was zero, $0.2 million and $0.6 million, respectively.

Issuance of Common Stock for Services

During the years ended December 31, 2020, 2019 and 2018, the Company issued approximately 42 thousand, 113 thousand and 75 thousand shares, respectively, of common stock to members of the board of directors who elected to receive stock in lieu of their cash fees under the Company's Non-Employee Director Compensation Program. The shares issued during the years ended December 31, 2020, 2019 and 2018 were valued at $0.3 million for each year, respectively, based on the fair value of the common stock on the date of grant.

Employee Stock Purchase Plan

The Company adopted the 2014 Employee Stock Purchase Plan ("ESPP") and initially reserved approximately 0.2 million shares of common stock as of its effective date of June 18, 2014. If approved by the Administrator of the ESPP, on the first day of each calendar year, ending in 2024, the number of shares in the reserve will increase by an amount equal to the lesser of (i) one percent (1.0%) of the shares of common stock outstanding on the last day of the immediately preceding fiscal year and (ii) such number of shares of common stock as determined by the board of directors; provided, however, no more than 2,230,374 shares of our common stock may be issued under the ESPP.

The following table summarizes ESPP activity in the year ended December 31, 2020:

	Shares Available for Grant	Number of Shares Purchased	Purchase Price per Share	Gross Proceeds (in thousands)
Balance at December 31, 2019	519,578	491,680		
Shares purchased	(169,931)	169,931	$ 4.91	$ 834
Balance at December 31, 2020	349,647	661,611		

The following table illustrates the weighted-average assumptions for the Black-Scholes option-pricing model used in determining the fair value of ESPP purchase rights granted to employees:

	Year Ended December 31, 2020
Expected term (years)	0.5
Expected volatility	79.4 %
Risk-free interest rate	0.48 %
Dividend yield	— %

Stock-based Compensation

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

	Year Ended December 31,		
	2020	2019	2018
Research and development	$ 4,061	$ 4,104	$ 3,666
General and administrative	6,522	5,832	5,560
Total	$ 10,583	$ 9,936	$ 9,226

At December 31, 2020, the Company had total unrecognized stock-based compensation expense, net of estimated forfeitures, of the following (dollars in thousands):

	At December 31, 2020	
	Unrecognized Compensation Expense	Average Remaining Vesting Period (Years)
Stock options grant	$ 17,662	2.8
RSU grants	$ 860	3.9
ESPP	$ 108	0.1

9. PROPERTY AND EQUIPMENT

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

	December 31,	
	2020	2019
Laboratory equipment	$ 7,268	$ 7,243
Office equipment and furniture	1,133	870
Leasehold improvements	7,985	7,949
Property and equipment, gross	16,386	16,062
Less: accumulated depreciation	(14,450)	(12,626)
Total property and equipment, net	$ 1,936	$ 3,436

Depreciation expense totaled $1.8 million, $2.5 million, and $2.7 million for the years ended December 31, 2020, 2019 and 2018, respectively.

10. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	December 31,	
	2020	2019
Accrued clinical expenses	$ 2,197	$ 3,451
Accrued contract manufacturing expenses	1,840	1,414
Derivative liability for exit fee	1,376	969
Accrued sales and marketing expenses	593	122
Accrued professional and consulting services	243	201
Accrued regulatory services	123	342
Other	285	749
	$ 6,657	$ 7,248

11. LEASES

The Company has recorded right-of-use operating lease assets under three lease agreements. The Company has evaluated its facility leases and determined that, effective upon the adoption of Topic 842, the leases evaluated are all operating leases. The Company has performed an evaluation of its other contracts with suppliers and collaborators in accordance with Topic 842 and has determined that, except for the facility leases described below, none of the Company's contracts contain a lease.

The Company has recorded a right-of-use operating lease asset located in Fremont, California under a lease agreement entered into in September 2008 that was amended in December 2012 to extend the lease agreement to September 2016. In September 2014, the Company signed the second amendment to its facility lease agreement to add space and to extend the lease term through September 2019. In May 2016, the Company signed a third amendment to its facility lease agreement in Fremont, California to add space and to extend the lease term through September 2021 (the "Third Amendment"). The office space consists of 72,500 square feet, that includes an additional 10,716 square feet added in September 2019, with the entire lease terminating in September 2021. The Company will not exercise its option to renew the lease at our current Fremont location and expect to enter into a new facility lease in Fremont, California during the first quarter of 2021.

The Company has recorded a right-of-use operating lease asset located in Waltham, Massachusetts under a lease agreement entered into in October 2018. The office space consists of 3,520 square feet with the lease terminating in September 2021. We have not renewed the lease at our current Waltham, Massachusetts facility. During December 2020, we entered into a new lease agreement for a different location in Waltham, Massachusetts which has an expected lease commencement date in April 2021.

The Company has recorded a right-of-use operating lease asset located in Milwaukee, Wisconsin under a lease agreement entered into in October 2020 with a lease commencement date in November 2020. The office space consists of 4,768 square feet with the lease terminating in February 2026. The Company has an option to extend the lease term by one five-year period. This option to extend the lease term has not been included in the calculation since currently the exercise of the option is uncertain and therefore deemed not probable. The Company recorded a $0.4 million right-of use asset and lease liability for the Milwaukee lease upon commencement of the lease.

All of the Company's leases are operating leases and each contain customary rent escalation clauses. Certain of the leases have both lease and non-lease components. The Company has elected to account for each separate lease component and the non-lease components associated with that lease component as a single lease component for all classes of underlying assets. As of December 31, 2020, the weighted average discount rate used for the calculations was 11.7% and the weighted average remaining lease term was 1.5 years.

The following table provides additional details of the leases presented in the balance sheets (dollars in thousands):

Facilities	
Right-of-use assets	$ 2,274
Current portion of lease liabilities	2,117
Operating lease liability, net of current portion	413
Total	$ 2,530
Weighted-average remaining life (years)	1.50
Weighted-average discount rate	11.7 %

The lease costs, which are included in operating expenses in our statements of operations, were as follows (in thousands):

	Year Ended December 31,	
	2020	**2019**
Operating lease expense	$ 2,608	$ 2,592
Cash paid for operating lease	$ 3,065	$ 2,645

The following table summarizes the Company's undiscounted cash payment obligations for its operating lease liabilities as of December 31, 2020 (in thousands):

Ending December 31,	
2021	$ 2,280
2022	104
2023	111
2024	115
2025	119
Thereafter	20
Total undiscounted operating lease payments	2,749
Imputed interest expenses	(219)
Total operating lease liabilities	2,530
Less: Current portion of operating lease liability	2,117
Operating lease liability, net of current portion	$ 413

Rent expense under operating leases was $2.6 million, $2.6 million and $1.8 million for the years ended December 31, 2020, 2019 and 2018, respectively.

12. COLLABORATION AND LICENSING AGREEMENTS

Kyowa Kirin Co., Ltd. (2019 KKC Agreement)

In November 2019, the Company entered into a research collaboration and option agreement with KKC ("the 2019 KKC Agreement"), to undergo research to identify two pre-clinical study-ready compounds for designation as development compounds, with one compound inhibiting the first undisclosed target ("Program 1") and a second inhibiting the second undisclosed target ("Program 2"). Pursuant to the 2019 KKC Agreement, upon completion of the research and designation by the research steering committee of one or more development candidates ("DCs"), KKC has the right to execute one or more separate collaborative agreements relating to the development and commercialization of one or both DCs in certain specified territories.

Under the terms of the 2019 KKC Agreement, KKC agreed to pay the Company a non-refundable, non-creditable upfront fee of $10.0 million, which was payable as follows: the first installment of $5.0 million within 30 days of the Effective Date, and the second installment of $5.0 million on the first anniversary of the Effective Date, unless the 2019 KKC Agreement was earlier terminated by KKC due to material breach by the Company. The term of the 2019 KKC Agreement commenced on November 11, 2019 ("the Effective Date") and ends on the earliest of: (a) two years following the Effective Date, or (b) the nomination of a program DC for both programs, (c) or the nomination of one program DC and the decision by the parties to cease research for the other program, (d) or the decision by the parties to cease research for both programs. The Company assessed the 2019 KKC Agreement in accordance with ASC 606 and concluded that the contract's counterparty, KKC, is a customer. Management also considered the modification guidance prescribed in ASC 606 and concluded that the 2019 KKC Agreement should be accounted for as a separate contract from the 2017 KKC Agreement, as defined and discussed below.

The Company identified various promises in the 2019 KKC Agreement, including the grant of an initial research license, the Program 1 research, the Program 2 research, the right to obtain certain development and commercialization rights with Program 1 in certain territories and the right to obtain development and commercialization rights with Program 2 in certain territories, and participation in a joint steering committee ("the JSC") and determined that KKC could not benefit from either of the research programs without the research license and participation in the JSC. As such, the combined license, research programs and participation in the JSC were deemed to be the highest level of goods and services that can be deemed distinct for each of the Program 1 research and Program 2 research. The Company concluded that the options to obtain additional development and commercialization rights that are exercisable by KKC under certain circumstances are not performance obligations of the contract at inception because the option fees reflect the standalone selling price of the options, and therefore, the options are not considered to be material rights.

At the outset of the 2019 KKC Agreement, the Company determined that the initial transaction price is $10.0 million and that revenue associated with the combined performance obligations will be recognized as services are provided using the input method. Since transfer of control occurs over time, in management's judgment this input method is the best measure of progress towards satisfying the performance obligations and reflects a faithful depiction of the transfer of goods and services. Revenue will be recognized over the Program 1 and Program 2 research periods. Management will re-evaluate the estimates related to the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur and adjust the timing of revenue recognition as necessary.

During the years ended December 31, 2020 and 2019, the Company recognized $5.4 million and $0.5 million, respectively, as revenue under the 2019 KKC Agreement in the statement of operations and comprehensive loss. The aggregate amount of the transaction price allocated to the Company's partially unsatisfied performance obligations as of December 31, 2019 was $9.5 million, of which $4.5 million was presented in the balance sheet as deferred revenue for the respective period. As of December 31, 2020, the Company expects to recognize the remaining transaction price allocated to the Company's partially unsatisfied performance obligations over the remaining research terms, which are currently expected to extend through the end of 2021.

Xuanzhu (HK) Biopharmaceutical Limited, or XuanZhu

In November 2019, the Company entered into a license agreement with XuanZhu ("the XuanZhu Agreement for a license to certain specific patent and patent applications. The Company assessed these arrangements in accordance with ASC 606 and concluded that the contract counterparty, XuanZhu, is a customer. Under the terms of the XuanZhu Agreement, the Company recognized $1.5 million in license fees when the agreement was executed, of which, $0.8 million was received upfront in November 2019 and achievement for the second $0.8 million payment was determined to be not materially at risk and probable of achievement and it was included in the transaction price and the amount was not probable of revenue reversal. Based on the Company's assessment, it identified that it has one combined performance obligation, which is the license and the specific patent grant.

In addition to the license fee of $1.5 million, the Company may be entitled to receive milestone payments. The variable consideration related to the remaining milestone payments has not been included in the transaction price as these were fully constrained at December 31, 2019.

For the years ended December 31, 2020 and 2019, zero and $1.5 million, respectively, of license revenue was recorded with no cost of revenue related to the XuanZhu Agreement.

2017 KKC Agreement

In November 2017, the Company entered into an exclusive license agreement with KKC, or the 2017 KKC Agreement, for the development, commercialization and distribution of tenapanor in Japan for cardiorenal indications. The Company granted KKC an exclusive license to develop and commercialize certain NHE3 inhibitors including tenapanor in Japan for the treatment of cardiorenal diseases and conditions, excluding cancer. The Company retained the rights to tenapanor outside of Japan, and also retained the rights to tenapanor in Japan for indications other than those stated above. Pursuant to the License Agreement, KKC is responsible for all of the development and commercialization costs for tenapanor in treatment of cardiorenal diseases and conditions, excluding cancer in Japan. Under the 2017 KKC Agreement, the Company is responsible for supplying the tenapanor drug product for KKC's use in development and during commercialization until KKC has assumed such responsibility. Additionally, the Company is responsible for supplying the tenapanor drug substance for KKC's use in development and commercialization throughout the term of the 2017 KKC Agreement, provided that KKC may exercise an option to manufacture the tenapanor drug substance under certain conditions

The Company assessed these arrangements in accordance with ASC 606 and concluded that the contract counterparty, KKC, is a customer. Under the terms of the 2017 KKC Agreement, the Company received $30.0 million in up-front license fees which was recognized as revenue when the agreement was executed. Based on the Company's assessment, it identified that the license and the manufacturing supply services were its material performance obligations at the inception of the agreement, and as such each of the performance obligations are distinct. Additionally, on January 1, 2018, the Company recorded unbilled revenue under current assets of $5.0 million and an increase in uncharged license fees under current liabilities of $1.0 million related to the first milestone under the 2017 KKC Agreement that KKC achieved in February 2019, reflecting revenues and cost of revenue, respectively, that would have been recognized in the fourth quarter 2017 if the Company had adopted ASC 606 prior to January 1, 2018. On KKC's achievement of the milestone in February 2019, the balance related to unbilled revenue was adjusted to zero. Correspondingly, the $1.0 million balance related to uncharged license fees that the Company owed to AstraZeneca was reclassified to accounts payable during the first quarter of 2019, and subsequently paid to AstraZeneca during the second quarter of 2019.

In addition to the up-front license fee received of $30.0 million, the Company may be entitled to receive up to $55.0 million in total development milestones, of which $5.0 million has been received to date, 8.5 billion Japanese yen for commercialization milestones, or approximately $82.4 million at the currency exchange rate on December 31, 2020, as well as reimbursement of cost, plus a reasonable overhead for the supply of product and high-teen royalties on net sales throughout the term of the agreement. The variable consideration related to the remaining development milestone payments has not been included in the transaction price as these were fully constrained at December 31, 2020 and 2019.

For the years ended December 31, 2020, 2019 and 2018, $1.4 million, $0.3 million, and $0.3 million, respectively, of product supply revenue was recorded for manufacturing supply of tenapanor and other materials to KKC for its product development and clinical trials in Japan, in accordance with the Company's agreement with KKC, and for each period, negligible cost of revenue was recorded pursuant to the AstraZeneca Termination Agreement.

Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. , or Fosun Pharma

In December 2017, the Company entered into an exclusive license agreement with Fosun Pharma, or the Fosun Agreement, for the development, commercialization and distribution of tenapanor in China for both hyperphosphatemia and irritable bowel syndrome with constipation, or IBS-C. The Company assessed these arrangements in accordance with ASC 606 and concluded that the contract counterparty, Fosun Pharma, is a customer. Under the terms of the Fosun Agreement, the Company received $12.0 million in up-front license fees which was recognized as revenue when the agreement was executed. Based on the Company's assessment, it identified that the license and the manufacturing supply services were its material performance obligations at the inception of the agreement, and as such each of the performance obligations are distinct.

In addition, the Company may be entitled to additional development and commercialization milestones of up to $110.0 million, as well as reimbursement of cost plus a reasonable overhead for the supply of product and tiered royalties on net sales ranging from the mid-teens to 20%. The variable consideration related to the remaining development milestone payments has not been included in the transaction price as these were fully constrained at December 31, 2019.

For the year ended December 31, 2019, $3.0 million revenue was recorded towards achievement of a milestone related to the Fosun Agreement, and for the years ended December 31, 2020 and 2018, no revenue was recorded.

Knight Therapeutics, Inc. , or Knight

In March 2018, the Company entered into an exclusive license agreement with Knight Therapeutics, Inc., or the Knight Agreement, for the development, commercialization and distribution of tenapanor in Canada for hyperphosphatemia and IBS-C. The Company assessed these arrangements in accordance with ASC 606 and concluded that the contract counterparty, Knight, is a customer. Based on the Company's assessment, it identified that the license and the manufacturing supply services were its material performance obligations at the inception of the agreement, and as such each of the performance obligations are distinct.

Under the terms of the agreement, the Company is eligible to receive up to CAD 25.0 million in total payments, or $19.6 million at the currency exchange rate on December 31, 2020, including an up-front payment and development and sales milestones, reimbursement of supply costs on a schedule specifying cost per tablet, with a reasonable mark up for overhead, as well as tiered royalty rates on net sales ranging from the mid-single digits to the low twenties. The variable consideration related to the remaining development milestone payments has not been included in the transaction price as these were fully constrained at December 31, 2020.

For the years ended December 31, 2020, 2019 and 2018, $0.7 million, zero and $2.3 million of revenue was recorded, respectively, related to the Knight Agreement. For the year ended December 31, 2020, $0.1 million product supply revenue was recorded related to the Knight Agreement. There was no product revenue related to the Knight Agreement in 2019 or 2018. Pursuant to the AstraZeneca Termination Agreement, $0.1 million, zero and $0.5 million of cost of revenue was recorded during 2020, 2019 and 2018, respectively.

AstraZeneca

In June 2015, the Company entered into a termination agreement with AstraZeneca, or the AstraZeneca Termination Agreement, pursuant to which the Company remains liable to pay AstraZeneca license fees for (i) future royalties at a royalty rate of 10% of net sales of tenapanor or other NHE3 products by the Company or its licensees, and (ii) 20% of non-royalty revenue received from a new collaboration partner should the Company elect to license, or otherwise provide rights to develop and commercialize tenapanor or certain other NHE3 inhibitors, up to a maximum of $75.0 million in

aggregate for (i) and (ii). To date in aggregate, the Company has recognized $10.6 million of the $75.0 million, recorded as cost of revenue, as follows (in thousands):

	Cost of Revenue	
	Recognized	Amount Paid
Year 2017	$ 9,400 *	$ 6,000
Year 2018	466	2,864
Year 2019	600	1,002
Year 2020	145	742
Total	$ 10,611	$ 10,608
Maximum payment per termination agreement		75,000
Remaining potential commitment		$ 64,392

* Includes the $1,000 adjustment recorded pursuant to the adoption of ASC 606, as discussed in Note 2.

13. INCOME TAXES

The components of the provision for income taxes for the year ended December 31, 2020, 2019 and 2018, are as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Current:			
State	$ 2	$ 2	$ 4
Foreign	—	301	—
Total current	2	303	4
Deferred:			
Federal	—	—	—
Total deferred	—	—	—
Provision for income taxes	$ 2	$ 303	$ 4

The following is a reconciliation of the statutory federal income tax rate to the Company's effective tax rate:

	Year Ended December 31,		
	2020	2019	2018
Change in valuation allowance	(22.3)%	(21.9)%	(22.5)%
Income tax at the federal statutory rate	21.0	21.0	21.0
Tax credits	1.3	1.6	1.4
State taxes, net of federal benefit	0.7	0.3	0.6
Stock based compensation	(0.1)	(0.9)	(1.2)
Other	(0.6)	(0.4)	0.7
Income tax provision	— %	(0.3)%	— %

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows as of December 31, 2020 and 2019 (in thousands):

	December 31, 2020	December 31, 2019
Deferred tax assets:		
Amortization and depreciation	$ 51,370	$ 45,555
Net operating loss carryforwards	53,436	40,896
Tax credits	11,777	10,136
Stock-based compensation	5,524	4,853
Lease obligation	1,804	984
Other	—	940
Gross deferred tax assets	123,911	103,364
Valuation allowance	(123,402)	(102,344)
Deferred tax assets net of valuation allowance	509	1,020
Deferred tax liabilities		
Right-of-use asset	(479)	(834)
Revenue recognition	—	(158)
Other	(30)	(28)
Net deferred tax assets	$ —	$ —

Realization of deferred tax assets is dependent on future taxable income, if any, the timing and the amount of which are uncertain. The Company assesses the available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. A significant component of objective negative evidence evaluated was the Company's cumulative loss incurred over the three-year period ended December 31, 2020. Such objective evidence limits the ability to consider other subjective evidence, such as our projections for future growth. On the basis of this evaluation, as of December 31, 2020, December 31, 2019 and December 31, 2018, a full valuation allowance has been recorded against Company's net deferred tax asset. The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased or if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence such as our projections for growth.

As of December 31, 2020, the Company had net operating loss carryforwards for federal income tax purposes of approximately $287.9 million, of which approximately $151.0 million can be carried forward indefinitely and the remaining net operating losses expire beginning in 2030, if not utilized. Federal research and development tax credit carryforwards of approximately $13.5 million that expire beginning in 2027, if not utilized, and foreign tax credit carryforwards of approximately $1.2 million that expire in 2027, if not utilized.

In addition, the Company had net operating loss carryforwards for California income tax purposes of approximately $88.3 million that expire beginning of 2030, if not utilized, and state research and development tax credit carryforwards of approximately $7.4 million which can be carried forward indefinitely. The Company had approximately $0.1 million of minimum tax credit carryovers for California income tax purposes. The minimum tax credits have no expiration date. The Company had other state net operating losses of approximately $1.9 million that begin to expire in 2035.

The future utilization of net operating loss and tax credit carryforwards and credits may be subject to an annual limitation, pursuant to Internal Revenue Code Sections 382 and 383, as a result of ownership changes that may have occurred previously or that could occur in the future. Due to the existence of the valuation allowance, limitations under Section 382 and 383 will not impact the Company's effective tax rate.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted and signed into law in response to coronavirus disease 2019 ("COVID-19"). The CARES Act, among other things, included several significant provisions that impacted corporate taxpayers' accounting for income taxes. Prior to the enactment of the CARES Act, the 2017 Tax Cuts and Jobs Act generally eliminated the ability to carryback net operating losses ("NOLs"),

and permitted the NOLs arising in tax years beginning after December 31, 2017 to be carried forward indefinitely, limited to 80% of the taxpayer's income. The CARES Act amended the NOL rules, suspending the 80% limitation on the utilization of NOLs generated after December 31, 2017 and before January 1, 2021. Additionally, the CARES Act allows corporate NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021, to be carried back to each of the five taxable years preceding the taxable year of the loss. Also, the CARES Act allows companies to defer making certain payroll tax payments until future years. With the enactment of the CARES Act, the company does not expect a financial statement impact from income taxes.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	December 31,		
	2020	2019	2018
Balance at beginning of year	$ 24,538	$ 23,052	$ 20,734
Additions (subtractions) based on tax positions related to prior year	(1,388)	755	1,634
Additions based on tax positions related to current year	474	731	684
Balance at end of year	$ 23,624	$ 24,538	$ 23,052

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Income tax positions must meet a more likely than not recognition at the effective date to be recognized. The unrecognized tax benefits, if recognized and in absence of full valuation allowance, would impact the income tax provision by $13.3 million, $13.2 million, and $9.8 million as of December 31, 2020, 2019 and 2018, respectively.

The Company has elected to include interest and penalties as a component of tax expense. During the years ended December 31, 2020, 2019 and 2018, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits. Although the timing and outcome of an income tax audit is highly uncertain, the Company does not anticipate that the amount of existing unrecognized tax benefits will significantly change during the next 12 months.

The Company files income tax returns in the U.S. federal, Arizona, California, Colorado, DC, Florida, Georgia, Illinois, Indiana, Massachusetts, Michigan, New York, New York MTA, Oregon, Tennessee, Texas and Wisconsin tax jurisdictions. Due to the Company's net operating loss and tax credit carryforwards, the income tax returns remain open to U.S. federal and state tax examinations. The Company is not currently under examination in any tax jurisdiction.

14. GEOGRAPHIC INFORMATION AND CONCENTRATIONS

Revenue by geographic areas for the years ended December 31, 2020, 2019 and 2018, are as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
United States	$ —	$ —	$ —
International:			
North America (1)	806	—	2,320
Asia Pacific (2) (3) (4)	6,765	5,281	287
Total revenue	$ 7,571	$ 5,281	$ 2,607

(1) Revenues from North America are comprised of amounts earned from Canada in accordance with the Knight Agreement.

(2) Revenues from Asia Pacific in 2020 are comprised of amounts earned from Japan in accordance with the 2017 KKC Agreement and 2019 KKC Agreement.

(3) Revenues from Asia Pacific in 2019 were comprised of $0.8 million from Japan in accordance with the 2017 KKC Agreement and 2019 KKC Agreement, $1.5 million from Hong Kong in accordance with the XuanZhu Agreement and $3.0 million from China in accordance with the Fosun Agreement.

(4) Revenues from Asia Pacific in 2018 were comprised of amounts earned from Japan in accordance with the 2017 KKC Agreement.

Revenues are attributed to geographical areas based on the domicile of the Company's collaboration partners.

Revenues recorded in the years ended December 31, 2020, 2019 and 2018, were wholly from collaboration partnerships. Collaboration partnerships accounting for more than 10% of total revenues during the years ended December 31, 2020, 2019 and 2018 are as follows:

	Year Ended December 31,		
	2020	2019	2018
KKC	89 %	15 %	11 %
Knight	11 %	— %	89 %
Fosun Pharma	- %	57 %	— %
XuanZhu	- %	28 %	— %

15. NET LOSS PER SHARE

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, less shares subject to repurchase, and excludes any dilutive effects of stock-based awards and warrants. Diluted net loss per common share is computed giving effect to all potential dilutive common shares, including common stock issuable upon exercise of stock options, and unvested restricted common stock and stock units. As the Company had net losses for the years ended December 31, 2020, 2019 and 2018, all potential common shares were determined to be anti-dilutive. The following table sets forth the computation of net loss per common share (in thousands, except per share amounts):

	Year Ended December 31,		
	2020	2019	2018
Numerator:			
Net loss	$ (94,313)	$ (94,940)	$ (91,298)
Denominator:			
Weighted average common shares outstanding - basic and diluted	89,582,138	64,478,066	56,219,919
Net loss per share - basic and diluted	$ (1.05)	$ (1.47)	$ (1.62)

For the years ended December 31, 2020, 2019 and 2018, the total numbers of securities that could potentially dilute net income per share in the future that were not considered in the diluted net loss per share calculations because the effect would have been anti-dilutive were as follows:

	Year Ended December 31,		
	2020	2019	2018
Options to purchase common stock	9,246,047	7,128,247	5,378,008
Warrants to purchase common stock	932,091	2,172,899	2,172,899
Restricted stock units	26,121	—	199,135
Performance-based restricted stock units	—	867,506	395,791
ESPP shares issuable	94,466	78,761	63,413
Total	10,298,725	10,247,413	8,209,246

The number of potential common shares that would have been included in diluted income per share had it not been for the anti-dilutive effect caused by the net loss, computed by converting these securities using the treasury stock method during the years ended December 31, 2020, 2019 and 2018, was approximately 2.1 million, 1.1 million and 1.0 million, respectively.

16. COMMITMENTS AND CONTINGENCIES

Guarantees and Indemnifications

The Company indemnifies each of its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at our request in such capacity, as permitted under Delaware law and in accordance with our certificate of incorporation and bylaws. The term of the indemnification period lasts as long as an officer or director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity.

The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance, which allows the transfer of risk associated with our exposure and may enable the Company to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations for any period presented.

Legal Proceedings and Claims

From time to time the Company may be involved in claims arising in connection with its business. Based on information currently available, management believes that the amount, or range, of reasonably possible losses in connection with any pending actions against the Company will not be material to the Company's financial condition or cash flows, and no contingent liabilities were accrued as of December 31, 2020 or 2019.

17. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

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

	2020 Quarter Ended			
	March 31	June 30	September 30	December 31
Total revenue	$ 1,213	$ 1,836	$ 2,713	$ 1,809
Operating expenses	$ 22,982	$ 26,043	$ 19,874	$ 29,452
Net loss	$ (22,373)	$ (24,956)	$ (18,108)	$ (28,876)
Net loss per share - basic and diluted	$ (0.25)	$ (0.28)	$ (0.20)	$ (0.32)

	2019 Quarter Ended			
	March 31	June 30	September 30	December 31
Total revenue	$ —	$ 18	$ 3,013	$ 2,250
Operating expenses	$ 25,498	$ 24,846	$ 25,102	$ 21,098
Net loss	$ (26,144)	$ (25,467)	$ (23,539)	$ (19,790)
Net loss per share - basic and diluted	$ (0.42)	$ (0.41)	$ (0.37)	$ (0.27)

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2020, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2020, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our CEO and CFO, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that accurately and fairly reflect in reasonable detail the transactions and dispositions of the assets of our company;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

- Provide reasonable assurances regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material adverse effect on our financial statements.

Our management assessed our internal control over financial reporting as of December 31, 2020, the end of the period covered by this Annual Report on Form 10-K. Management based its assessment on criteria established in "Internal Control—Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on management's assessment of our internal control over financial reporting, management concluded that, as of December 31, 2020, our internal control over financial reporting was effective.

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission on Schedule 14A in connection with our 2020 Annual Meeting of Stockholders (the "Proxy Statement"), which will be filed not later than 120 days after the end of our fiscal year ended December 31, 2020, under the headings "Executive Officers," "Election of Directors," "Corporate Governance," and " Section 16(a) Beneficial Ownership Reporting Compliance," and is incorporated herein by reference.

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

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item regarding executive compensation will be incorporated by reference to the information set forth in the sections titled "Executive Compensation" in our Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item regarding security ownership of certain beneficial owners and management will be incorporated by reference to the information set forth in the section titled "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in our Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item regarding certain relationships and related transactions and director independence will be incorporated by reference to the information set forth in the sections titled "Certain Relationships and Related Party Transactions" and "Election of Directors", respectively, in our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item regarding principal accountant fees and services will be incorporated by reference to the information set forth in the section titled "Principal Accountant Fees and Services" in our Proxy Statement.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

1. Financial Statements

   See Index to Financial Statements at Item 8 herein.

2. Financial Statement Schedules

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

3. Exhibits

   See the Exhibit Index immediately following this page.

ITEM 16. FORM 10-K SUMMARY

None.

Exhibit Index

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	8-K	6/24/2014	3.1	
3.2	Amended and Restated Bylaws	8-K	6/24/2014	3.2	
4.1	Reference is made to Exhibits 3.1 and 3.2				
4.2	Form of Common Stock Certificate	S-1/A	6/18/2014	4.2	
4.3	Form of Warrant issued pursuant to the Securities Purchase Agreement by and among Ardelyx, Inc. and the purchasers signatory thereto, dated June 2, 2015	S-3	7/13/2015	4.3	
4.4	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934				X
10.1	Termination Agreement, dated June 2, 2015, by and between AstraZeneca AB and Ardelyx, Inc.	10-Q	8/12/2015	10.1	
10.2	Amendment No. 1 to Termination Agreement and to Manufacturing and Supply Agreement, dated November 2, 2015 by and between AstraZeneca AB and Ardelyx, Inc.	10-K	3/4/2016	10.1(d)	
10.3(a)	Lease, dated August 8, 2008, by and between 34175 Ardenwood Venture, LLC and Ardelyx, Inc.	S-1	5/19/2014	10.4(a)	
10.3(b)	First Amendment to Lease, dated December 20, 2012, by and between 34175 Ardenwood Venture, LLC and Ardelyx, Inc.	S-1	5/19/2014	10.4(b)	
10.3(c)	Second Amendment to Lease, dated September 5, 2014, by and between Ardelyx, Inc. and 34175 Ardenwood Venture, LLC	8-K	9/9/2014	10.1	
10.3(d)	Third Amendment to Lease, dated April 28, 2016, by and between Ardelyx, Inc. and 34175 Ardenwood Venture, LLC	10-Q	8/8/2016	10.3	
10.4(a)#	Ardelyx, Inc. 2008 Stock Incentive Plan, as amended	S-1	5/19/2014	10.5(a)	
10.4(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2008 Stock Incentive Plan, as amended	S-1	5/19/2014	10.5(b)	
10.4(c)#	Form of Restricted Stock Purchase Grant Notice and Restricted Stock Purchase Agreement under the 2008 Stock Incentive Plan, as amended	S-1	5/19/2014	10.5(c)	
10.5(a)#	Ardelyx, Inc. 2014 Equity Incentive Award Plan	S-8	7/14/2014	99.3	
10.5(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2014 Equity Incentive Award Plan	S-1/A	6/9/2014	10.6(b)	
10.5(c)#	Form of Restricted Stock Award Agreement and Restricted Stock Unit Award Grant Notice under the 2014 Equity Incentive Award Plan	S-1/A	6/9/2014	10.6(c)	
10.6#	Form of Indemnification Agreement for directors and officers	S-1/A	6/9/2014	10.7	
10.7#	Amended and Restated Executive Employment Agreement, dated June 6, 2014, by and between Ardelyx, Inc. and Michael Raab	S-1/A	6/9/2014	10.8	
10.8#	Amended and Restated Change in Control Severance Agreement, dated June 6, 2014, by and between Ardelyx, Inc. and Jeffrey Jacobs, Ph.D.	S-1/A	6/9/2014	10.17	
10.9#	Offer Letter, dated May 2, 2008, by and between Ardelyx, Inc. and Jeff Jacobs, Ph.D.	S-1/A	6/9/2014	10.12	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.10#	Offer Letter, dated December 28, 2009, by and between Ardelyx, Inc. and David Rosenbaum, Ph.D.	S-1/A	6/9/2014	10.13	
10.11#	Offer Letter, dated November 21, 2012, by and between Ardelyx, Inc. and Elizabeth Grammer, Esq.	S-1/A	6/9/2014	10.14	
10.12#	Ardelyx, Inc. 2014 Employee Stock Purchase Plan	S-8	7/14/2014	99.6	
10.13(a)#	Non-Employee Director Compensation Program	S-1/A	6/9/2014	10.21	
10.13(b)#	Description of amendments to Non-Employee Director Compensation Program	8-K	3/9/2017	N/A	
10.14	Registration Rights Agreement by and among Ardelyx, Inc. and the investors signatory thereto, dated June 2, 2015	S-3	7/13/2015	99.1	
10.15	Registration Rights Agreement by and among Ardelyx, Inc. and the investors signatory thereto, dated July 14, 2016	10-Q	8/8/2016	10.2	
10.16(a)#	Ardelyx, Inc. 2016 Employment Commencement Incentive Plan	S-8	11/10/2016	99.1	
10.16(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2016 Employment Commencement Incentive Plan	S-8	11/10/2016	99.2	
10.16(c)#	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2016 Employment Commencement Incentive Plan	S-8	11/10/2016	99.3	
10.16(d)#	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2016 Employment Commencement Incentive Plan	S-8	11/10/16	99.4	
10.17††	License Agreement, dated November 27, 2017, by and between Kyowa Hakko Kirin Co. , Ltd. and Ardelyx, Inc.	10-K	3/14/2018	10.35	
10.18††	License Agreement, dated December 11, 2017, by and between Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. and Ardelyx, Inc.	10-K	3/14/2018	10.36	
10.19#	Second Amended and Restated Change in Control and Severance Agreement by and between Ardelyx, Inc. and Elizabeth Grammer.	10-Q	5/8/2018	10.0	
10.20#	Second Amended and Restated Change in Control and Severance Agreement by and between Ardelyx, Inc. and David P. Rosenbaum, Ph.D.	10-Q	5/8/2018	10.1	
10.21	Loan and Security Agreement, dated May 16, 2018, by and between the Company and Solar Capital Ltd. and Western Alliance Bank.	10-Q	8/7/2018	10.1	
10.22	Exit Fee Agreement, dated May 16, 2018, by and between the Company and Solar Capital Ltd. and Western Alliance Bank.	10-Q	8/7/2018	10.2	
10.23#	Transition and Separation Agreement dated July 8, 2018, by and between the Company and Reginald Seeto, MBBS.	10-Q	8/7/2018	10.3	
10.24(a)#	Amended and Restated Non-Employee Director Compensation Program.	10-Q	5/7/2019	10.1	
10.25#	Transition and Separation Agreement dated November 25, 2019, by and between the Company and Mark Kaufmann.	10-K	3/6/2020	10.3	
10.26#	Offer Letter, dated April 27, 2020, by and between Ardelyx, Inc. and Susan Rodriguez	10-Q	8/6/2020	10.1	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.27#	Change in Control Severance Agreement dated June 2, 2020, by and between Ardelyx, Inc. and Susan Rodriguez	10-Q	8/6/2020	10.2	
10.28#	Offer Letter, dated June 2, 2020, by and between Ardelyx, Inc. and Justin Renz	10-Q	8/6/2020	10.3	
10.29#	Change in Control Severance Agreement, dated June 8, 2020, by and between Ardelyx, Inc. and Justin Renz	10-Q	8/6/2020	10.4	
10.30††	Manufacturing Services Agreement, dated May 18, 2020, between Ardelyx, Inc. and Patheon Pharmaceuticals Inc.	10-Q	8/6/2020	10.5	
10.31	Lease Agreement, dated December 30, 2020, by and between Ardelyx, Inc. and Prospect Fifth Ave, LLC.				X
23.1	Consent of Independent Registered Public Accounting Firm				X
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C §1350				X
101.INS	Inline XBRL Instance Document				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	Cover Page Interactive Data File				

† Confidential treatment granted as to portions of this Exhibit. The confidential portions of this Exhibit have been omitted and are marked by asterisks.

†† Certain portions have been omitted pursuant to a confidential treatment request. Omitted information has been filed separately with the Securities and Exchange Commission.

# Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Ardelyx, Inc.

Date: March 8, 2021

By:/s/ Michael Raab

Michael Raab
President Chief Executive Officer and Director
(Principal Executive Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Michael Raab and Justin Renz, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Michael Raab Michael Raab	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 8, 2021
/s/ Justin Renz Justin Renz	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 8, 2021
/s/ David Mott David Mott	Chairman of the Board of Directors	March 8, 2021
/s/ Robert Bazemore Robert Bazemore	Director	March 8, 2021
/s/ William Bertrand, Jr. William Bertrand, Jr.	Director	March 8, 2021
/s/ Geoffrey A. Block Geoffrey A. Block, M.D.	Director	March 8, 2021
/s/ Onaiza Cadoret-Manier Onaiza Cadoret-Manier	Director	March 8, 2021
/s/ Jan M. Lundberg Jan M. Lundberg, Ph.D.	Director	March 8, 2021
/s/ Gordon Ringold Gordon Ringold, Ph.D.	Director	March 8, 2021
/s/ Richard Rodgers Richard Rodgers	Director	March 8, 2021

Exhibit 4.4

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

Ardelyx, Inc. ("we," "us," or "our") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, $0.0001 par value per share ("common stock").

Description of Capital Stock

The following summary describes our capital stock and does not purport to be complete. It is subject to and qualified in its entirety by reference to the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.4 is a part, as well as of the Delaware General Corporation Law. For a complete description, we encourage you to read amended and restated certificate of incorporation, our amended and restated bylaws and the applicable provisions of the Delaware General Corporation Law for additional information.

General

Our amended and restated certificate of incorporation authorizes 300,000,000 shares of common stock, $0.0001 par value per share, and 5,000,000 shares of preferred stock, $0.0001 par value per share.

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. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. In addition, the affirmative vote of holders of 66 2/3% of the voting power of all of the then outstanding voting stock will be required to take certain actions, including amending certain provisions of our amended and restated certificate of incorporation, such as the provisions relating to amending our amended and restated bylaws, the classified board and director liability.

Dividends

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

Liquidation

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

Fully Paid and Nonassessable.

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Preferred Stock – Limitations on Rights of Holders of Common Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock.
The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. No shares of preferred stock are outstanding, and we have no present plan to issue any shares of preferred stock.

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

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

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

Delaware Anti-Takeover Statute

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

Undesignated Preferred Stock

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

Special Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board of directors, Chief Executive Officer or President, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

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

Elimination of Stockholder Action by Written Consent

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

Classified Board; Election and Removal of Directors; Filling Vacancies

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders, 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, our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation provides for the removal of any of our directors only for cause and requires at least a 66 2/3% stockholder vote. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by a resolution of the board of directors unless the board of directors determines that such vacancies shall be filled by the stockholders. This system of electing and removing directors and filling vacancies may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Choice of Forum

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty, or other wrongdoing by, any of our directors, officers, employees or stockholders; any action asserting a claim against us or any of our directors, officers or employees arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us or any of our directors, officers or employees that is governed by the internal affairs doctrine. Although our amended and restated certificate of incorporation contains the choice of forum provision described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

Amendment of Charter Provisions

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

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

Limitations of Liability and Indemnification Matters

Our amended and restated certificate of incorporation contains provisions that limit the liability of our directors for monetary damages for breach of fiduciary duty as a director to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director’s duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys’ fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors’ and officers’ liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might

benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage.

The NASDAQ Global Market Listing

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

Transfer Agent and Registrar

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

Exhibit 10.31

LEASE

THIS INSTRUMENT IS A LEASE (including all exhibits, the "Lease"), dated as of December 30, 2020 by and between **Prospect Fifth Ave, LLC,** a Massachusetts limited liability company, as ("Landlord"), and **Ardelyx, Inc.** a Delaware corporation, as ("Tenant"), which relates to space in the building known as 400 Fifth Avenue (the "Building") located in Waltham, Massachusetts. The parties to this instrument (the "Parties") hereby agree with each other as follows:

ARTICLE I
BASIC LEASE PROVISIONS

1.1 INTRODUCTION. The following terms and provisions set forth basic data and, where appropriate, constitute definitions of the terms hereinafter listed:

1.2 BASIC DATA.

Landlord: Prospect Fifth Ave, LLC, a Massachusetts limited liability company

Landlord's Original Address:
465 Waverley Oaks Rd, Suite 500
Waltham, MA 02452

Tenant: Ardelyx, Inc.

Tenant's Original Address:
34175 Ardenwood Blvd.
Fremont, CA 94555

Basic Rent:

Monthly Period	**per r.s.f**	**Monthly Payment**
1* – 12	$27.75	$29,748.00
13 – 24	$28.44	$30,487.68
25 – 36	$29.15	$31,248.80
37 – 48	$29.88	$32,031.36
49 – 60	$30.63	$32,835.36
61– 63	$31.40	$33,660.80

***** Notwithstanding the Basic Rent set forth above, so long as this Lease is in full force and effect and Tenant is not in Default under any of the terms and conditions of this Lease, Tenant shall be entitledto an abatement of the monthly installment of Basic Rent for the first three (3) months (not to exceed91 days) of the Term of the Lease ("Free Rent Period"). Tenant shall be responsible for the paymentof any separately metered utilities and all other applicable charges under the Lease during the Free Rent Period, as and to the extent provided in this Lease.

Additional Free Rent: Tenant has requested finishes and materials for certain components of the Landlord's Work that are in excess of the Building Standard. In the event Tenant had not requested such upgrades, the Building Standard cost for such portion of the Landlord's Work would have been approximately $43,000.00. Landlord shall provide this amount as a credit to Tenant ("Upgrade Credit"). The Upgrade Credit shall be used first to cover the cost and expense of any separate work order(s) requested by Tenant of Landlord, and approved in writing (email being sufficient) by Tenant, during the Landlord's Work period, thereafter any remaining portion or all of the Upgrade Credit shall be applied to extend the Free Rent Period on a per diem basis until the Upgrade Credit has been exhausted. The upgraded finishes and materials shall be performed by Creative Office Pavilion ("Creative") for the installation of a DIRRT glass offices and partition system (as highlighted in yellow and marked with the letter x on the Plan attached hereto labeled "Glass and Furniture Plan", included in Exhibit A), and related appurtenances including but not limited to the installation of all Tenant required lock hardware on the doors. Landlord has reviewed and approved the general scope of work provided by Creative dated December 22, 2020, but all finals plans for work to be performed by Creative shall be subject to the prior review and approval of the Landlord. Tenant shall be responsible for all costs, fees, and expenses associated with the work performed by Creative, which shall be paid directly by Tenant to Creative in a timely fashion. In the event Creative's work or lead time for its materials causes delays to the performance of the Landlord's Work, it shall be considered a Tenant Delay extending the Commencement Date on a day for day basis until Landlord can resume its work and/or deliver the Premises.

Commencement Date: The "Commencement Date" shall be the date upon which the Substantial Completion (as defined below) of the Landlord's Work, as described in Exhibit B attached hereto is Achieved and Landlord delivers full possession of the Premises to Tenant, otherwise in the condition required by this Lease. Subject to Tenant Delays and the occurrence of the Force Majeure Event outlined below, the targeted Commencement Date is ninety (90) days after the Effective Date.

Notwithstanding the timeframes listed above, the Parties acknowledge that a Force Majeure Event has occurred that may delay the Substantial Completion Date. The Force Majeure Event that has occurred includes but is not limited to: (i) the declaration of a state of emergency by the Governor of Massachusetts on March 10, 2020; (ii) Order of the Massachusetts Governor Assuring Continued Operation of Essential Services in the Commonwealth, Closing Certain Workplaces and Prohibiting Gatherings of More than 10 People dated March 23, 2020, March 31, 2020, and April 28, 2020, as may be further amended or extended, (iii) the City of Waltham's Building Department closure to the public on March 18, 2020, possibly delaying and/or preventing the LESSOR from submitting a building permit application, and thereafter delays in scheduling and conducting necessary inspections, (iv) a high likelihood that there may be a shortage of or inability to obtain labor, materials, or equipment, and (v) the possibility that a further order, regulation, rule, or law may be promulgated by an applicable governmental entity that may prohibit the Landlord from commencing or continuing with the Landlord's Work. This paragraph shall serve as formal written notice of the occurrence of a Force Majeure Event, and all future correspondence regarding this matter shall be sent via email.

Rent Commencement Date: Three (3) months (not to exceed 91 days) after the Commencement Date.

Premises Rentable Area: 12,864 rentable square feet. Said rentable area is agreed to by the parties and is not subject to further measurement or computation.

Permitted Use: General office use and uses accessory thereto, as permitted by governing law, only.

Escalation Factor: 11.34%, as computed in accordance with the Escalation Factor Computation.

Initial Term: The period beginning as of the Commencement Date and expiring at 11:59 p.m. on the last day of the sixty-third (63rd) full calendar month thereafter (the "Expiration Date"). Notwithstanding the foregoing, if the Commencement Date falls on a day other than the first day of a calendar month, the Initial Term of the Lease will be measured from the first day of the next full calendar month following in which the Commencement Date occurs, and the Expiration Date shall be the last day of the 63rd month thereafter.

First Month's Rent: $29,748.00, to be deposited with Landlord at Lease Execution.

Security Deposit: $62,497.60, to be deposited with Landlord at Lease Execution and held as described in Section 14.17, which may be in cash or in the form of a letter of credit.

Base Operating Expenses/Year: 2021/calendar year

Base Taxes/Year: 2021/calendar year

1.3 ADDITIONAL DEFINITIONS

Anticipated Delivery Date: Ninety (90) days after the Effective Date.

Manager: Prospect Fifth Ave, LLC

Building Rentable Area: 113,399 rentable square feet, which is not subject to reduction on a remeasurement by more than one (1%) percent.

Business Days: All days except Saturday, Sunday, New Year's Day, Martin Luther King Day, President's Day, Patriots Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veteran's Day, Thanksgiving Day, Christmas Day (and the following day when any such day occurson Sunday.)

Effective Date: The Date this Lease is signed by Landlord and returned by Tenant with all required deposits made in good and sufficient funds and the Parties have mutually agreed to a final Plan, Exhibit A, and Landlord's Work, Exhibit B.

Default: As defined in Section 13.1.

Escalation Charges: The amounts prescribed in Article VIII and Article IX.

Escalation Factor Computation: Premises Rentable Area divided by Building's Rentable Area.
Force Majeure: Collectively and individually, strike or other labor trouble, fire or other casualty, governmental preemption of priorities or other controls in connection with a national or other public emergency or shortages of, or inability to obtain, fuel, supplies or labor resulting therefrom, or any other cause, whether similar or dissimilar, beyond a Landlord's or Tenant's reasonable control (as applicable). Excluded in all events from the foregoing Force Majeure provisions, is the Tenant's obligation to pay its rent and other monetary obligations as and when due under the terms of this Lease.

Tenant's Liability Insurance: As set forth in Section 10.2.

Land Parcel: The parcel of land upon which the Building is located, shown as Parcel 1 on a plan entitled "Subdivision Plan of Land, Prospect Hill Executive Office Park Waltham, Mass.", dated September 19, 1980, drawn by R.E. Cameron & Associates, Inc., recorded with Middlesex South Registry of Deeds as Plan No. 38 of 1981 and rights appurtenant thereto.

Lease Year or lease year: Each consecutive twelve (12) calendar month period commencing on the Commencement Date and each anniversary thereof. Notwithstanding the preceding sentence, if the Commencement Date shall not be the first day of a calendar month, the second and subsequent lease years shall commence on the first day of the calendar month following the first anniversary of the Commencement Date and each anniversary thereof.

Operating Expenses: As set forth in Article IX.

Operating Year: As defined in Section 9.1.

Premises: The portion of the 2nd (Suite 210) and 3rd (Suite 300) Floors of the Building shown on Exhibit A annexed hereto.

Property: The Building and the Land Parcel.

Tax Year: As defined in Section 8.1

Taxes: As determined in accordance with Section 8.1.

Tenant's Removable Property: As defined in Section 5.2.

Term of this Lease: The Initial Term and any extension thereof in accordance with the provisions hereof.

Exhibits: The following Exhibits are annexed to this Lease and incorporated herein by this reference:Exhibit A – Plan showing Premises

Exhibit B - Landlord's Work Exhibit
Exhibit B-1 – Building Standards
Exhibit C – Building Services Exhibit
D – Operating Expenses Exhibit E –
Rules and Regulations
Exhibit F – Sample Commencement Date Agreement
Exhibit G – Appraisal Methodology for Extension Option Basic Rent
Exhibit H – Form Letter of Credit

ARTICLE II
PREMISES AND APPURTENANT RIGHTS

2.1 LEASE OF PREMISES. Landlord hereby demises and leases to Tenant for the Term of this Lease and upon the terms and conditions hereinafter set forth, and Tenant hereby accepts from Landlord, the Premises. Subject to the terms of this Lease, Tenant shall have access to and use of the Premises for the Permitted Use twenty-four (24) hours per day, seven (7) days perweek, and three hundred sixty-five (365) days per year, subject to the terms of this Lease.

2.2 APPURTENANT RIGHTS AND RESERVATIONS. (a) Tenant shall have, as appurtenantto the Premises, the non-exclusive right to use, and permit its invitees to use in common with others, the parking areas and walkways on the Land Parcel, public or common lobbies, hallways, stairways and elevators and common walkways necessary for access to the Building, and if the portion of the Premises on any floor includes less than the entire floor, the common toilets, corridors and elevator lobby of such floor. Tenant shall have the right touse up to 3.4 parking spaces per 1,000 rentable square feet contained in the Premises, or thirty four (34) parking spaces, provided that Tenant hereby acknowledges that such parking shall be available on a first come, first serve basis and such spaces shall not be "reserved" for Tenant's exclusive use. Tenant acknowledges that Landlord may from time to time designate certain parking spaces on the Land Parcel as reserved for "visitors" of all tenants of the Building. Tenant shall additionally have the right through out the term (as the same may be extended), in common with other tenants of the Building, to use the Cafeteria and Fitness Center, as defined in Exhibit C.

Tenant shall have no other appurtenant rights other than those specifically set forth in this Section 2.2(a) and all such rights shall always be subject to reasonable rules and regulations from time to time established by Landlord pursuant to Section 14.7 and to the right of Landlord to designate and change from time to time areas and facilities so to be used. Notwithstanding the foregoing, Landlord shall not materially impede or obstruct access to and from the Premises or the availability of proximate parking in the manner provided as of the Effective Date.

(b) Excepted and excluded from the Premises are the ceiling, floor, perimeter walls and exterior windows, except the inner surfaces thereof and any space or areas in the Premises used for shafts, pipes, stacks, conduits, fan rooms ducts, electricity or other utilities, mechanical rooms or other Building facilities, but the entry doors (and related glass and finish work) to the Premises are a part thereof. Tenant agrees that Landlord shall have the right to place in the Premises interior storm windows, subcontrol devices (by way of illustration, an electric sub panel, etc.), utility lines, pipes, equipment and the like, in, over and upon the Premises.

3.1 **PAYMENT.** (a) Tenant agrees to pay to Landlord, or as directed by Landlord, commencing on the Commencement Date (but subject to abatement, delay or credit as expressly provided by this Lease), the Basic Rent and, if and when due and payable, Escalation Charges. Such Basic Rent and Escalation Charges shall be payable in equal monthly installments, in advance, on the first day of each and every calendar month during the Term of this Lease in lawful money of the United States. Until notice of some other designation is given, Basic Rent and Escalation Charges, and all other charges for which provision is herein made shall be paid by remittance payable to Landlord and addressed to 465 Waverley Oaks Road, Suite 500, Waltham, MA 02452 and all remittances so received as aforesaid, or by any subsequently designated recipient, shall be treated as a payment to Landlord. In the event that monthly installment of Basic Rent or the Escalation Charges, if applicable, is not paid within two (2) Business Days of when due, Tenant shall pay, in addition to any other additional charges due under this Lease, an administrative fee equal to five percent (5%) ofthe overdue payment.

(b) Basic Rent for any partial month shall be pro-rated on a daily basis, and if the first day on which Tenant must pay Basic Rent shall be other than the first day of a calendar month, the first payment which Tenant shall make to Landlord shall be equal to a proportionate partof the monthly installment of Basic Rent for the partial month from the first day on which Tenant must pay Basic Rent to the last day of the month in which such day occurs, plus the installment of Basic Rent for the succeeding calendar month.

3.2 **GROSS LEASE.** (a) This Lease is a gross lease, and the Basic Rent includes rent on the Premises plus the Tenant's pro rata share of Operating Expenses and Taxes. Basic Rent and Escalation Charges payable by Tenant hereunder shall be paid without notice or demand, and without setoff, counterclaim, defense, abatement, suspension, deferment, reduction or deduction, except as expressly provided by this Lease.

(b) This Lease shall not terminate, nor shall Tenant have any right to terminate this lease, nor shall the obligations and liabilities of Tenant set forth herein be otherwise affected, except as expressly provided by this Lease.

(c) Tenant waives all rights (i) to any abatement, suspension, deferment, reduction or deduction of or from the Basic Rent or other charges payable by Tenant hereunder or (ii) to quit, terminate or surrender this Lease or the Premises or any part thereof, except as expressly provided herein.

(d) It is the intention of the parties hereto that the obligations of Tenant hereunder shall be separate and independent covenants and agreements, that the Basic Rent or other charges payable by Tenant hereunder shall continue to be payable in all events and that the obligations of Tenant hereunder shall continue unaffected, unless the requirement to pay or perform the same shall have been terminated, suspended or abated pursuant to an express provision of thisLease.

ARTICLE IV
COMMENCEMENT AND CONDITION

4.1 **COMMENCEMENT DATE.** The Commencement Date shall be the date specified in Section 1.2. Notwithstanding the foregoing, if Tenant's personnel shall occupy all or any part of the Premises for the material conduct of its business prior to the Commencement Date, such date shall for all purposes of this Lease be the Commencement Date. The Tenant shall, upon demand of the Landlord, execute with Landlord a certificate confirming the Commencement Date as it is determined in accordance with the provisions of this Section 4.1 and similar to the form Commencement Date Agreement attached hereto as Exhibit F. Notwithstanding the foregoing, Tenant's early access to the Premises for installation of wiring, cabling, and otherwise shall in no event constitute Tenant's conduct of its business hereunder.

4.2 **PREMISES TO BE DELIVERED "AS IS".** Landlord shall deliver to Tenant on or about the Anticipated Delivery Date full possession of the Premises (free and clear or all rights, claims, and possessions of Landlord and others) and with all of the Landlord's Work Substantially Completed and ready for Tenant's immediate occupancy and use for the Permitted Use. Except as provided in the preceding sentence and subject to the Substantial Completion of the Landlord's Work (hereinafter defined), the Premises are to be delivered by Landlord "as is," in their present condition, and Landlord shall not be required to perform any work to the Premises or the Building prior to the Commencement Date. Tenant acknowledges that it has inspected the Premises, and that it is not relying on any representations and warranties by Landlord or any agreements by Landlord not expressly set forth in this Lease. Notwithstanding the foregoing, Landlord represents to Tenant and covenants that all mechanical and operating systems, electrical systems and equipment and plumbing systems shall as of the Commencement Date be in good working order.

4.3 **LANDLORD'S WORK.** Landlord shall cause, at Landlord's sole cost and expense, to be performed the work required by Exhibit B ("Landlord's Work") to be substantially completeon or about the Anticipated Delivery Date. All such work shall be done in a good and workmanlike manner employing building standard methods using contractors licensed in Massachusetts, for the trade required, and shall comply with all laws, regulations, orders, and authorizations applicable thereto. Landlord shall be obligated to obtain at Landlord's sole cost and expense all permits necessary for Landlord's Work and a certificate of occupancy as of or soon after Substantial Completion, thereof. Tenant agrees that Landlord may make any immaterial changes in such work which may become reasonably necessary or advisable, without approval of Tenant; and Landlord may make material changes in such work but only with the prior approval of Tenant or it is required by any applicable change in law or regulation. Tenant agrees to review and approve or disapprove plans or specifications or proposed changes to Landlord Work for which Tenant's approval is required within five (5) days of submittal to Tenant. If Tenant does not so respond, such plans or specifications shall be deemed approved. The term "Substantially Complete" or "Substantial Completion," as used herein, shall mean: (i) that Landlord's Work to be performed pursuant to Exhibit B has been completed, with the exception of minor punch list items which can be fully completed within sixty (60) days of Substantial Completion and without material interference with Tenant's use and occupancy for the Permitted Use, and other items which

because of season or weather or the nature of the item are not practicable to do at the time, provided that none of said items are necessary to make the Premises tenantable for the Permitted Use by Tenant; and (ii) Landlord has obtained all approvals necessary for the issuance of a Certificate of Occupancy from the City of Waltham for the Premises as improved by the Landlord's Work, with such certificate issuing in due course of the City's normal course of business. Landlord shall retain the risk in the event the City of Waltham delays or fails to issue a permanent Certificate of Occupancy. Landlord shall indemnify and hold Tenant harmless for any related claims for any such delay or non-issuance of the Certificate of Occupancy. Subject to the foregoing, Tenant's use of the Premises for the Permitted Use and material operation of its business within the Premises shall be deemed conclusive evidence of Substantial Completion of Landlord's Work.

4.4 **DELAYS**. Subject to the occurrence of a Force Majeure Event, any changes to the Force Majeure Event references in Section 1.2, and Tenant Delays, if Landlord fails to Substantially Complete the Landlord's work and deliver to Tenant possession of the Premises in the condition required by this Lease: (i) as of ninety (90) days after the Anticipated Delivery Date, Tenant shall receive a credit equal to one (1) day's free Basic Rent for each day from and after the sixty first (61st) day after the Anticipated Date until the actual Commencement Date and possession of the Premises is delivered to Tenant in the condition required by this Lease, with all of the Landlord's Work Substantially Complete;
(ii) as of one hundred and twenty (120) days after the Anticipated Delivery Date, Tenant shall receive a credit equal to two (2) day's free Basic Rent for each day from and after the ninety first (91st) day after the Anticipated Delivery Date until the actual Commencement Date and possession of the Premises is delivered to Tenant in the condition required by thisLease, with all of the Landlord's Work Substantially Complete; and (iii) as of one hundred eighty (180) days after the Anticipated Delivery Date (without regard to the occurrence of Force Majeure Event, but subject to extension for Tenant Delays), Tenant shall thereafter have the right to Terminate this Lease with thirty (30) days' written notice, in which event Landlord shall promptly refund to Tenant all prepaid rent and the Security Deposit (except as provided for below) and this Lease shall terminate and be of no further force or effect. Provided however, in the event Landlord can deliver the Premises within the foregoing thirty
(30) days Tenant's right to terminate shall be null and void. Any credit of free Basic rent hereunder shall be applied to Basic rent due and payment immediately after expiration of the Free Rent Period. Provided if the Landlord's failure to Substantially Complete the Landlord's Work and deliver the Premises is solely due to the occurrence of a Force Majeure Event or a change in circumstances in the present Force Majeure Event described above and not due to the delay or negligence of the Landlord, and the Lease is ultimately terminated, Tenant shall be responsible for half of the costs, expenses, and fees incurred by Landlord in performance of the Landlord's Work in accordance with the agreed upon budget for Landlord's Work, through the actual termination date ("Landlord's Work Reimbursement"). The Landlord's Work Reimbursement shall be billed to Tenant after the actual termination date and due within thirty (30) days of Tenant's receipt of such billing. Landlord may elect to apply the Tenant's prepaid rent and Security Deposit against the Landlord's Work Reimbursement.

ARTICLE V USE OF PREMISES

5.1 PERMITTED USE. (a) Tenant agrees that the Premises shall be used and occupied by Tenant and Tenant's employees only for the Permitted Use and for no other purpose.

(b) Tenant agrees to conform to the following provisions during the Term of this Lease:

(i) Tenant shall cause all freight to be delivered to or removed from the Building and the Premises in accordance with reasonable rules and regulations established by Landlord therefor;

(ii) Tenant shall not place or permit to be placed or maintained on any doors, exterior walls, windows (including both interior and exterior surfaces of windows and doors) of the Premises any sign (free standing or otherwise), awning or canopy (if applicable), or advertising matter or other thing of any kind, and shall not place or maintain any decoration, lettering, sign, or advertising matter on the glass of any window or door of the Premises or anywhere in the interior of the Premises visible from the exterior or from the common areas thereof without first obtaining Landlord's prior written consent. Tenant further agrees to maintain such signs, awnings or canopies (if applicable), decorations, lettering, advertising matter or other things as may be installed by Tenant and approved by Landlord in good condition, operating order, and repair at all times. All approved signs of Tenant visible from the common areas of the Building shall be in good taste, professionally lettered, and shall conform to the standards of design, motif, and décor from time to time established by Landlord for the Building. No flashing signs shall be permitted. No credit card signs, advertisements, free-standing signs nor any hand lettered signs shall be visible from the common areas. Tenant shall install professionally lettered signs on its service/second door,if applicable. Tenant will not place on the exterior of the Premises (including both interior and exterior surfaces of doors and interior surfaces of windows) or on any part of the Building outside the Premises, any signs (free-standing or otherwise), symbol, advertisements or the like visible to public view outside of the Premises. Landlord shall provide Tenant with building standard identity signage (i) on the main building lobby directory at Landlord's expense, and (ii) on the main entry to the Premises, at Tenant's expense, (either on the door or on the wall immediately adjacent to the main entry to the Premises, consistent with building standard practices);

(iii) Tenant shall not perform any act or carry on any practice which injure the Premises, or any other part of the Building, or cause offensive odors or loud noise or constitute a nuisanceor menace to any other tenant or tenants or other persons in the Building;

(iv) Tenant shall, in its use of the Premises, comply with the requirements of all applicable governmental laws, rules and regulations including, without limitation, the Americans With Disabilities Act of 1990, as amended and any regulations promulgated thereunder to the extent applicable to the Premises; and

(v) Tenant shall throughout the Term of this Lease occupy the Premises for the Permitted

Use and for no other purposes.

5.2 **INSTALLATION AND ALTERATIONS BY TENANT.** (a) Tenant shall make no alterations, additions (including, for the purposes hereof, wall-to-wall carpeting), or improvements in or to the Premises without Landlord's prior written consent. Any such alterations, additions or improvements shall (i) be in accordance with complete plans and specifications prepared by Tenant where appropriate given the nature of the alterations, additions, and improvements and approved in advance by Landlord; (ii) be performed in a good and workmanlike manner and in compliance with all applicable laws including, without limitation, The Americans with Disabilities Act of 1990, as amended and any regulations promulgated thereunder; (iii) be performed and completed in the manner required in Section 5.2(d) hereof; (iv) be made at Tenant's sole expense and at such times as Landlord may from time to time designate; and (v) become a part of the Premises and the property of Landlord (and Tenant shall have no obligation to remove such alterations, additions, or improvements made by or on behalf of Tenant or to restore the Premises, unless otherwise directed by Landlord in the applicable written consent instrument). Notwithstanding the foregoing, Tenant may make alterations, additions, and improvements having a total cumulative cost of less than $25,000.00 annually during the term of the Lease and that do no involve the structural portions of the Building or common mechanical or operating systems without Landlord’s approval, but with prior written notice.

(b) All articles of personal property and all machinery, equipment, removable fixtures, and furniture owned or installed by Tenant in the Premises ("Tenant's Removable Property") shall remain the property of Tenant and may be removed by Tenant at any time prior to the expiration of this Lease, provided that Tenant, at its expense, shall repair any damage to the Building caused by such removal.

(c) Notice is hereby given that Landlord shall not be liable for any labor or materials furnished or to be furnished to Tenant upon credit, and that no mechanic’s or other lien for any such labor or materials shall attach to or affect the reversion or other estate or interest of Landlord in and to the Premises. Whenever and as often as any mechanic's lien shall have been filed against the Premises based upon any act or interest of Tenant or of anyone claiming through Tenant, Tenant shall forthwith take such actions by bonding, deposit or payment as will remove or satisfy the lien.

(d) All of the Tenant's alterations, additions and installation of furnishings shall be reasonably coordinated with any work being performed by Landlord and in such manner as to maintain harmonious labor relations (but without obligation for Tenant to use unionized labor) and not damage the Property or interfere with Building construction or operation and, except for installation of furnishings, shall be performed by contractors or workmen first approved by Landlord. Installation and moving of furnishings, equipment and the like shall be performed only with labor not reasonably objectionable to Landlord for work in or to the Building. Except for work by Landlord's general contractor, Tenant, before its work is started shall: secure all licenses and permits necessary therefor; deliver to Landlord a statement of the names of all its contractors and subcontractors and the estimated cost of all

labor and material to be furnished by each of them; and cause each contractor to carry workmen's compensation insurance in statutory amounts covering all the contractor's and subcontractor's employees and commercial public liability insurance and property damage insurance with such limits as Landlord may reasonably require consistent with prevailing requirements for similar types of work in similar buildings where the Building is located, but in no event less than a combined single limit of Two Million and No/100ths ($2,000,000.00) Dollars (all such insurance to be written in companies reasonably approved by Landlord and insuring Landlord and Tenant as well as the contractors), and to deliver to Landlord certificates of all such insurance. Tenant agrees to pay promptly when due the entire cost of any work done on the Premises by Tenant, its agents, employees, or independent contractors, and not to cause or permit any liens for labor or materials performed or furnished in correlation therewith to attach to the Premises or the Property and immediately to discharge any such liens which may so attach and, at the request of Landlord to deliver to Landlord security reasonably satisfactory to Landlord against liens arising out of the furnishing of such labor and material where such lien arise, which is not so discharged. Upon completion of any work done on the Premises by Tenant, its agents, employees, or independent contractors, Tenant shall promptly deliver to Landlord original lien releases and waivers executed by each contractor, subcontractor, supplier, material men, architect, engineer or other party which furnished substantial labor, materials or other services in connection with such work and pursuant to which all liens, claims and other rights of such party with respect to labor, material or services furnished in connection with such work are unconditionally released and waived. Tenant shall pay within fourteen (14) days after being billed therefor by Landlord, as an additional charge hereunder, one hundred percent (100%) of any increase in real estate taxes on the Property not otherwise billed to Tenant which shall, at any time after commencement of the Term, directly attributable to any alteration, addition or improvement to the Premises made by or on behalf of Tenant (excluding Tenant's original installation and Tenant's subsequent alterations, additions, substitutions and improvements) whether done prior to or after the commencement of the Term of this Lease. Notwithstanding the foregoing, Tenant shall have the right, if diligently exercised and prosecuted, to contest any such liens or claims without discharge or release (or payment) thereof if reserves or security reasonably acceptable to Landlord are established.

ARTICLE VI
ASSIGNMENT AND SUBLETTING

6.1 PROHIBITION. (a) Tenant covenants and agrees that whether voluntarily, involuntarily, by operation of law or otherwise, neither this Lease nor the term and estate hereby granted, nor any interest herein or therein, will be assigned, mortgaged, pledged, encumbered or otherwise transferred and that neither the Premises nor any part thereof will be encumbered in any manner by reason of any act or omission on the part of Tenant, or used or occupied, by anyone other than Tenant, or for any use or purpose other than a Permitted Use, or be sublet (which term, without limitation, shall include granting of concessions, licenses and the like) in whole or in part, or be offered or advertised for assignment or subletting, without in each such case the written consent of Landlord (which consent to any assignment of this Lease or sublease of all of the Premises shall not be unreasonably withheld, delayed or

conditioned where use of the Premises continues for the Permitted Use and the assignee, sublessee or transferee has a financial condition not less than that of Tenant as of the Effective Date).

(b) The provisions of paragraph (a) of this Section shall apply to a transfer (by one or more transfers) of a majority of the stock or partnership interests, or other evidences of ownership of Tenant as if such transfer were an assignment of this Lease; but such provisions shall not apply to (and the consent or approval of Landlord shall not be required, but with notice no later than thirty (30) days of such transfer) transactions with an entity into or with which Tenant is merged or consolidated or to which substantially all of Tenant's assets are transferred or to any entity which controls or is controlled by Tenant or is under common control with Tenant (a “Merger/Sale”), provided that in any of such events (i) the successor to Tenant has a net worth computed in accordance with generally accepted accounting principles at least equal to the net worth of Tenant at the time of execution and delivery of this Lease as evidenced by the financial information provided to Landlord by Tenant prior to execution and delivery of this Lease, (ii) evidence reasonably satisfactory to Landlord (financial statements consistent with those provided by the original named Tenant hereunder in connection with Landlord’s entering into this Lease being deemed satisfactory) of such net worth shall have been delivered to Landlord at least ten (10) days prior to the effective date of any such transaction, and (iii) the assignee agrees directly with Landlord, by written instrument in form reasonably satisfactory to Landlord, to be bound by all the obligations of Tenant hereunder including, without limitation, the covenant against further assignment or subletting, except as expressly permitted by this Lease. In addition to a Merger/Sale, Tenant may expressly assign this Lease, sublease or license all or any portion of the Premises or otherwise make a transfer (a Merger/Sale and each of the following being a "Permitted Transfer") without Landlord’s consent or approval, for transfers of registered ownership interests on a recognized exchange.

(c) If this Lease is assigned, or if the Premises or any part thereof is sublet or occupied by anyone other than Tenant other than under a Permitted Transfer (and in such case, only after a Default under this Lease), Landlord may, at any time and from time to time, collect rent and other charges from the assignee, subtenant or occupant, and apply the net amount collected to the rent and other charges herein reserved, but no such assignment, subletting, occupancy, collection or modification of any provisions of this Lease shall be deemed a waiver of the foregoing covenant where applicable, or the acceptance of the assignee, subtenant or occupant as a tenant or a release of the original named Tenant from the further performance by the original named Tenant hereunder. No assignment or subletting hereunder shall relieve Tenant from its obligations hereunder and Tenant shall remain fully and primarily liable therefor. No assignment or subletting, or occupancy shall affect Permitted Use.

(d) If Tenant shall request Landlord to consent to an assignment of this Lease or a subletting (a "Request"), Tenant shall submit to Landlord in writing: (i) the name of the proposed assignee or subtenant, (ii) such information as to its financial responsibility and

standing as Landlord may reasonably require, and (iii) all terms and provisions upon which the proposed assignment or subletting is to be made.

(e) In any case where such consent is required and Landlord consents to an assignment or subletting, Landlord shall be entitled to receive fifty (50%) percent of all rental amounts after the deduction for all reasonable costs and expenses related to such sublease or assignment (the "Overages") received by Tenant in excess of Basic Rent, Escalation Charges and other items of additional rent reserved under this Lease attributable to the space sublet or assigned including, without limitation, all lump sum rental payments made in connection therewith. Payments of Overages shall be made by Tenant to Landlord as additional rent within five (5) days of receipt thereof by Tenant.

(d) Landlord shall never be deemed unreasonable in denying its consent to an assignment of this Lease or a subletting of all or any portion of the Premises where such consent is required: (i) in the event that Landlord, in its reasonable judgment, shall determine that the net worth or financial capability of such proposed subtenant or assignee is insufficient to perform its financial obligations under this Lease as an assignee or subtenant; or (ii) if a subletting, such subletting would result in more than two (2) subtenants; or (iii) if such assignment or subletting would require the Premises be used for other than the Permitted Use or require alterations to the Premises inconsistent with the Permitted Use or (iv) if such assignment or subletting is to an existing tenant or occupant of the Building or a prospective Tenant who has inquired about space within the last twelve (12) months; or (v) if there is a vacancy in the Building of space of a similar size and amenity, if the terms and conditions of the assignment or subletting are less favorable than those conditions on which Landlord is then offering to lease such vacant space for a comparable term (or, if Landlord is not then offering space in the Building for lease, those terms and conditions which, in Landlord's reasonable opinion, Landlord would offer to lease space in the Building) consistent with proposals for space within the Building offered within the prior twelve (12) months.

ARTICLE VII
RESPONSIBILITY FOR REPAIRS AND CONDITIONS OF PREMISES SERVICES TO BE FURNISHED BY LANDLORD

7.1 **LANDLORD REPAIRS.** (a) Except as otherwise provided in this Lease, Landlord agrees to keep and maintain in good working order, condition and repair (and replace as necessary) the foundation, roof, common areas, public areas (including loading dock areas, exterior landscaping and parking areas on the Land Parcel), exterior walls (including exterior glass) and structure of the Premises and the Building (including weight bearing walls and columns, plumbing, mechanical, operating and electrical systems, including without limitation, common heating, ventilation and air conditioning, but excluding any systems installed specifically for Tenant's benefit and which exclusively serve the Premises), all insofar as they affect the Premises, except that Landlord shall in no event (other than due to the gross negligence or act of Landlord, its agents, employees or contractors) be responsible to Tenant for the condition of glass in the Premises or for the doors (or related glass and finish work) leading to the Premises, or for any condition in the Premises or the Building caused by any act or neglect of Tenant, its agents, employees, invitees or contractors. The fact that Landlord

is responsible for the foregoing described repairs shall not be construed to prohibit the costs thereof from being included in Operating Expenses. Landlord shall not be responsible to make any improvements or repairs to the Building other than as expressly provided in this Section 7.1 or unless expressly provided otherwise in this Lease.

(b) Landlord shall never be liable for any failure to make repairs which Landlord has undertaken to make under the provisions of this Section 7.1 or elsewhere in this Lease; unless Tenant has given notice to Landlord of the need to make such repairs, and Landlord has failed to commence to make such repairs within a reasonable time after receipt of such notice,or fails to proceed with reasonable diligence to complete such repairs.

(c) Any services which Landlord is required to furnish pursuant to the provisions of this Lease may, at Landlord's option be furnished from time to time, in whole or in part, by employees of Landlord or by the Manager of the Property or by one or more third persons.

7.2 **TENANT'S AGREEMENT.** (a) Tenant will keep neat and clean and maintain in good order, condition and repair the Premises and every part thereof, excepting only those repairs for which Landlord is responsible under the terms of this Lease, reasonable wear and tear of the Premises, and damage by fire or other casualty and as a consequence of the exercise of the power of eminent domain, and Tenant shall surrender the Premises, at the end of the Term, in such condition. Without limitation, Tenant shall continually during the Term of this Lease maintain the Premises in all material respects in accordance with all laws, codes and ordinances from time to time in effect and all directions, rules and regulations of the proper officers of governmental agencies having jurisdiction, and of the applicable Board of Fire Underwriters, and shall, at Tenant's own expense, obtain all permits, licenses and the like required by applicable law from and after the Commencement Date in connection with the operation of Tenant's business within the Premises. Notwithstanding the foregoing or any of the other provisions of this Article VII, Tenant shall be responsible for the cost of repairs which is necessary by reason of damage to the Property caused by any act or neglect of Tenant or its agents, employees, contractors or invitees (including any damage by fire or any other casualty arising therefrom).

Without limitation of the foregoing, Tenant shall not do or perform, and shall not permit its agents, servants, employees, contractors or invitees to do or perform any act or thing in or upon the Property which will invalidate or be in conflict with the certificate of occupancy for the Premises or the Building or violate any statute, law, rule, by-law or ordinance of any governmental entity having jurisdiction over the Property (the "Requirements"). Tenant shall, at Tenant's sole cost and expenses, take all action, including the making of any improvements or alterations to the Premises necessary to comply with all Requirements (including, but not limited to the Americans With Disabilities Act of 1990 (the "ADA") taking effect from and after the Commencement Date, as modified and supplemented from time to time) which shall, with respect to the Premises or with respect to any abatement of nuisance, impose any violation, order or duty upon Landlord or Tenant arising from, or in connection with the Premises, Tenant's occupancy, use or manner of use of the Premises (including, without limitation, any occupancy, use or manner of use that constitutes a "place of public accommodation" under the ADA), or any installations in the Premises made by or

for the Tenant (but excluding work associated with the Landlord's Work), or required by reason of a breach of any of Tenant's covenants or agreements under this Lease, whether or not such Requirements shall now be in effect or hereafter enacted or issued, and whether or not any work required shall be ordinary or extraordinary or foreseen or unforeseen at the date hereof. Notwithstanding the preceding sentence, Tenant shall not be obligated to perform any alterations necessary to comply with any Requirements, unless compliance shall be required by reason of (i) any cause or condition arising from and after the Commencement Date out of any alterations or installations in the Premises (whether made by Tenant or by Landlord on behalf of Tenant but excluding any cause or condition arising out of Landlord's Work), (ii) Tenant's particular use, manner of use or occupancy of the Premises (as opposed to mere use as executive, general and administrative offices), (iii) any breach of any of Tenant's covenants or agreements under this Lease, or (iv) any wrongful act or omission by Tenant or Tenant's agents, servants, employees, contractors or invitees, or (v) Tenant's use or manner of use or occupancy of the Premises as a "place of public accommodation" within the meaning of the ADA.

(b) If repairs are required to be made by Tenant pursuant to the terms hereof, Landlord may demand that Tenant make the same forthwith (but subject to Tenant's ability to obtain permits, labor and materials and subject to occurrence of a Force Majeure Event), and if Tenant refuses or neglects to commence such repairs and complete the same with reasonable dispatch after such demand (but subject to Tenant's ability to obtain permits, labor and materials and subject to the occurrence of Force Majeure Event), Landlord may (but shall not be required to do so) make or cause such repairs to be made (the provisions of Section 14.18 being applicable to the reasonable out of pocket costs thereof) and shall not be responsible to Tenant for any loss or damage that may accrue to Tenant's stock or business by reason thereof. Notwithstanding the foregoing, Landlord may elect to take action hereunder immediately and without notice to Tenant (but Landlord shall in such event make reasonable effort to provide Tenant with advance telephonic notice) if Landlord reasonably believes an emergency to exist which imminently threatens loss or damage to persons or property.

7.3 **FLOOR LOAD – HEAVY MACHINERY.** (a) Tenant shall not place a load upon any floor in the Premises exceeding the floor load per square foot of area which such floor was designed to carry, and which is allowed by law. Business machines and mechanical equipment shall be placed and maintained by Tenant at Tenant's expense in settings sufficient, in Landlord's reasonable judgment, to absorb and prevent vibration, noise and annoyance of a type or degree which would (i) cause damage to the Premises or the Building or (ii) constitute a nuisance or annoyance for other tenants of the Building (giving due regard to the commercial nature of the Building).

(b) If such safe, machinery, equipment, freight, bulky matter or fixtures requires special handling, Tenant agrees to employ only persons holding a Master Rigger's License to do such work, and that all work in connection therewith shall comply with applicable laws and regulations. Any such moving shall be at the sole risk and hazard of Tenant, and Tenant will exonerate, indemnify and save Landlord harmless against and from any liability, loss, injury, claim or suit resulting directly or indirectly from such moving, except to the extent arising

from the negligence or willful misconduct of Landlord or its employees, contractors, agentsor invitees.

7.4 **BUILDING SERVICES.** Subject to the terms and provisions of Exhibit C, Landlord shall provide the Building Services described in Exhibit C. Tenant will pay to the Landlord a reasonable charge for any extra cleaning of the Premises required because of the unusual generation of waste or cleaning needs due to Tenant's use of the Premises above that required for typical general office usage but not including general cleaning requirements related to the pending COVID-19 emergency (which shall be Landlord's obligation within the common areas of the Building and the Tenant's obligation within the Premises), additional/augmented cleaning within the Premises requested by Tenant and/or otherwise required by applicable state and local requirements but not including general cleaning requirements related to the pending COVID-19 emergency, and for any Additional Services rendered at the request of Tenant. If the cost of cleaning the Premises shall be increased due to the installation in the Premises, at Tenant's request, of any unique or special materials, finish or equipment (after Tenant's having been notified of the resulting increased cost), Tenant shall pay to Landlord an amount equal to such increase in cost. All charges for additional services due under this Lease shall be due and payable within ten (10) days of the date on which they are billed.

ARTICLE VIII
REAL ESTATE TAXES

8.1 **PAYMENTS ON ACCOUNT OF TAXES.** (a) For the purposes of this Article, the term "Tax Year" shall mean each calendar year in which any part of the Term of this Lease shall fall; and the term "Taxes" shall mean all taxes and assessments of every kind and nature imposed, assessed or levied by a governmental authority on the Land Parcel, the Premises, or the Building of which the Premises is a part, including without limitation all real estate taxes, betterments, assessments (ordinary or extraordinary), water rents, sewer, other charges, or methods of assessment. Any betterment assessment, so-called "rent tax" or any other tax levied or imposed by any governmental authority assessed to the Land Parcel in addition to, in lieu of or as a substitute for real estate taxes, shall nevertheless be deemed to be real estate taxes for the purposes of this Paragraph. Betterments and assessments, if includable in Taxes hereunder shall be paid over the longest period of time permitted by governing authority. The term "Taxes" shall not include any inheritance or estate taxes, or any taxes on income to the extent applicable to Landlord's net income. If the Land Parcel is improved by more than one Building, Taxes and any Tenant obligation for payment of a portion thereof shall be equitably prorated (taking into account any allocation of assessed valuation made by governing authority).

(b) In the event that, for any reason, Taxes shall be greater during any Tax Year than Base Taxes set forth in Section 1.2, Tenant shall pay to Landlord, as an Escalation Charge, an amount equal to (i) the excess of Taxes over Base Taxes, multiplied by (ii) the Escalation Factor, such amount to be apportioned for any fraction of a Tax Year in which the Commencement Date falls or the Term of this Lease ends. Landlord shall provide Tenant

with copies of applicable tax bills in connection with each respective request for paymentof amounts payable by Tenant pursuant to this Section 8.1(b) and in connection with adjustments of the estimated monthly amounts payable by Tenant pursuant to Section 8.1 (c) hereof and at the time of any year end recapitulation of Tenant's obligations hereunder, unless the Landlord has previously provided the most up to date tax bills.

(c) Estimated payments by Tenant on account of Taxes shall be made monthly and at the time and in the fashion herein provided for the payment of Basic Rent. The monthly amount so to be paid to Landlord shall be sufficient to provide Landlord by the time tax payments are due a sum equal to Tenant's required payments, as reasonably estimated by Landlord from time to time, on account of Taxes for the then current Tax Year, with minimum estimates payments being 105% of the prior year's actual tax payments. Promptly after receipt by Landlord of bills for such Taxes, Landlord shall advise Tenant in writing of the amount thereof and Landlord's computation of Tenant's payment on account thereof. Landlord shall not adjust the estimated amounts required to be paid by Tenant more than two (2) times with respect to any Tax Year and at the time of advising Tenant of tenant's Tax obligation, Landlord shall provide Tenant with copies of the applicable tax bills upon which such adjustments are made. If estimated payments theretofore made by Tenant for the Tax Year covered by such bills exceed the required payments on account thereof for such Tax Year, Landlord shall credit the amount of overpayment against subsequent obligations of Tenant on account of Taxes due for the immediately next succeeding month (with a prompt refund of any balance to Tenant or, promptly refund to Tenant such overpayment if the Term of this Lease has ended and Tenant has no further Tax obligation to Landlord); but if the required payments on account thereof for such Tax Year due from Tenant under this Lease are greater than estimated payments theretofore made on account thereof for such Tax Year, Tenant shall make payment to Landlord within thirty (30) days after being so advised by Landlord. Landlord shall have the same rights and remedies for the non-payment by Tenant of any payments due on account of Taxes as Landlord has hereunder for the failure of Tenant to pay Basic Rent.

8.2 **ABATEMENT.** If Landlord shall receive any tax refund or reimbursement of Taxes or sum in lieu thereof with respect to any Tax Year which is not due to vacancies in the Building, then out of any balance remaining thereof after deducting Landlord's reasonable out-of-pocket expenses reasonably incurred in obtaining such refund, Landlord shall pay to Tenant, provided no event of Tenant Default has occurred (which is not remedied after required notice and before expiration of applicable grace and cure periods), an amount equal to such refund or reimbursement or sum in lieu thereof (exclusive of any interest) multiplied by the Escalation Factor; provided, that in no event shall Tenant be entitled to receive more than the payments made by Tenant on account of tax increases for such Year pursuant to paragraph (b) of Section 8.1 or to receive any payments or abatement of BasicRent if Taxes for any Tax Year are less than Base Taxes or Base Taxes are abated.

8.3 **ALTERNATE TAXES.** (a) If some method or type of taxation shall replace the current

method of assessment of real estate taxes in whole or in part, or the type thereof, or if additional types of taxes are imposed upon the Property or Landlord relating to the Property, Tenant agrees that Tenant shall pay a proportionate share of the same as an additional charge computed in a fashion consistent with the method of computation herein provided, to the end that Tenant's share thereof shall be, to the maximum extent practicable, comparable to that which Tenant would bear under the foregoing provisions.

(b) If a tax (other than Federal or State income tax) is assessed on account of the rents or other charges payable by Tenant to Landlord under this Lease (but not including any tax on income or profits), Tenant agrees to pay the same as an additional charge within ten (10) days after billing therefor, unless applicable law prohibits the payment of such tax by Tenant.

ARTICLE IX OPERATING EXPENSES

9.1 **DEFINITIONS.** For the purposes of this Article, the following terms shall have the following respective meanings:

(i) **Operating Year:** Each calendar year in which any part of the Term of this Lease shall fall.

Operating Expenses: The aggregate costs or expenses incurred by Landlord with respect to the operation, administration, cleaning, repair, maintenance and management of the Property for the general benefit of tenants of the Building including, without limitation those matters set forth in Exhibit D annexed hereto, provided that, if during any portion of the Operating Year for which Operating Expenses are being computed, less than ninety-five percent (95%) of Building Rentable Area was occupied by tenants or if Landlord is not supplying all tenants with the services being supplied hereunder, actual Operating Expenses incurred shall be reasonably extrapolated by Landlord on an item by item basis to the estimated Operating Expenses that would have been incurred if the Building were ninety-five percent (95%) occupied for such Operating Year and such services were being supplied to all tenants, and such extrapolated amount shall, for the purposes hereof, be deemed to be the Operating Expenses for such Operating Year.

Notwithstanding anything to the contrary contained in this Lease, Tenant's aggregate responsibility for Controllable Operating Expenses (defined below), in any calendar year under this Lease shall not increase by more than 5% per year over the immediately preceding calendar year, compounded yearly, for Controllable Operating Expenses, only, during the Term of this Lease, as said term may be extended under this Lease. "Controllable Operating Expenses" shall be defined as all Operating Expenses due under this Lease, except the following "Uncontrollable Operating Expenses": (i) utilities (e.g. electric, water and sewer), (ii) real and personal property taxes and assessments, (iii) snow and ice removal, (iv) landscaping, (v) expenditures for necessary capital repairs and replacements, and (vii) insurance premiums and deductibles. Uncontrollable Operating Expenses shall not be subject to the foregoing 5% per cap.

9.2 **TENANT'S PAYMENTS.** (a) In the event that for any Operating Year Operating Expenses shall exceed Base Operating Expenses, Tenant shall pay to Landlord, as an Escalation Charge, an amount equal to (i) such excess Operating Expenses multiplied by (ii) the Escalation Factor, such amount to be apportioned for any partial Operating Year in which the Commencement Date falls or the Term of this Lease ends. (b) Estimated payments by Tenant on account of Operating Expenses shall be made monthly and at the time and in the fashion herein provided for the payment of Basic Rent. The monthly amount so to be paid to Landlord shall be sufficient to provide Landlord by the end of each Operating Year a sum equal to Tenant's required payments, as reasonably estimated by Landlord from time to time during each Operating Year, on account of Operating Expenses for such Operating Year. Within ninety (90) days after the end of each Operating Year, Landlord shall submit to Tenant a reasonably detailed accounting of Operating Expenses for such Operating Year, with estimated installments being 105% of the prior year's actual Operating Expenses. If estimated payments theretofore made for such Operating Year by Tenant exceed Tenant's required payment on account thereof for such Operating Year, Landlord shall credit the amount of overpayment against subsequent obligations of Tenant with respect to Operating Expenses due for the next immediately succeeding month (with a prompt refund of any balance to Tenant or promptly refund to Tenant such overpayment if the Term of this Lease has ended and Tenant has no further obligation to Landlord), but, if the required payments on account thereof for such Operating Year are greater than the estimated payments (if any) theretofore made on account thereof for such Operating Year, Tenant shall make payment to Landlord within thirty (30) days after being advised in writing by Landlord of Tenant's additional payment obligation hereunder. Landlord shall have the same rights and remedies for the nonpayment by Tenant of any payments due on account of Operating Expenses as Landlord has hereunder for the failure of Tenant to pay Basic Rent.

9.3 Landlord shall maintain such books and records as to Operating Expenses in accordance with generally accepted accounting principles. Landlord shall permit Tenant, at Tenant's expense and during normal business hours at the offices of Landlord, but only one (1) time with respect to any Operating Year, to review Landlord's invoices and statements relating to the Operating Expenses for the purpose of verifying the Operating Expenses and Tenant's share thereof; provided that notice of Tenant's desire to so review is given to Landlord not later than thirty (30) days after Tenant receives an annual statement from Landlord, and provided that such review is thereafter commenced and prosecuted by Tenant with due diligence. Any Operating Expenses statement or accounting by Landlord shall be binding and conclusive upon Tenant unless: (a) Tenant duly requests such review within such 30-day period, and (b) within three (3) months after such review request, Tenant shall notify Landlord in writing that Tenant disputes the correctness of such statement, specifying the particular respects in which the statement is claimed to be incorrect. Tenant shall have no right to conduct a review or to give Landlord notice that it desires to conduct a review at any time Tenant is in default under the Lease, except Tenant shall have an audit right in the event the Tenant default is due only to its failure to make Operating Expenses payments. If Tenant's review of such books and records discloses that Operating Expenses paid by Tenant for any Operating Year(s) exceed Tenant's obligation therefor under the Lease, Landlord promptly apply such overpayment to Tenant's rental account; if the Tenant's review of such books and records discloses that Operating

Expenses paid by Tenant for any Operating Year(s) is less the amount previously paid, Tenant shall promptly pay such underpayment to Landlord. The party conducting the review shall be compensated on an hourly basis and shall not be compensated based upona percentage of overcharges it discovers. No subtenant shall have any right to conduct a review, and no assignee shall conduct a review for any period during which such assignee was not in possession of the Premises. Tenant agrees that the results of any Operating Expense review shall be kept strictly confidential by Tenant and shall not be disclosed to any other person or entity except to comply with the obligations of law or any government authority or in connection with any claims brought under this Lease.

ARTICLE X
INDEMNITY AND PUBLIC LIABILITY INSURANCE

10.1 **TENANT'S INDEMNITY.** To the maximum extent this agreement may be made effective according to law, Tenant agrees to defend, indemnify and save harmless Landlord from and against all claims, loss, liability, costs and damages of whatever nature arising from any default by Tenant under this Lease and the following: (i) from any accident, injury, death or damage whatsoever to any person, or to the property of any person, occurring in or about the Premises after the Commencement Date; (ii) from any accident, injury, death or damage occurring outside of the Premises but on the Property, where such accident, damage or injury results from an act or omission on the part of Tenant or Tenant's agents, employees, invitees or independent contractors; or (iii) in connection with the conduct or management of the Premises by Tenant or of Tenant's business therein, or anything or work whatsoever done, or any condition created (other than by Landlord) in or about the Premises by Tenant; and, in any case, occurring after the date of this Lease, until the end of the Term of this Lease, and thereafter so long as Tenant is in occupancy of the Premises. This indemnity and hold harmless agreement shall include indemnity against all reasonable out of pocket costs, expenses and liabilities incurred in, or in connection with, any such claim or proceeding brought thereon, and the defense thereof, including, without limitation, reasonable out of pocket attorneys' fees and costs at both the trial and appellate levels. Nothing contained in this Section 10.1 shall be deemed or construed to exculpate Landlord from liability arising from its own negligence, or that of any of its employees, agents, contractors or Invitees. The foregoing indemnification shall be subject to, and shall exclude causes giving rise to, Tenant's rights of remedy as set forth in Section 4.3. The provisions of this Section 10.1 shall survive the expiration or any earlier termination of this Lease.

10.2 **TENANT'S LIABILITY INSURANCE.** (a) Tenant shall obtain and keep in force and effect during the Term, at its own cost and expense, commercial general liability insurance, on an occurrence basis, in an amount of not less than One Million Dollars ($1,000,000), and a general aggregate limit of not less than Two Million Dollars ($2,000,000), for injury, death, property damage or other loss arising out of any one occurrence or in the aggregate, protecting Tenant as insured, and naming Landlord, Landlord's Affiliates, Landlord's mortgagees, property managers and managing agents as additional insureds ("Additional Insureds"), on a primary and non-contributory basis, against any and all claims for bodily injury, personal injury, death, property damage or other loss occurring in, upon, adjacent to or connected with the Premises or any part thereof. The policy shall not contain any intra-

insured exclusions as between insured persons or organizations, but shall include coverage for liability assumed under this Lease as an “insured contract” for the performance of Tenant’s indemnity obligations under this Lease. The policy shall cover host liquor liability exposure, and should contemplate coverage for pollution liability claims arising out of Bodily Injury or Property Damage arising out of heat, smoke or fumes caused by a hostile fire. A Waiver of Subrogation shall be provided in favor of Landlord, Landlord’s Affiliates and each as Additional Insureds. Landlord may from time to time during the Term increase the coverages required of Tenant hereunder to that customarily carried in the area in which the Premises is located on property similar in use, amenity and size to the Premises; and

(b) Tenant further agrees to maintain: (a) workers’ compensation insurance with a limit of liability as required by law to be maintained, including a Waiver of Subrogation in favor of Landlord, Landlord’s Affiliates and each Additional Insured; (b) employer's liability insurance with a minimum limit of coverage of One Million Dollars ($1,000,000), including a Waiver of Subrogation in favor of Landlord, Landlord’s Affiliates and each Additional Insured; (c) so called “Special Form” insurance coverage for all of its contents, furniture, furnishings, equipment, improvements, fixtures and personal property located at the Premises providing protection in an amount equal to one hundred percent (100%) of the replacement cost basis of said items, (subject to reasonable deductible amounts) without deduction for depreciation of the covered items and in amounts that meet any co-insurance clauses of the policies of insurance; (d) business interruption and extra expense insurance coverage(s) reasonably satisfactory to Landlord but not to exceed Tenant’s rental obligations under this Lease; (e) automobile liability insurance covering all owned, hired, and non-owned vehicles with a combined single limit of not less than One Million Dollars ($1,000,000); and (f) a minimum umbrella liability limit of Three Million Dollars ($3,000,000) covering any general commercial liability, employer’s liability, and auto liability policies, with the Additional Insureds and Waiver of Subrogation provisions mirroring the underlying policies. With respect to automobile liability insurance, Landlord, Landlord’s mortgagees, property managers and managing agents shall be afforded additional insured status on a primary and non-contributory basis, and Waiver of Subrogation shall be provided in favor of Landlord and Landlord’s Affiliates; and

(c) The insurance required hereunder shall be written in form and substance reasonably satisfactory to Landlord consistent with prevailing requirements for similar properties and uses within the location of the Property by a good and solvent insurance company of recognized standing, admitted to do business in Massachusetts, with a general policyholder’s rating of not less than A- VIII (as rated in the most current Best’s Insurance Reports), which company shall be reasonably satisfactory to Landlord. Tenant shall procure, maintain and place such insurance and pay all premiums and charges therefor, and upon failure to pay all premiums and charges when due and payable (and without limiting any other remedies on account thereof), Landlord may, upon reasonable prior notice to Tenant and Tenant’s continued failure to procure the same, but shall not be obligated to, procure, maintain and place such insurance or make such payments, and in such event, Tenant agrees to pay the amount thereof to Landlord on demand, as additional rent hereunder; and

(d) Tenant shall cause to be included in all such insurance policies a provision to the effect that the same will be non-cancelable except upon thirty (30) days written notice to Landlord.

Prior to the Commencement Date, the appropriate certificates of insurance shall be deposited with the Landlord. Any renewals, replacements and endorsements shall also be deposited with Landlord, in the case of renewals, same shall be so deposited at least thirty (30) days prior to the expiration of the prior policy; and

(e) Landlord and Tenant mutually agree that, with respect to any hazard which is covered by property insurance then being carried by them, respectively, the one carrying such insurance and suffering such loss releases the other of and from any and all claims with respect to such loss, to the extent of such coverage; and they further mutually agree that their respective insurance companies shall have no right of subrogation against the other on account thereof. Such waiver shall be included in the policy, or such other party shall be named as an additional insured in such policy, and the other party shall reimburse the party paying such premium the amount of such extra premium. Each such policy which shall so name a party hereto as an additional insured shall contain the agreement of the insurer that the policy will not be canceled without at least thirty (30) days' notice to both insureds and that the act or omission of an insured shall not invalidate the policy as to the other insured.

10.3 **TENANT'S RISK.** To the maximum extent this agreement may be made effective according to law, Tenant agrees to use and occupy the Premises and to use such other portions of the Property as Tenant is herein given the right to use at Tenant's own risk. Landlord shall have no responsibility or liability for any loss of or damage to Tenant's Removable Property or for any inconvenience, annoyance, interruption or injury to business arising from Landlord's making any repairs or changes which Landlord is permitted by this Lease or required by law to make in or to any portion of the Premises or other sections of the Property, or in or to the fixtures, equipment or appurtenances thereof, except to the extent caused by the negligence or willful misconduct of Landlord or its employees, contractors, agents or invitees. The provisions of this Section 10.3 shall be applicable from and after the execution of this Lease and until the end of the Term of this Lease, and during such further period as Tenant may use or be in occupancy of any part of the Premises or of the Building. The provisions of this Section 10.3 shall survive any expiration or earlier termination of the Term of this Lease.

10.4 **INJURY CAUSED BY THIRD PARTIES.** To the maximum extent this agreement may be made effective according to law, Tenant agrees that Landlord shall not be responsible or liable to Tenant, or to those claiming by, through or under Tenant, for any loss or damage that may be occasioned by or through the acts or omissions of persons (other than Landlord's employees, agents, contractors or invitees) occupying adjoining premises or any part of the premises adjacent to or connecting with the Premises or any part of the Property, or otherwise. The provisions of this Section 10.4 shall survive the expiration or any earlier termination of this Lease.

10.5 **LANDLORD'S INSURANCE.** Landlord shall maintain and keep in effect throughout the term of this Lease (a) insurance against loss or damage to the Building and other improvements to the Land Parcel by fire or other casualty as may be included within either fire and extended coverage insurance or "all-risk" insurance in an amount equal to the full replacement cost of the Building (exclusive of foundations) and (b) comprehensive general liability insurance in amounts reasonably determined by Landlord consistent with prudent

ownership of compatible properties having similar uses within the location of the Property. Such coverage may be affected directly and/or through the use of blanket insurance coverage covering more than one location and may contain such deductibles as Landlord may elect.

ARTICLE XI
LANDLORD'S ACCESS TO PREMISES

11.1 LANDLORD'S RIGHTS. Landlord shall have the right upon reasonable advance oral or written notice to Tenant, of not less than twenty-four (24) hours or less time based on the mutual agreement of the parties (email and telephonic notice sufficient), to enter the Premises at all reasonable hours for the purposes of inspecting or making repairs. Provided however, during any time period in which the Tenant is under physical audit by any applicable professional organization, state or federal agency or other compliance related event materially restricting Tenant's availability, Tenant may require no less than three (3) Business Days prior oral or written notice from Landlord to access the Premises (email and telephonic notice sufficient), to enter the Premises at all reasonable hours for the purposes of inspecting and making repairs. Notwithstanding the forgoing, no notice shall be required (prior Landlord telephonic notice shall be attempted) in the case of an emergency threatening imminent loss or damage to persons or property for which Landlord may enter the Premises at any hour of the day for the purpose of inspecting or making repairs to the same. Landlord shall also have the right upon such advance notice to make access available at all reasonable hours to prospective or existing mortgagees, purchasers or tenants of any part of the Property. In exercising its rights pursuant to this Section 11.1, Landlord shall use good faith efforts to avoid unreasonable interference with Tenant's use of the Premises and an employee Landlord's property management division shall accompany all service professionals working with Premises.

ARTICLE XII
FIRE, EMINENT DOMAIN, ETC.

12.1 ABATEMENT OF RENT. If the Premises, the Building, all access thereto or more than seventy five (75%) percent of the parking therefor shall be materially damaged by fire or casualty, Basic Rent and Escalation Charges payable by Tenant shall abate proportionately for the period in which, by reason of such damage, there is substantial interference with Tenant's use of the Premises for the Permitted Use, having regard to the extent to which Tenant may be required to discontinue Tenant's beneficial use of all or a portion of the Premises for the Permitted Use, but such abatement or reduction shall end if and when Landlord shall have substantially restored the Premises (excluding any alterations, additions or improvements made by Tenant pursuant to Section 5.2), the Building, access thereto and parking therefor to the condition in which they were immediately prior to such damage. If the Premises, the Building, access thereto or substantial portion of the parking therefor shall be affected by any exercise of the power of eminent domain, Basic Rent and Escalation Charges payable by Tenant shall be justly and equitably abated and reduced according to the nature and extent of the loss of beneficial use of the Premises for the Permitted Use suffered by Tenant. In no event shall Landlord have any liability for damages to Tenant for inconvenience, annoyance, or interruption of business arising from such fire, casualty or

eminent domain, except as otherwise expressly provided by this Lease.

12.2 **RIGHT OF TERMINATION.** If (a) the Premises or the Building are substantially damaged by fire or casualty (the term "substantially damaged" meaning damage of such a character that the same cannot, in the ordinary course, reasonably be expected to be repaired within one hundred twenty (120) days from the time the repair work would commence), or (b) any mortgagee then holding a mortgage on the Property or any interest of Landlord therein, should require that insurance proceeds payable as a result of a fire, casualty or action by taking authority be applied to the mortgage debt and the balance thereof remaining, if any, is insufficient for the cost to repair or restore the Premises and the Building or (c) if any material part of the Building is taken by any exercise of the right of eminent domain, then, in the case of (a), (b), or (c) above, Landlord shall have the right to terminate this Lease (even if Landlord's entire interest in the Premises may have been divested) by giving notice of Landlord's election so to do to Tenant within sixty (60) days after the occurrence of such casualty or the effective date of such taking, whereupon this Lease shall terminate thirty (30) days after the date of such notice with the same force and effect as if such date were the date originally established as the expiration date hereof.

12.3 **RESTORATION: TENANT'S RIGHT OF TERMINATION.** If the Premises is damaged by fire or casualty or as a result of a taking and if this Lease shall not be terminated pursuant to Section 12.2, Landlord shall thereafter use due diligence to restore the Premises, the Building, access thereto and parking therefor to substantially its conditions immediately prior to such fire or casualty, (exclusive of any alterations, additions, or improvements made by Tenant). If Landlord is then carrying insurance to the extent required under Section 10.5 of this Lease, Landlord's obligation to restore shall be limited to the amount of insurance proceeds actually made available to the Landlord for the purpose of restoration plus any deductible amount carried by Landlord, or the condemnation awards actually made available to Landlord therefor and provided, further, that Landlord shall have no obligation to restore the Premises or the Building as and to the extent the same cannot be lawfully restored under then applicable zoning and building laws. If, for any reason, restoration of the Premises, the Building, access thereto and parking therefor to the condition required hereby shall not be substantially completed as aforesaid within 180 days after the date of casualty or the effective date of such taking (or the earlier date of Tenant’s loss of beneficial use of the Premises for Tenant’s Permitted Use) (which 180 day period may not be extended for such periods of time as Landlord is prevented from proceeding with or completing such restoration for any cause beyond Landlord's reasonable control, but may be extended on a day for day basis for the period of any delay directly caused by Tenant), Tenant shall have the right to terminate this Lease by giving notice to Landlord thereof within (30) days after the expiration of such period (as so extended). Landlord agrees to give notice to Tenant prior to claiming any extension of time under the preceding sentence. Upon the giving of such notice, this Lease shall (effective as of a date set forth in such notice which date shall not be sooner than 30 nor later than 60 days after the giving of such notice) cease and come to an end without further liability or obligation on the part of either party unless, within such 30-day period, Landlord substantially completes such restoration to the condition required by this Lease. Such right of termination shall be Tenant's sole and exclusive remedy at law or in equity for Landlord's failure to complete such restoration.

Landlord shall not be liable for any inconvenience or annoyance to Tenant or injury to the business of Tenant resulting in any way from damage from fire or other casualty or the repair thereof (except as otherwise expressly provided by this Lease), but Tenant shall be entitled to an abatement of Basic Rent and Escalation Charges as and to the extent expressly provided in this Lease. Tenant understands that Landlord will not carry insurance of any kind on improvements or alterations made by Tenant or on furniture or furnishings or on any fixtures or equipment removable by Tenant under the provisions of the Lease, and that Landlord shall not be obligated to repair any damage thereto or replace the same. If Tenant desires any other or additional repairs for restoration and if Landlord consents thereto, the same shall be done at Tenant's expense. Tenant acknowledges that Landlord shall be entitled to the full proceeds of any insurance coverage, carried by Landlord and Tenant, for damage to the Premises and any alterations therein (but only to the extent Landlord undertakes restoration and repair thereof and excluding insurance proceeds for Tenant's furniture, fixtures, equipment installations, lost business and costs of relocation.

12.4 **AWARD.** Landlord shall have and hereby reserves and excepts, and Tenant hereby grants and assigns to Landlord, all rights to recover for damages to the Property and the leasehold interest hereby created, and to compensation accrued or hereafter to accrue by reason of such taking and related damage or destruction, and by way of confirming the foregoing, Tenant hereby grants and assigns, and covenants with Landlord to grant and assign to Landlord, all rights to such damages or compensation. Nothing contained herein shall be construed to prevent Tenant from, at its sole cost and expense, prosecuting a separate condemnation proceeding with respect to a claim for the value of any of Tenant's Removable Property installed in the Premises by Tenant at Tenant's expense and for relocation expenses, provided that such action shall not affect the amount of compensation otherwise recoverable by Landlord from the taking authority.

ARTICLE XIIIDEFAULT

13.1 **TENANT'S DEFAULT.** (a) If at any time subsequent to the date of this Lease any one or more of the following events (herein referred to as a "**Default**") shall happen:

(i) Tenant shall fail to pay the Basic Rent, Tenant's Electrical Charge, or Escalation Charges within five (5) days after written notice that said payment has not been received, provided that the Tenant shall only be entitled to two (2) such written notices within any twelve (12) month period and after the second written notice within a twelve (12) month period if Tenant has an additional failure to pay the Basic Rent, Tenant's Electrical Charge, Escalation Charge within five (5) days after the date said payment is due then Tenant shall be Default; or

(ii) Tenant shall be provided a minimum of ten (10) days' notice of unpaid amounts due (email containing such billing from Landlord or Landlord's construction division shall be sufficient) to review and confirm all other sums payable under this Lease, thereafter in

the event Tenant fails to pay such sums payable hereunder within such ten (10) days written notice that said payment had not been received, provided that the Tenant shall only be entitled to two (2) such written notices within any twelve (12) month period and after the second written notice within a twelve (12) month period if Tenant has an additional failure to pay such other sums payable under this Lease within ten (10) days after the date said payment is due then Tenant shall be Default; or

(iii) Tenant shall neglect or fail to perform or observe any other covenant herein contained on Tenant's part to be performed or observed, and Tenant shall fail to remedy the same within thirty (30) days after Landlord forwarding a notice to terminate to Tenant specifying such neglect or failure, or if such failure is of such a nature that Tenant cannot reasonably remedy the same within such thirty (30) day period, Tenant shall fail to commence promptly to remedy the same and to prosecute such remedy to completion with diligence and continuity for such longer period reasonably required therefor, but not to exceed ninety (90) days after receive of written notice; or

(iv) Tenant's leasehold interest in the Premises shall be taken on execution or by other process of law directed against Tenant; or

(v) Tenant shall make an assignment for the benefit of creditors or shall file a voluntary petition in bankruptcy or shall be adjudicated bankrupt or insolvent, or shall file any petition or answer seeking any reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief for itself under any present or future Federal, State or other statute, law or regulation for the relief of debtors, or shall seek or consent to or acquiesce in the appointment of any trustee, receiver or liquidator of Tenant or of all or any substantial part of its properties, or shall admit in writing its inability to pay its debts generally as they become due; or

(vi) A petition shall be filed against Tenant in bankruptcy or under any other law seeking any reorganization, arrangement, composition, readjustment, liquidation, dissolution, or similar relief under any present or future Federal, State or other statute, law or regulation and shall remain undismissed or unstayed for an aggregate of sixty (60) days (whether or not consecutive), or if any debtor in possession (whether or not Tenant) trustee, receiver or liquidator of Tenant or of all or any substantial part of its properties or of the Premises shall be appointed without the consent or acquiescence of Tenant and such appointment shall remain unvacated or unstayed for, an aggregate *of* sixty (60) days (whether or not consecutive); or

(vi) If a Default of the kind set forth in clauses (i) or (ii) above shall occur and if either (a) Tenant shall cure such Default within the applicable grace and cure period after required notice, if any, or (b) Landlord shall, in its sole discretion, permit Tenant to cure such Default after the applicable grace period has expired, and an event which would constitute a similar Default if not cured within the applicable grace and cure period after required notice shall occur more than two (2) times within the next 365 days, whether or not such event is cured within the applicable grace and cure period after required notice; then in any such case

(1) if such Default shall occur prior to the Commencement Date, this Lease shall ipso facto, and without further act on the part of Landlord, terminate, and (2) if such Default shall occur after the Commencement Date, Landlord may terminate this Lease by notice to Tenant, and thereupon this Lease shall come to an end as fully and completely as if such date, were the date herein originally fixed for the expiration of the Term of this Lease (Tenant hereby waiving any rights of redemption) and Tenant will then quit and surrender the Premises to Landlord, but Tenant shall remain liable as hereinafter provided.

(b) If this Lease shall be terminated as provided in this Article, or if any execution or attachment shall be issued against Tenant or any of Tenant's property whereupon the Premises shall be taken or occupied by someone other than Tenant, then Landlord may, without notice, re-enter the Premises, either by force, summary proceedings, ejectment or otherwise, and remove and dispossess Tenant and all other persons and any and all property from the same, as if this Lease had not been made, and Tenant hereby waives the service of notice of intention to re-enter or to institute legal proceedings to that end.

(c) In the event of any termination upon a Default of Tenant as provided hereunder, Tenant shall pay the Basic Rent, Escalation Charges and other sums payable hereunder up to the time of such termination, and thereafter Tenant, until the end of what would have been the Term of this Lease in the absence of such termination, and whether or not the Premises shall have been relet, shall be liable to Landlord for, and shall pay to Landlord, as liquidated current damages, the Basic Rent, Escalation Charges and other sums which would be payable hereunder if such termination had not occurred, less the net proceeds, if any, of any reletting of the Premises, after deducting all reasonable out of pocket expenses in connection with such reletting, including, without limitation, all repossession costs, brokerage commissions, reasonable out of pocket legal expenses, reasonable out of pocket attorneys' fees, advertising, expenses of employees, alteration costs and expenses of preparation for such reletting Tenant shall pay such current damages to Landlord monthly on the days which the Basic Rent would have been payable hereunder if this Lease had not been terminated.

(d) At any time after such termination, whether or not Landlord shall have collected any such current damages, as liquidated final damages and in lieu of all such current damages beyond the date of such demand, at Landlord's election, Tenant shall pay to Landlord an amount equal to the excess, if any, of the Basic Rent, Escalation Charges and other sums as hereinbefore provided which would be payable hereunder from the date of such demand (assuming that, for the purposes of this paragraph, annual payments by Tenant on account of Taxes and Operating Expenses would be the same as the payments required for the immediately preceding Operating Year or Tax Year) for what would be the then unexpired Term of this Lease if the same had remained in effect, over the then fair net rental value of the Premises for the same period.

(e) In the case of any Default, re-entry, expiration and dispossession by summary proceeding or otherwise, Landlord may (i) re-let the Premises or any part or parts thereof, either in the name of Landlord or otherwise, for a term or terms which may at Landlord's

option be equal to or less than or exceed the period which would otherwise have constituted the balance of the Term of this Lease and may grant concessions or free rent to the extent that Landlord considers advisable and reasonably necessary to re-let the same and (ii) may make such reasonable alterations, repairs and decorations in the Premises as Landlord in its sole reasonable judgment considers advisable and necessary for the purpose of reletting the Premises; and the making of such alterations, repairs and decorations shall not operate or be construed to release Tenant from liability hereunder as aforesaid. Landlord shall in no event be liable in any way whatsoever for failure to re-let the Premises, or, in the event that the Premises are re-let, for failure to collect the rent under such re-letting. Tenant hereby expressly waives any and all rights of redemption granted by or under any present or future laws in the event of Tenant being evicted or dispossessed, or in the event of Landlord obtaining possession of the Premises, by reason of the violation by Tenant of any of the covenants and conditions of this Lease resulting in a termination of this Lease for Default.

(f) The specified remedies to which Landlord may resort hereunder are not intended to be exclusive of any remedies or means of redress to which Landlord may at any time be entitledto lawfully, and Landlord may upon a Default by Tenant invoke any remedy (including the remedy of specific performance) allowed at law or in equity as if specific remedies were not herein provided for. All reasonable out of pocket costs and expenses incurred by or on behalfof Landlord (including, without limitation, reasonable out of pocket attorneys' fees and expenses) in enforcing its rights hereunder and/or occasioned by any Default of Tenant shall be paid by Tenant.

13.2 **LANDLORD'S DEFAULT.** Landlord shall in no event be in default in the performance of any of Landlord's obligations hereunder unless and until Landlord shall have failed to perform such obligations within thirty (30) days, or such additional time as is reasonably required to correct any such default, after written notice by Tenant to Landlord properly specifying wherein Landlord has failed to perform any such obligation. It is the express understanding and agreement of the parties and a condition of Landlord's agreement to execute this Lease that in no event shall Tenant have the right to terminate this Lease or seek an abatement to or offset from Basic Rent or Escalation Charges as a result of Landlord's default, but Tenant shall be entitled to seek all other remedies, at law or equity, as a result of such default. Tenant hereby waives its right to recover punitive, special or consequential damages arising out of any act, omission or default by Landlord (or any party for whom Landlord is responsible). Except as otherwise expressly provided by this Lease, this Lease and the obligations of Tenant hereunder shall not be affected or impaired because Landlordis unable to fulfill any of its obligations hereunder or is delayed in doing so, if such inabilityor delay is caused by reason of a Force Majeure Event (as defined below), and, except as otherwise expressly provided by this Lease, the time for Landlord's performance shall be extended for the period of any such delay. Any claim, demand, right or defense by Tenant that arises out of this Lease or the negotiations which preceded this Lease shall be barred unless Tenant commences an action thereon, or interposes a defense by reason thereof, within six (6) months after the date of the inaction, omission, event or action that gave rise to such claim, demand, right or defense, or (ii) if such inaction, omission, event or action was not discoverable within such six (6) months, then within sixty (60) days after its discovery. Tenant shall look solely to the equity of the Landlord in the Building and the Land

Parcel and all proceeds, net income and profits therefore for the satisfaction of Tenant's remedies. As used herein, a "Force Majeure Event" shall be any delay caused by or resulting from acts of God, war, civil commotion, fire, flood or other casualty, labor difficulties, shortages of or inability to obtain labor, materials or equipment, government regulations, unusually severe weather, or other causes beyond such party's reasonable control.

ARTICLE XIV
MISCELLANEOUS PROVISIONS

14.1 **EXTRA HAZARDOUS USE.** Tenant covenants and agrees that Tenant will not do or permit its employees, agents, contractors or invitees to do anything in or upon the Premisesor the Property, or bring in anything or keep anything therein, which shall increase the rate of property or liability insurance on the Premises or on the Property above the standard rate applicable to premises being occupied for the Permitted Use; and Tenant further agrees that, in the event that Tenant shall do any of the foregoing, Tenant will promptly pay to Landlord, on demand, any such increase resulting therefrom, which shall be due and payable as an additional charge hereunder.

14.2 **WAIVER.** (a) Failure on the part of Landlord or Tenant to complain of any action or non•action on the part of the other, no matter how long the same may continue, shall never be a waiver by Tenant or Landlord, respectively, of any of the other's rights hereunder. Further, no waiver at any time of any of the provisions hereof by Landlord or Tenant shallbe construed as a waiver of any of the other provisions hereof, and a waiver at any time ofany of the provisions hereof shall not be construed as a waiver at any subsequent time of the same provisions. The consent or approval of Landlord or Tenant to or of any action bythe other requiring such consent or approval shall not be construed to waive or render unnecessary Landlord's or Tenant's consent or approval to or of any subsequent similar act by the other.

(b) No payment by Tenant, or acceptance by Landlord, of a lesser amount than shall be due from Tenant to Landlord shall be treated otherwise than as a payment on account of the earliest installment of any payment due from Tenant under the provisions hereof. The acceptance by Landlord of a check for a lesser amount with an endorsement or statement thereon, or upon any letter accompanying such check, that such lesser amount is payment in full, shall be given no effect, and Landlord may accept such check without prejudice to any other rights or remedies which Landlord may have against Tenant.

14.3 **COVENANT OF QUIET ENJOYMENT.** Subject to the terms and provisions of this Lease, on payment of the Basic Rent and Escalation Charges if and when due and payable under this Lease and observing, keeping and performing all of the other terms and provisionsof this Lease on Tenant's part to be observed, kept and performed, Tenant shall lawfully, peaceably and quietly have, hold, occupy and enjoy the Premises during the term hereof, without hindrance or ejection by any persons lawfully claiming under Landlord to have titleto the Premises superior to Tenant. The foregoing covenant of quiet enjoyment is in lieu of any other covenant, express or implied.

14.4 **LANDLORD'S LIABILITY.** (a) Tenant specifically agrees to look solely to Landlord's then equity interest in the Property at the time owned, and all proceeds, net income and profit therefrom, for recovery of any judgment from Landlord; it being specifically agreed that Landlord (original or successor) shall never be personally liable for any such judgment, or for the payment of any monetary obligation to Tenant.

(b) With respect to any services or utilities to be furnished by Landlord to Tenant, Landlord shall in no event be liable for failure to furnish the same when prevented from doing so by Force Majeure, strike, lockout, breakdown, accident, order or regulation of or by any governmental authority, or failure of supply, or inability by the exercise of reasonable diligence to obtain supplies, parts or employees necessary to furnish such services, or because of war or other emergency, or for any cause beyond Landlord's reasonable control, or for any cause due to any act or neglect of Tenant or Tenant's servants, agents, employees, licensees or any person claiming by, through or under Tenant; nor shall any such failure give rise to any claim in Tenant's favor that Tenant has been evicted, either constructively or actually, partially or wholly.

(c) In no event shall Landlord ever be liable to the Tenant for any loss of business or any other indirect or consequential damages suffered by Tenant from whatever cause.

(d) With respect to any repairs or restoration which are required or permitted to be made by Landlord, the same may be made during normal business hours and Landlord shall have no liability for damages to Tenant for inconvenience, annoyance of interruption of business arising therefrom. In exercising its rights hereunder, Landlord shall use good faith efforts to avoid unreasonable interference with Tenant's use of the Premises for the Permitted Use.

(e) In no event shall Landlord be liable for any breach of any term, condition or covenant during the Term unless the same shall occur during and within the period of time that it is the owner of the Building. In no event and under no circumstances shall Landlord be liable to Tenant for any consequential or special damages in connection with any act of Landlord, its agents, employees, invitees or independent contractors or otherwise.

14.5 **NOTICE TO MORTGAGEE OR GROUND LESSOR.** After receiving written notice from any person, firm or other entity that it holds a mortgage or a ground lease which includes the Premises, no notice from Tenant to Landlord alleging any default by Landlord shall be effective unless and until a copy of the same is given to such holder or ground lessor (provided Tenant shall have been furnished with the name and address of such holder or ground lessor), and the curing of any of Landlord’s defaults within applicable cure periods under this Lease by such holder or ground lessor shall be treated as performance by Landlord.

14.6 **ASSIGNMENT OF RENTS AND TRANSFER OF TITLE.** (a) With reference to any assignment by Landlord of Landlord's interest in this Lease, or the rents payable hereunder, conditional in nature or otherwise, which assignment is made to the holder of a mortgage on property which includes the Premises, Tenant agrees that the execution thereof by Landlord, and the acceptance thereof by the holder of such mortgage, shall never be treated as an assumption by such holder of any of the obligations of Landlord hereunder unless such holder shall, by notice sent to Tenant, specifically otherwise elect and that, except as aforesaid, such holder shall be treated as having assumed Landlord's obligations hereunder only upon (i) foreclosure of such holder's mortgage (but only if such holder shall purchase such property at

foreclosure), or (ii) the entry and taking of possession of the Property by such holder (but only as to matters which shall accrue or arise during the period of possession by such holder).

(b) In no event shall the acquisition of Landlord's interest in the Property by a purchaser which, simultaneously therewith, leases Landlord's entire interest in the Property back to the seller thereof be treated as an assumption by operation of law or otherwise, of Landlord's obligations hereunder, but Tenant shall look solely to such seller-lessee, and its successors from time to time in title, for performance of Landlord's obligations hereunder. In any such event, this Lease shall be subject and subordinate to the lease to such purchaser. For all purposes, such seller•lessee, and its successors in title, shall be the Landlord hereunder unless and until Landlord’s position shall have been assumed by such purchaser lessor.

(c) Except as provided in paragraph (b) of this Section, in the event of any transfer of title to the Property by Landlord, Landlord shall thereafter be entirely freed and relieved from the performance and observance of all covenants and obligations hereunder which areto be performed or observed from and after the date of such transfer, provided Landlord’s obligations with respect to any Security Deposit shall remain in effect until actual delivery thereof to its successor in title.

14.7 **RULES AND REGULATIONS.** Tenant shall abide by rules and regulations from time to time established by Landlord, it being agreed that such rules and regulations will be established and applied by Landlord in a non-discriminatory fashion, such that all rules and regulations shall be generally applicable to other tenants of the Building of similar nature to the Tenant named herein. Landlord agrees to use reasonable efforts to ensure that any such rules and regulations are uniformly enforced, but Landlord shall not be liable to Tenant for violation of the same by any other tenant or occupant of the Building, or persons having business with them. In the event that there shall be any conflict between such rules and regulations and the provisions of this Lease, the provisions of this Lease shall control. The current rules and regulations of the Building are attached as Exhibit E. In each instance where Tenant’s compliance with Landlord rules and regulations is required in this Lease, such requirement shall be subject to this Section 14.7.

14.8 **ADDITIONAL CHARGES.** If Tenant shall fail to pay when due any sums under this Lease designated or payable as an additional charge, Landlord shall have the same rights and remedies as Landlord has hereunder for failure to pay Basic Rent.

14.9 **INVALIDITY OF PARTICULAR PROVISIONS.** If any term or provision of this Lease, or the application thereof to any person or circumstance shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such term or provision to persons or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby, and each term and provision of this Lease shallbe valid and be enforced to the fullest extent permitted by law.

14.10 **PROVISIONS BINDING, ETC.** Except as herein otherwise provided, the terms hereof shall be binding upon and shall inure to the benefit of the successors and assigns, respectively, of Landlord and Tenant and, if Tenant shall be an individual, upon and to his

heirs, executors, administrators, successors and assigns. Each term and each provision of this Lease to be performed by Tenant shall be construed to be both a covenant and a condition. The reference contained to successors and assigns of Tenant is not intended to constitute a consent to assignment by Tenant, but has reference only to those instances in which Landlord may later give consent to a particular assignment as required by those provisions of Article VI hereof or where assignment by Tenant is expressly permitted by this Lease.

14.11 **RECORDING.** Tenant agrees not to record this Lease, but each party hereto agrees, on the request of the other, to execute a so-called notice of lease in form recordable and complying with applicable law and reasonably satisfactory to Landlord's attorneys. In no event shall such document set forth the rent or other charges payable by Tenant under this Lease; and any such document shall expressly state that it is executed pursuant to the provisions contained in this Lease, and is not intended to vary the terms and conditions of this Lease.

14.12 **NOTICES.** Whenever, by the terms of this Lease, notices, consents or approvals and other communications ("notices") shall or may be given either to Landlord or to Tenant, such notices shall be in writing and shall be sent by (i) registered or certified mail, return receipt requested, postage and handling prepaid or (ii) reputable overnight courier with evidence of receipt, postage and handling prepaid, or (iii) by hand delivery with acknowledgment of receipt; or (iv) by electronic mail or facsimile transmission with confirming receipt:

If intended for Landlord, addressed to Landlord at 465 Waverley Oaks Road, Suite 500, Waltham, MA 02452(or to such other address or addresses within the continental United States as may from time to time hereafter by designated by Landlord by like notice), with electronic mail to Robert L. Duffy, Jr. at bobduffy@duffyproperties.com.

If intended for Tenant, addressed to Tenant at Tenant's Original Address until the Commencement Date and thereafter to the Premises (or to such other address or addresses within the continental United States as may from time-to-time hereafter be designated by Tenant by like notice), with electronic mail to_____at _____.

All such notices shall be effective upon receipt thereof by the addressee provided that the same are received in ordinary course at the address to which the same were sent. Provided further however that rejection or refusal to accept or inability to deliver because of change of address (without proper notice of such change of notice address as required hereunder) shall be deemed receipt of the notice sent as of the first day of refusal or rejection or the firstdate of attempted delivery to the address specified herein in the case of a change of notice address without proper notice of such change of address as aforesaid.

14.13 **WHEN LEASE BECOMES BINDING.** The submission of this document for examination and negotiation does not constitute an offer to lease, or a reservation of, or option for, the Premises, and this document shall become effective and binding only upon the execution and

delivery hereof by both Landlord and Tenant. All negotiations, considerations, representations and understandings between Landlord and Tenant are incorporated herein and this Lease expressly supersedes any proposals or other written documents relating hereto. This Lease may be modified or altered only by written agreement between Landlord and Tenant, and no act or omission of any employee or agent of Landlord shall alter, change or modify any of the provisions hereof.

14.14 **PARAGRAPH HEADINGS.** The paragraph headings throughout this instrument are for convenience and reference only, and the words contained therein shall in no way be held to explain, modify, amplify or aid in the interpretation, construction, or meaning of the provisions of this Lease.

14.15 **RIGHTS OF MORTGAGEE OR GROUND LESSOR.** This Lease shall be subordinate to any mortgage or ground lease from time to time encumbering the Premises, whether executed and delivered prior to or subsequent to the date of this Lease, if the holder of such mortgage or ground lease shall so elect, provided that (i) the holder shall execute a subordination and non-disturbance agreement in favor of Tenant to provide that in the event of the foreclosure of such mortgage or the exercise of rights of possession under such ground lease, Tenant's rights under this Lease shall not be affected so long as Tenant continues to pay the Basic Rent, Escalation Charges and other sums and charges provided for in this Lease and otherwise complies with each and every one of its obligations hereunder and otherwise in form reasonably satisfactory to Landlord and Tenant (an "SNDA"), and (ii) the lien of such mortgage shall not cover any of Tenant's personal property or any of the Tenant's fixtures, furnishings, alterations or improvements installed by Tenant or Tenant's contractors and which Tenant is permitted to remove from the Premises pursuant to the terms of this Lease. Subject to the foregoing, if this Lease is subordinate to any mortgage or ground lease and the holder thereof (or successor) shall succeed to the interest of Landlord, at the election of such holder (or successor) Tenant shall attorn to such holder and this Lease shall continue in full force and effect between such holder (or successor) and Tenant. Tenant agrees to execute such instruments of subordination subject to the aforesaid condition or attornment in confirmation of the foregoing agreement (provided such holder shall agree to assume in writing all of the obligations of the Landlord under this Lease) as such holder may request.

14.16 **STATUS REPORT.** Recognizing that Landlord may find it necessary to establish to third parties, such as accountants, banks, mortgagees, ground lessors, or the like, the then current status of performance of Tenant or Landlord hereunder, Tenant on the written request of Landlord made from time to time, will within ten (10) Business Days of any such request furnish to Landlord, or the holder of any mortgage or ground lease encumbering the Premises, or to any other third party designated by Landlord and holding an interest in the Premises, as the case may be, a statement of the status of any matter pertaining to this Lease, including, without limitation, acknowledgment that (or the extent to which) each party is in compliance with its obligations under the terms of this Lease. From time to time, upon not less than fifteen (15) days prior written request, Landlord shall execute, acknowledge and deliver to Tenant, a statement in writing certifying: (a) that the Lease is unamended (or specifying any amendments); (b) that this Lease is in full force and effect (if such be the case); (c) the dates through which Basic Rent and Escalation Charges and any other payments

have been paid; (d) any claims, defenses, offsets and counterclaims which Landlord has at the time of execution of such statement or that there are none; and (e) such other data as may reasonably requested by Tenant.

14.17 **SECURITY DEPOSIT.** Simultaneously with the execution and delivery of this Lease, Tenant shall deliver to Landlord a security deposit (the "Security Deposit"), which Security Deposit shall be in the Security Deposit Amount (as defined in Section 1.2) and shall consisteither of cash or of a clean, irrevocable letter of credit satisfactory in a form similar to Exhibit H, and issued by an FDIC insured bank located in Boston reasonably satisfactory to Landlordin favor of the Landlord. During the Term hereof, and any extensions thereof, and for ninety (90) days after the expiration of the Term, or for so long thereafter as Tenant is in possessionof the Leased Premises or has unsatisfied obligations hereunder to Landlord, the Security Deposit shall be security for the full and timely performance of Tenant's obligations under this Lease; which cash may be used or letter of credit drawn upon by Landlord in the event of Default and applied from time to time against outstanding obligations of Tenant hereunder without notice or demand. Tenant shall have no right to require Landlord to so apply the Security Deposit, nor shall Tenant be entitled to credit the same against rents or other sums payable hereunder; no interest shall accrue thereon. If the Security Deposit is in the form of a letter of credit, during the entire Term hereof, including any extension thereof, Tenant shall cause said letter of credit to be renewed, in identical form to that delivered herewith, no later than thirty (30) days prior to the date of expiration of same. Without limiting any other remedies of Landlord, in the event that Tenant fails to renew any letter of credit given hereunder at least thirty (30) days prior to the date of expiration thereof, then Landlord shall have the right to draw down the entire amount of said letter of credit and hold such sums as a cash deposit. If and to the extent that Landlord makes such use of the Security Deposit, or any part thereof, the sum so applied by Landlord (from cash or from a drawing on the letter of credit) shall be restored to the Security Deposit, in cash, by Tenant upon notice from Landlord, and failure to pay Landlord the amount to be so restored (within the grace period applicable to Fixed Rent hereunder) shall be a Default hereunder giving rise to all of Landlord's rights and remedies applicable to a Default in the payment of rent. In the event of a change of circumstance relating to the bank issuing the letter of credit, or Landlord otherwise reasonably believes the financial conditions of the issuing bank has been degraded, Landlordreserves the right to require Tenant to replace the letter of credit from time to time with a substitute similar letter of credit issued by another bank satisfactory to Landlord. No trust relationship is created herein between Landlord and Tenant with respect to said Security Deposit. Tenant acknowledges that the Security Deposit is not an advance payment of any kind or a measure of Landlord's damages in the event of Tenant's Default; Landlord shall notbe obliged to keep the Security Deposit as a separate fund or pay interest thereon but may commingle the Security Deposit with its own funds. Tenant hereby waives the provisions of any law which is inconsistent with this Section 14.17.

14.18 **REMEDYING DEFAULTS.** Landlord shall have the right, but shall not be required, to pay such sums or to do any act which requires the expenditure of monies which may be necessaryor appropriate by reason of the failure or neglect of Tenant to perform any of the provisionsof this Lease following Default therein by Tenant, and in the event of the exercise of such right by Landlord following a Default therein by Tenant, Tenant agrees to pay to Landlord forthwith upon demand all such sums, together with interest thereon at a rate equal to twelve

percent (12%) as an additional charge. Any payment of Basic Rent, Escalation Charges or other sums payable hereunder not paid within two (2) Business Days of when due shall, at the option of Landlord, bear interest at a per annum rate equal to 5% from the due date thereof and shall be payable forthwith on demand by Landlord, as an additional charge.

14.19 **HOLDING OVER.** Any holding over by Tenant after the expiration or earlier termination of the Term of this Lease shall be treated as a monthly tenancy at sufferance at a rate equal one hundred fifty (150%) for the first (1st) month, and thereafter two hundred (200%) for every month thereafter of the Basic Rent and Escalation Charges in effect on the date immediately preceding such expiration or earlier termination date. Beginning in the second(2nd) month of holding over, Tenant shall also pay to Landlord all damages, direct and/or indirect (including any loss of a tenant or rental income), sustained by reason of any such holding over. Otherwise, such holding over shall be on the terms and conditions set forth in this Lease as far as applicable (except there shall be no options to extend the Term if any be contained in this Lease).

14.20 **SURRENDER OF PREMISES.** Upon the expiration or earlier termination of the Term of this Lease, Tenant shall peaceably quit and surrender to Landlord the Premises in neat and clean condition and in good order, condition and repair, together with all alterations, and additions and improvements, including, without limitation, data wiring and cabling, which may have been made or installed in, on or to the Premises prior to or during the Term of this Lease, excepting only ordinary wear and use and damage by fire, other casualty or as the result of eminent domain proceedings for which, under other provisions of this Lease, Tenant has no responsibility of repair and restoration. Tenant shall remove all of Tenant's Removable Property and, to the extent specified by Landlord in the consent to alterations, all alterations and additions made by Tenant and all partitions wholly within the Premises and shall repair any damage to the Premises or the Building caused by such removal. To the extent Landlord requires removal of alterations or additions permitted to be made by Tenant without Landlord prior written consent, Landlord shall submit such removal request in writing to Tenant at least thirty (30) days prior to expiration or termination of the Lease. Any Tenant's Removable Property which shall remain in the Building or on the Premises after the expiration or termination of the Term of this Lease shall be deemed conclusively to have been abandoned, and either may be retained by Landlord as its property or may be disposed of in such manner as Landlord may see fit, at Tenant's sole reasonable cost and expense.

14.21 **APPROVALS.** Tenant shall reimburse Landlord, as additional rent, promptly on demand, and in all events within thirty (30) days of notice of demand for all reasonable out-of-pocket expenses, including but not limited to legal, engineering or other professional services or expenses incurred by Landlord in connection with any request(s) by Tenant for consents or approvals hereunder made from and after the Commencement Date (but in no event in connections with Landlord's Work, fitup and delivery of the Premises to Tenant prior thereto). Landlord shall not, in connection with any request(s) by Tenant for consents or approvals under this Lease, unreasonably withhold, delay, or condition such consent or approval.

14.22 **BROKERAGE.** Each of Landlord and Tenant warrants and represents that it has dealt with no broker in connection with the consummation of this Lease, other than NAI Hunneman

(Landlord) and Jones Lang LaSalle (Tenant), and in the event of any brokerage claims against either party predicated upon prior dealings with the other party, such party agrees to defend the same and indemnify the other against any such claim. Landlord shall be responsible for payment of all finder's fees, commissions and costs and expenses due said named brokers.

14.23 **SPECIAL TAXATION PROVISIONS.** Landlord shall have the right at any time and from time to time, to amend the provisions of this Lease if Landlord is advised by its counsel that all or any portion of the monies paid by Tenant to Landlord hereunder are, or may be deemed to be, unrelated business income within the meaning of the United States Internal Revenue Code, or regulation issued thereunder, and Tenant agrees that it will execute all documents or instruments reasonably necessary to effect such amendment or amendments, provided that no such amendment shall result in an increase in the overall economics of this lease for Tenant, and provided that no such amendment shall result in Tenant receiving under the provisions of this Lease less services or amenities than it is entitled to receive nor services or amenities of a lesser quality, or otherwise adversely interfere with or affect Tenant's use of the Premises for the Permitted Use or create any greater liability or obligation for Tenant.

Anything contained in the foregoing provisions of this Lease (including, without limitation, Article VI hereof) to the contrary notwithstanding, neither Tenant nor any other person having an interest in the possession, use, occupancy or utilization of the Premises shall enter into any lease, sublease, license, concession or other agreement for use, occupancy or utilization of space in the Premises which provides for rental or other payment for such use, occupancy or utilization based, in whole or in part, on the net income or profits derived by any person from the premises leased, used, occupied or utilized (other than an amount based on a fixed percentage or percentages of receipts or sales), and any other agreements shall be absolutely void and ineffective as a conveyance of any right or interest in the possession, use, occupancy or utilization of any part of the Premises.

14.24 **HAZARDOUS MATERIALS.** Tenant shall not (either with or without negligence) cause or permit its employees, agents or contractors to cause the escape, disposal, release or threat of release of any biologically or chemically active or other Hazardous Materials (as said term is hereafter defined) on, in, upon or under the Property or the Premises. Tenant shall not allow the generation, storage, use or disposal of such Hazardous Materials by its employees, agents or contractors in any manner prohibited by law, nor allow to be brought into the Property by its employees, agents or contractors any such Hazardous Materials except for use in the ordinary course of Tenant's business, and (if other than customary office and cleaning products) then only after written notice is given to Landlord of the identity of such Hazardous Materials. Hazardous Materials shall include, without limitation, any material or substance which is (i) petroleum, (ii) asbestos, (iii) designated as a "hazardous substance" pursuant to Section 311 of the Federal Water Pollution Control Act, 33 U.S.C. §1251 et seq. (33 U.S.C. § 1321) or listed pursuant to §307 of the Federal Water Pollution Control Act (33 U.S.C. § 1317), (iv) defined as a "hazardous waste" pursuant to Section 1004 of the Resource Conservation and Recovery Act, 42 U.S.C. § 6901 et seq. (42 U.S.C. § 6903), (v) defined as a "hazardous substance" pursuant to Section 101 of the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. § 9601 et seq. (42 U.S.C. § 9601), as amended, or (vi) defined as "oil" or a "hazardous waste", a "hazardous

substance", a "hazardous material" or a "toxic material" under any other law, rule or regulation applicable to the Property, including, without limitation, Chapter 21E of the Massachusetts General Laws, as amended. If any lender or governmental agency shall during the Term require testing to ascertain whether or not there has been any release of Hazardous Materials by Tenant in the Premises, in each case , of which such party in good faith and on reasonable belief of Tenant's violation of its obligations hereunder, then the reasonable costs thereof shall be reimbursed by Tenant to Landlord upon demand as additional chargesbut only if such requirement applies solely to the Premises or is the result of the acts or omissions of Tenant during the Term of this Lease. In addition, Tenant shall execute affidavits, representations and the like, from time to time, at Landlord's reasonable request concerning Tenant's best knowledge and belief without requirement for inquiry or due diligence regarding the presence of Hazardous Materials on the Premises. In all events, Tenant shall indemnify and save Landlord harmless from any release or the presence or existence of Hazardous Materials on the Premises occurring from and after the Commencement Date while Tenant is in possession, or elsewhere on the Property if causedby Tenant, its employees, agents or contractors. The covenants and indemnity set forth in this Section 14.24 shall survive the expiration or earlier termination of the Term of this Lease. Landlord expressly reserves the right to enter the Premises during Tenant's businesshours and after reasonable prior notice (of not less than three (3) Business Days) to Tenant to perform regular inspections and testing with respect to the presence, existence, release or threat of release of Hazardous Materials, provided Landlord shall use reasonable efforts to minimize disturbance to Tenant's Permitted Use.

14.25 **RIGHT OF FIRST OFFER.** Provided (a) Tenant is not in Default under this Lease beyond expiration of applicable notice and cure period; (b) Tenant originally named herein (or a related entity or any assignee, sublessee or transferee under a Permitted Transfer or to whom Landlord otherwise consents) continues to occupy and operate all or substantially all of the Premises; (c) subject to the existing rights of other tenant leases, renewals (whether by option or not), extensions, options to lease, or any rights of first notice or first offer to lease granted pursuant to those certain leases and/or occupancy agreements between Landlord and any other tenants or occupants of the Building executed prior to the Effective Date, Tenant shall have a right of first offer on the following defined suites in their current rentable square foot configuration on the second (2nd) and third (3rd) floors of the Building being Suite 200 (10,039 rsf), Suite 310 (4,247 rsf), Suite 330 (7,227 rsf), and Suite 350 (2,778 rsf) (collectively "Specific Suites"), as such suits become Available (as herein after defined) during the term of this Lease or any extension thereof. At any time during the Term of this Lease, so long as at least twenty-four (24) months of the then term of the Lease remains (which may include an executed extension period), the procedure for Tenant affecting the right of first offer shall be exercised in the following manner:

(i) Within one hundred and sixty (60) days of any Specific Suites becoming Available, Landlord shall give written notice (email being sufficient to Tenant's President or legal counsel) describing to Tenant the Availability of or the projected Availability of any Specific Suites subject to the terms described herein ("Availability Notice"). "Available"

or “Availability” shall mean that any Specific Suites, is not subject to a lease and (a) is vacant; or (b) Landlord has received written notice of termination or non-renewal, whether by renewal option or not, and will become free of leasehold commitment within the six (6) month period and thereafter obtains actual and legal possession of said Specific Suites free and clear of all claims, interests (except for Building tenants that have superior rights), tenants, and debris, and Landlord is free, and has elected to lease space to third parties without restriction. The prsf basic rent for any Available Specific Suites shall be the same as the then current prsf basic rent for the Premises, and shall increase at the same rate and on the same change dates; and

(ii) Tenant shall have fifteen (15) days to exercise its right of first offer by written notice (email being sufficient to Robert L. Duffy, Jr.) to Landlord to accept or reject Landlord’s Availability Notice for any Specific Suites offered; and

(iii) Except as otherwise provided herein, any Specific Suites shall be delivered in “as-is” condition, and shall become part of the Premises hereunder upon the delivery of any Specific Suites to Tenant and Landlord shall have no obligation to complete any work or provide any allowance to prepare any Specific Suites for Tenant’s occupancy. Following such election by Tenant, and effective as of the date the Tenant takes possession of any Specific Suites and for the balance of the then term of the Lease, and any extension thereof: (a) the “Premises”, as used in this Lease, shall include any Specific Suites; (b) the “Premises Rentable Area” shall be increased to include the rentable square footage of any Specific Suites taken by Tenant; and (c) the basic annual rent shall equal the sum of the basic rent for the Premises provided for in this Lease plus any Specific Suites basic rent; the Parties shall within thirty (30) days of Tenant’s written response, execute a lease agreement or lease modification to reflect any Specific Suites taken by Tenant, the adjusted terms of the Lease, if any, and such other changes as may be required to reflect the addition of any Specific Suites; and

(iv) In the event Tenant does not accept any Specific Suites detailed in the Landlord’s Availability Notice within the fifteen (15) day period outlined above, or in the event the parties are unable to conclude a lease agreement or modification for any Specific Suites within the above thirty (30) day period, the Tenant shall be deemed to have refused the particular Specific Suites detailed in the Availability Notice and Landlord may offer and contract for lease such Specific Suites to third parties, and the Tenant’s right of first offer under this Section 14.25 of the Lease shall lapse and be of no further force or effect, until such time as the Landlord has leased the Specific Suite(s) detailed in the Landlord’s Availability Notice to a third party and such Specific Suite(s) thereafter becomes Available; and

(v) The terms of this right of first offer are not applicable if any Specific Suites becomes Available pursuant to another tenant’s default or sublease clause (unless and until Landlord obtains actual and legal possession thereof); or if any Specific Suites may be subject to a new lease, renewal (whether by option or not), extension or amendment by the current occupant or successor in interest thereto; or any Specific Suites which is

subject to a fully executed proposal for rental terms with a third party which predates the Commencement Date.

14.26 **OPTION TO EXTEND THE TERM.** Provided no Tenant Default has occurred; the Premises has not been reduced by more than fifty (50%) percent; the Premises (as constituted at lease execution) has not been sublet or assigned except pursuant to a Permitted Transfer or with the consent of Landlord; and Tenant continues to occupy the entire Premises (but excluding subleased premises under a Permitted Transfer);; then Tenant shall have one (1) five (5) year option to extend the Lease Term at a rent equal to the market rate for equivalent office spacein similarly located buildings within the Waltham market. Tenant must give Landlord written notice it is exercising its extension option no later than nine (9) months prior to the expiration of the then current Lease Term ("Extension Notice"). Landlord shall provide Tenant with Landlord reasonable estimate of the basic rent rate for the extended Term within thirty (30) days of receiving the Extension Notice, which estimate shall reflect Landlord's good faith determination of then applicable market rate rent. If Tenant does not object to Landlord's determination of the basic rent for the extension term by written notice to Landlord within ten (10) days after receipt of Landlord's notice of Landlord's determination of market rate basic rent, then Tenant shall be deemed to have accepted basic rent as set forth in Landlord's notice. If Tenant does timely object within said ten (10) day period to Landlord's determination, then the parties shall use commercially reasonable efforts to agree upon the basic rent for such extension term; provided however, if the parties cannot agree upon basic rent for the extension term within ten (10) days after Landlord receives Tenant's objection (the "FMR Resolution Period"), then the Parties shall proceed as provided in Exhibit G attached hereto and incorporated herein by reference. Tenant shall be responsible for all payments necessary to maintain a security deposit equivalent to a minimum of two (2) month's Basic Rent. Unless provided otherwise by Landlord, all other terms and provisions under the Lease, other than Landlord's Work, other tenant improvements, any rent deferral or abatement, or any other terms the Landlord and Tenant agree to mutually amend, shall continue through the extended Lease Term. In the event the Tenant does not provide the Extension Notice, execute a lease amendment and provide payment as provided herein, the Tenant shall be deemed to have waived its option to extend the Lease Term and this Lease shall terminate upon the expiration of the then current Term.

14.27 **EARLY ACCESS.** Provided no event of Tenant Default has occurred and the Tenant does not interfere with the rights of other tenants or the Landlord's Work, Tenant and Tenant's vendors will be allowed, upon reasonable Tenant notice and approval of the Landlord, reasonable access to the Premises fifteen (15) days prior to the Commencement Date to permit Tenant to install telephone and data cabling, security systems, modular furniture, fixtures, furniture, and equipment to allow for a transition into the Premises. During such access, Tenant shall be bound by all of the obligations of the Tenant under the Lease, including any and all insurance requirements, but, provided that said access is solely for the purposes listed

above to allow for a transition into the Premises, excluding the payment of Base Rent and Tenant's proportionate share of Real Estate Taxes and Operating Expense during the above referenced early access period and without obligation for payment of utilities or other charges.

14.28 **FINANCIAL STATEMENTS.** Within ten (10) days after Landlord has made a written request, Tenant agrees to deliver to Landlord a complete financial statement certified by an independent certified public accounting firm, g firm, provided such request shall not be made more than once in any twelve (12) month period and all information received shall be maintained in confidence and shall not be disclosed to third parties except Landlord's lenders, investors, accountants and legal advisors, and, in each such case, subject to reasonable confidentiality requirements.

14.29 **GOVERNING LAW.** This Lease shall be governed exclusively by the provisions hereof and by the laws of the Commonwealth of Massachusetts.

14.30 **TIME OF THE ESSENCE.** Landlord and Tenant each agree that time is of the essence to each and every term and provision of this Lease.

14.31 **AUTHORITY FOR EXECUTION.** The person executing this Lease on behalf of Tenant hereby covenants and warrants that he or she was duly authorized to so execute this Lease and that this Lease is the valid and binding obligation of Tenant.

14.32 **FORCE MAJEURE**. It is understood and agreed that in any case where Tenant is required to do any act (other than the payment of money due under this Lease), delays caused by or resulting from an Act of God, war, civil commotion, fire or other casualty, labor difficulties, shortages of labor, materials or equipment, governmental regulations or orders, pandemic or other causes beyond Tenant's reasonable control shall not be counted in determining the time when the performance of such act must be completed, whether such time be designated by fixed time, a fixed period of time or a "reasonable time."

[SIGNATURE PAGE TO FOLLOW]

IN WITNESS WHEREOF, Landlord and Tenant have caused this Lease to be duly executed, under seal, by persons hereunto duly authorized, in multiple copies, each to be considered an original hereof, as of the date first set forth above.

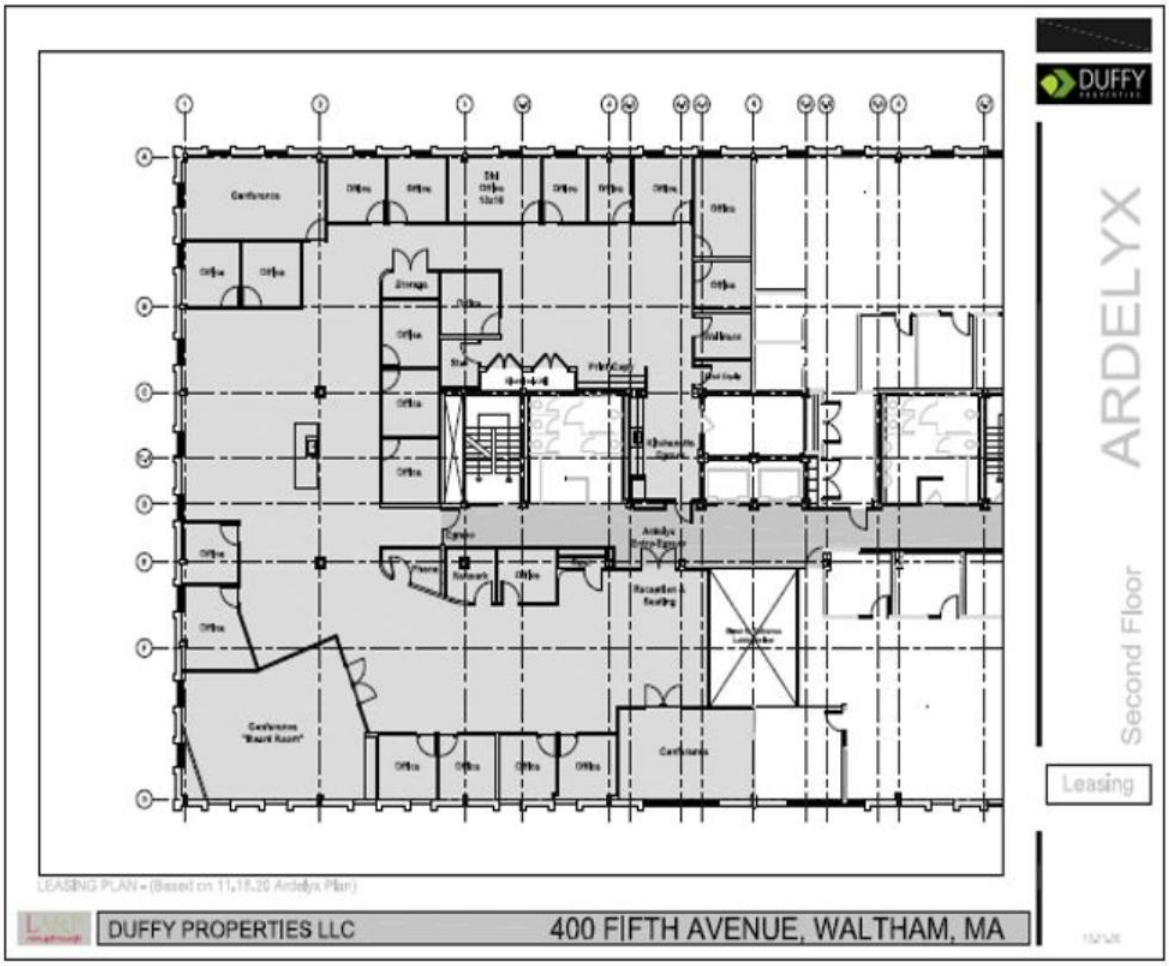
LANDLORD
Prospect Fifth Ave, LLC

/s/ Robert L. Duffy
By: Robert L. Duffy, Jr., Manager
Duly Authorized

TENANT
Ardelyx, Inc.

/s/ Mike Raab
By: Mike Raab, CEO
Duly Authorized

EXHIBIT A
PLAN
Suite 210



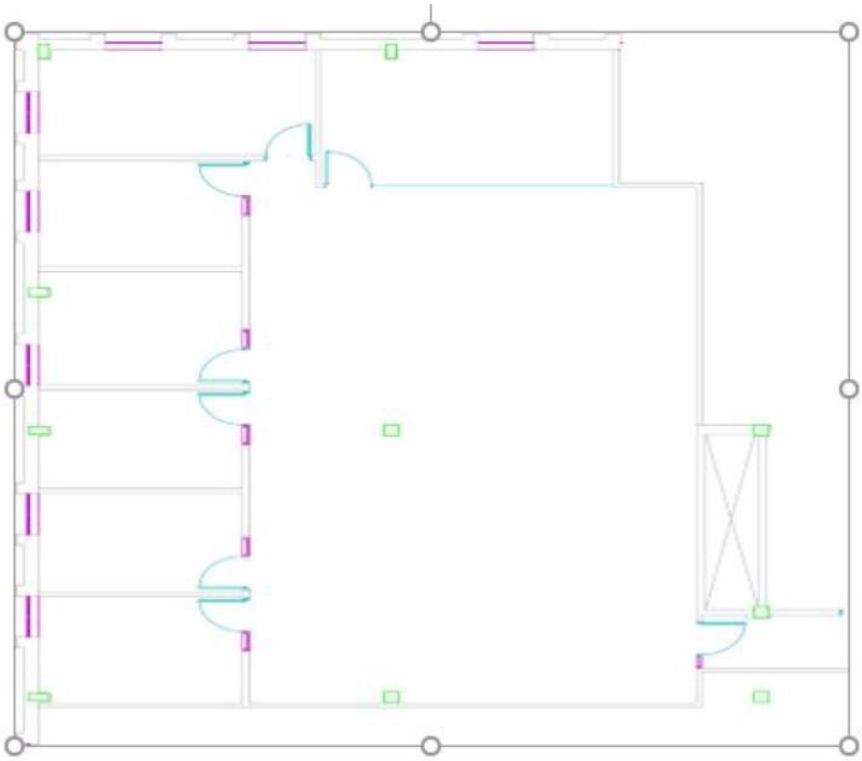
Plan as of 12/21/2020

Suite 210
Glass and Furniture Plan

Plan as 12/22/2020

Glass walls and doors marked on this Plan are highlighted in yellow and marked with letter x. Glass installation shall be a part of the work performed by Creative, at the Tenant's sole cost and expense. The glass and furniture are shown for informational and illustrative purposes only, and not included in the Landlord's Work.

Suite 300



Plan as of 12/15/2020

EXHIBIT B
Landlord's Work

Landlord shall conduct the following Landlord's Work using available building standard quantities and materials per the Building Standard attached hereto as Exhibit B-1, at the Landlord's sole cost and expense, building per the mutually approved Plan attached hereto as Exhibit A, including the following:

Suite 210

- Single and shared offices, as shown and defined by size on the Plan;
- Office walls shall go above ceiling tile grids, and CEO's office and conference room(s) walls shall go to the deck;
- Three (3) electrical outlets in standard office;
- Offices to be carpeted, kitchen to be V.C.T;
- Direct/indirect lighting fixtures;
- Approximately one (1) light per 100 square feet in each office;
- Conference rooms, as shown on the Plan;
- New paint and carpet, per Building Standard;
- Kitchen cabinets p-Lam, and hard surface countertops (all appliances on Tenant to provide,at its sole cost and expense);
- Deliver the premises with all HVAC/heating systems in good working order; and
- Costs associated with architectural/engineering expenses.

Tenant shall be solely responsible, at its sole cost and expense, for any of the following (as applicable):

1. Special engineering/design fees beyond those required for a building permit;
2. All costs associated with branding the space or logo work (Suites 210 and 300);
3. Extraordinary or specialty lighting and controls in the open ceiling area
4. Furniture, fixtures, and equipment;
5. The standard lease exceptions to the Landlord's Work listed below.

Suite 300

- Paint and carpet, similar to Suite 210; and
- Kitchenette.
- Otherwise, in "AS-Is, Where-Is Condition".

Not included in the Landlord's Work are any and all costs or work associated with:

(i) telephone/data/voice/network throughout the Premises; and

(ii) cubicles and/or open areas, including but not limited to costs or work associated with their purchase, installation or setup, and any telephone/data/voice/network and/or A/C power wiring, coring, through floor access modules, or other wiring therefore; and

(iii) Interior blinds; the installation of any interior blinds and/or window treatments which may be visible from the common area or outside the Premises is subject to the Landlord's written consent;

(iv) Coring the conference room floor(s) and/or the server room(s), if any (Landlord's Work shall include coring if required by applicable law); and

(v) Any furniture or appliances.

Except for the items noted above and subject to the requirements of Section 4.2 and Section 4.3 of

this Lease, the Premises shall be delivered in “AS IS” condition and Tenant acknowledges that by accepting possession of the Premises, the Premises “AS IS” are suitable for its intended use subject to Landlord’s satisfactory completion of all punchlist items. Tenant agrees that Landlord may make any immaterial changes to the Landlord’s Work listed above, if any, which may become reasonably necessary or advisable, without the approval of the Tenant; and Tenant may make material changes in such Landlord’s Work but only with the prior approval of Tenant or it required by any applicable law or regulation.

Tenant shall be solely responsible for all costs and expenses resulting from requests by Tenant for work, quantities or materials in excess of the Building Standards, Landlord’s Work noted above or otherwise by this Lease or as a result of Tenant Delays (as herein defined). “Tenant Delays” shall mean delays caused by: (a) requirements of the plans requested by Tenant that do not conform to Landlord’s Building Standards for office build-out; (b) any change in the plans requested by Tenant; (c) failure to approve the plans (or changes thereto or modifications thereof) within the time limits provided by Landlord’s construction representative; (d) any request by Tenant for a delay in the commencement or completion of Landlord’s Work for any reason other than due to Force Majeure Event once such work has commenced; or (e) any other act or omission of Tenant or its employees, agents or contractors. Tenant understands and agrees that changes to the Landlord’s Work/Plan(s) that may be needed or desired by Tenant after the execution of this Lease, and or the specification by Tenant of any components or finishes that are not building-standard or as depicted on the Plan(s), will be incorporated into the Plan(s), only if (i) such changes do not modify the scope or character of the Landlord’s Work or any material component thereof, and (ii) such changes will not, individuallyor in the aggregate, in Landlord’s reasonable opinion, result in a delay in the substantial completion of the Landlord’s Work (after taking into account any time savings achieved thereby). Tenant agrees that any additional cost resulting from such changes, as well as from any changes to the Landlord’s Work (including design and construction costs, including materials, labor and general conditions costs), after taking into account any cost savings achieved thereby, shall be the responsibility of Tenant and shall be paid in full b Tenant to Landlord within thirty (30) days of billing therefor by Landlord; and Tenant agrees that if such changes do result in delay in substantial completion, same shall be deemed a Tenant Delay and the Commencement Date shall be deemed to be the date Landlord’s Work would have been completed, if not for the Tenant’s change requests to the Landlord’s Work/Plan(s), as reasonably determined by Landlord. Notwithstanding the foregoing, no Tenant delay as used herein shall exist unless notice thereof is provided to Tenant and Tenant fails to rectify the cause thereof within seven (7) days of such notice.

The date of Substantial Completion shall be the date Landlord’s Work is substantially complete as defined in Section 4.3 of this Lease. Tenant opening for business in the Premises shall be deemed conclusive evidence of the Substantial Completion of the Landlord’s Work. Notwithstanding the foregoing, if any delay in the Substantial Completion of the Landlord’s Work is due to Tenant Delays, then the Substantial Completion Date shall be deemed to be the date Landlord’s Work would have been substantially completed, if not for same, as reasonably determined by Landlord.

EXHIBIT B-1
BUILDING STANDARDS

Flooring:	Carpet, commercial grade, 26 - 28 oz. glue down or carpet tile, (Shaw Contract or equal) Vinyl base, 4" commercial (with/without toe) VPI or equal. V.C.T., where specified orrequired to be Armstrong standard Exelon or equal, color by Tenant.
Paint:	Walls, Benjamin Moore Aqua Regal or equalOne coat primer tinted One coat finish, color by Tenant. Door frames, two coats Benjamin Moore Satin Impervo Color by Tenant
Electrical:	Every room shall have a light switch or occupancy sensor as required. Every office wall shall typically have one duplex electrical outlet on each wall. Floor outlets if requiredby code. All tel/data by tenant.
Hardware:	Schlage "A" series – nickel leverButts, 1 ½ pair per leaf All hardware Schlage unless noted otherwise Locksets or Store Room function provided for offices and other secure areas. Passage sets on all others.
Doors:	3' x 7' Birch or Maple veneer with hollow metal frames, with separate 24" – 30" sidelights per tenant requirement at select locations.
Acoustical:	Armstrong Prelude grid 15/16", 2' x 2' Mars Clima Plus Acoustical Ceiling Tile. Generally at 9' AFF
Lighting:	2' x 4' Avanti direct/indirect, approximately 1/100 square feet. LED
HVAC:	All zones, water source heat pumps. Cooling capacity, approximately 2.5 – 3.0 tons/1,000 sf.
Partitions:	Office, 2" x 4" 25gauge metal studs @ 16" o.c. insulated for sound attenuation at select locations. Typically 9'6" – 10' high. Tenant demising, 2" x 4" 25 gauge metal studs @ 16" o.c. to underside of deck with sound attenuation
Tenant Entry:	Single or pair of 3/0 x 7/0 glass doors with magnetic locks to be connected to Ardelyxsystem.
Tenant Interior Signage:	Building standard signage on lobby directory and at entry to suite.
Loading Docks:	One (1) public building dock (standard 48" tailgate height)
Exterior Window Treatments:	Vertical blinds as presently exist.

EXHIBIT C BUILDING
SERVICES

1. Heating and Cooling. Landlord shall supply, on Business Days as defined in Section 1.3, from 8:00 a.m. to 6:00 p.m. heating and cooling as normal seasonal changes may require to provide reasonably comfortable space temperature and ventilation for occupants of the Premises under normal business operation at an occupancy of not more than one person per 150 square feet of Premises Rentable Area and an electrical load not exceeding 3.0 watts per square foot of Premises Rentable Area. If Tenant shall require air conditioning, heating or ventilation outside the hours and days above specified, Landlord shall furnish such service and Tenant shall pay therefor such charges as may from time to time be in effect. The rate in effect as of the date of this Lease shall be $7.50 per ton per hour, and shall be subject to increase or decrease thereafter to reflect increases or decreases thereafter in utility rates. In the event Tenant introduces into the Premises personnel or equipment which overloads the capacity of the Building system, or in any other way interferes with the system's ability to perform adequately its proper functions, or is requested by Tenant, if and as needed, at Landlord's option or Tenant's election, the Landlord shall provide the supplementary systems, at Tenant's expense. The maintenance, repair, replacement, and expense to operate any supplementary systems during the term of the Lease, or any extension thereof, shall be the sole obligation of the Tenant.

2. Cleaning Schedule:

NIGHTLY: Between the hours of 5:00 p.m. and 6:00 a.m., Monday through Friday, legal holidays excluded.

1. Restrooms:

- Dust and spot clean all toilet partitions, tile walls and receptacles.
- Refill all dispensers including soap, toilet tissue, paper towels, etc.
- Dust mop or sweep floors thoroughly; wash and rinse using a germicidal detergent.
- Empty all trash receptacles and replace plastic liners.
- Clean and polish all chrome fittings and bright work, including shelves, flushometers and metal dispensers.
- Clean, sanitize and polish all fixtures including toilet bowls, urinals and sinks using a germicidal detergent solution.
- Clean and sanitize both sides of toilet seats with a germicidal detergent solution.
- Clean and polish all mirrors and glass.

2. Wash and clean water fountains with a germicidal detergent solution.
3. Office rubbish removal. Empty wastebaskets and replace liners, resulting from business office use, not including manufacturing or product packaging materials, the removal and disposal of this type of rubbish is Tenants responsibility.
4. Vacuum carpeted areas as needed.
5. Dry mop, wet mop and burnish tile floors to a polished appearance and/or vacuum and spot clean carpeting.
6. Wet wipe tabletops in employee lounge, including cleaning of any spills, if applicable.
7. Keep sidewalks and parking area clean and rubbish free.
8. Clean entrance door glass to remove finger marks, smudges, etc.

WEEKLY:

1. Dust rails and sills or as needed.
2. Sweep stairwells and landings or as needed.
3. Edge vacuum and moldings.
4. Keep lawn and landscaping properly maintained, if applicable.

QUARTERLY:

1. HVAC filters cleaning and/or changing filters on roof tops and air handlers.(Lab areas and specialized sections not included)

ANNUALLY:

1. Wash all windows inside and out.

*Note: Lab areas and specialized sections are not included in the above-mentioned cleaning schedule and are the sole responsibility of the Tenant.

COVID-19 Considerations:

Landlord shall be responsible for standard office janitorial and office rubbish removal inside of the Premises, including compliance with federal, state and local COVID-19 requirements then in effect,as may be amended or terminated in the future, while the cleaners are within the Premises performingsuch standard janitorial services and office rubbish removal (i.e. cleaners will be wearing a face mask). Tenant shall separately contract with the Landlord's cleaning provider for any cleaning services in excess of the Landlord's standard office cleaning within the Premises, as the Tenant elects to have performed or is otherwise required by federal, state, and local COVID-19 related requirementsand laws. Landlord will be responsible for compliance with COVID-19 heightened cleaning and signage pursuant to federal, state, and local requirements throughout the interior common areas of theBuilding, including proper signage at the entry doors and elevators, and enhanced cleaning of high touch interior common area surfaces. Compliance and enforcement of COVID-19 federal, state, andlocal requirements and laws, including but not limited such things as social distancing, compliance with signage, and the wearing of a face masks shall be the responsibility of the applicable governmental authority. Tenant shall be responsible for supplying face makes, hand sanitizer, and other PPE for Tenant's personnel, promulgating and enforcing company policies related to compliance with COVID-19 federal, state, and local requirements and laws. Landlord may amend or discontinue any heightened cleaning, additional signage, or any other services/notifications mandatedby federal, state, and local COVID-19 requirements and laws, as and when such federal, state, and local requirements and laws are amended, expire, or are otherwise no longer applicable.

Security Measures:

The Tenant will be entitled to provide, maintain, replace, remove, and install its own security system within the Premises during the Term, at its sole cost and expense; to install, in a workmanlike fashion, system components of the Tenant's choosing that include key systems (keyways & cylinder), security cameras and card readers (which may be mounted immediately outside the Premises in the common areas accessible from the Premises). Landlord shall endeavor to timely review and approve requests made by Tenant for the installation and use of additional security measures and equipment within the Premises and adjacent common areas of the Building as of and after the execution of the Lease.

Landlord's review and approval of such security measures and equipment shall be in its sole discretion, which shall include but is not limited to how such security measures and equipment may integrate into the Building's security systems, privacy rights of other tenants or visitors of the Building, and how Landlord, its agents or employees, or emergency responders will gain access to the Premises in the case of an emergency.

3. Electrical Service.

A. Landlord shall supply electricity to the Premises to meet a requirement not to exceed 3.0 watts per square foot of Premises Rentable Area for lighting and for office machines through standard receptacles for standard single-phase 120 volt alternating current. Tenant agrees in its use of the Premises not to exceed such requirement and that its total connected lighting load will not exceed the maximum from time to time permitted under applicable governmental regulations. Landlord shall purchase and install, at Tenant's expense (other than those in place as of the Commencement Date), all lamps, tubes, bulbs, starters and ballasts. Tenant shall pay all charges for electricity used or consumed in the Premises either directly if separately/check metered or as otherwise calculated as a pro rata share. Tenant shall pay the cost of any electric meter to be used or installed in the Premises unless included in Landlord's Work, and keep such meter in good operating condition. In order to assure that the foregoing requirements are not exceeded and to avert any possible adverse effect on the Building's electric system, Tenant shall not, without Landlord's prior written consent, which consent shall not be unreasonably withheld or delayed, connect any fixtures, appliances or equipment to the Building's electric distribution system other than typewriters, pencil sharpener, adding machines, handheld or desk top calculators, dictaphones, clocks, personal computers and radios and other customary general office machinery and equipment. The Tenant Electrical Rate of $1.75 prsf per annum is subject to review and adjustment by Landlord as hereinafter provided ("Tenant's Electrical Charge"), provided no adjustment or change therein shall be made prior to the second (2nd) anniversary of the Effective Date, and thereafter such adjustment or change shall be only be commiserate with the direct increase in the cost of supply thereof by the utility provider. Landlord shall provide written notice to the Tenant thirty (30) days prior to the effective date of any increase in the Tenant Electrical Rate.

B. If applicable, Tenant shall pay the Tenant's Electrical Charge for such service. Except as herein specifically set forth, the Tenant's Electrical Charge shall be unaffected by the extent of use of such service by Tenant and is deemed to be included as rental under this Lease payable as and when provided in Section 3.1 of this Lease. If Landlord reasonably determines, from time to time, that Tenant's use, demand and/or consumption of electricity exceeds the customary general office usage (any such excess use, demand or consumption of electricity by Tenant being hereinafter referred to as "Excess Electricity Use"), Landlord may, at its option, give written notice thereof to Tenant (any such notice being hereinafter referred to as an "Excess Electricity Notice") which notice shall specify the amount by which Landlord in good faith estimates that Landlord's cost of such Excess Electricity Use exceeds the cost had such customary office usage been applied extrapolated as a per rentable square foot charge for the Premises Rentable Area (any such excess cost being hereinafter referred to as an "Excess Electricity Use Charge"). The Excess Electricity Use Charge specified in such Excess Electricity Notice shall be due

and payable as additional rent as hereinafter provided. Any Excess Electricity Use Charge allocable to a period prior to the date of giving an Excess Electricity Notice shall, at the option of Landlord, be payable as additional rent within thirty (30) days after written demand is made therefor by Landlord. Excess Electricity Use Charges allocable to any period after the date of giving an Excess Electricity Notice shall be due and payable as additional rent monthly in advance in equal monthly installments for the balance of the Term of this Lease on the first day of each calendar month during the Term of this Lease with the first such installment being due and payable on the first day of the first full calendar month following the date of giving any such Excess Electricity Notice, provided, payment thereof shall cease if and when Tenant's usage is restored to customary general office usage (extrapolated as a per rentable square foot charge for the Premises Rentable Area).

C. If applicable, Landlord will determine Excess Electricity Use at Landlord's option, as follows: (i) by installing submeter(s) and/or check meter(s) and related wiring and equipment in the Premises at Landlord's expense and/or (ii) by estimating Excess Electricity Use in the Premises, such estimates to be prepared by an independent electrical engineer engaged by Landlord at Landlord's cost and expense and/or (iii) by any other reasonably reliable method reasonably selected by Landlord to estimate and/or calculate Excess Electricity Use. Excess Electricity Use Charges shall be established by Landlord based upon Excess Electricity Use established as aforesaid and based upon Landlord's estimate of the additional cost of such electricity to Landlord over and above the Tenant's Electrical Charge and any than existing Excess Electricity Use Charges in effect. The cost of such electric submeter(s) once installed as well as the cost of installation repair and replacement of any such additional electrical submeter(s) shall be borne by Tenant. Payments due Landlord from Tenant under the terms of this Section shall be deemed to beincluded within the term "Escalation Charges". Landlord shall have the right, at any time, during the Term of this Lease and as often as it may elect to determine whether Tenant is incurring Excess Electricity Use and to assess Excess Electricity Use Charges as aforesaid.

D. If Tenant shall require, demand, use or consume electricity in excess of the quantity, voltage or connected load specified in paragraph 3A of this Exhibit C Tenant shall, within thirty (30) days after demand, reimburse Landlord, for the cost of such excess electricity. Further, if (i) in Landlord's reasonable judgment, Landlord's facilities are inadequate for such excess requirements, or (ii) such excess use shall result in an additional burden on the Building's utility systems or additional cost on account thereof, as the case may be, Tenant shall, within thirty (30) days after demand, reimburse Landlord for all additional reasonable out of pocket costs related thereto. Further, if after the Commencement Date Tenant requires electricity in excess of the quantity, voltage or connected load specifiedin paragraph 3A of this Exhibit C, Landlord, upon written request from Tenant, and at the sole cost and expense of Tenant, will furnish and install such additional wire, conduits, feeders, switchboards and appurtenances as Landlord may reasonably require to supply suchadditional requirements of Tenant (if electricity therefor is then available to Landlord withoutaffecting the Building or Landlord's plans therefor); provided that Landlord shall have no obligation to furnish any such excess electricity unless the same shall be permitted by

applicable law and insurance regulations and shall not cause or threaten permanent damage or injury to the Building or the Premises or cause or create a dangerous or hazardous condition or entail excessive or unreasonable alterations or repairs or interfere with, or disturb other tenants or occupants of, the Building or interfere with Landlord's plans for the Building.

E. Landlord reserves the right to curtail, suspend, interrupt and/or stop the supply of water, sewage, electrical current, cleaning, and other services, and to curtail, suspend, interrupt and/or stop use of entrances and/or lobbies serving access to the Building, without thereby incurring any liability to Tenant, when necessary by reason of accident or emergency, or for repairs, alterations, replacements or improvements in the reasonable judgment of Landlord are desirable or necessary, or when prevented from supplying such services or use by strikes, lockouts, difficulty of obtaining materials, accidents or any other cause beyond Landlord's control, or by laws, orders or inability, by exercise of reasonable diligence, to obtain electricity, water, gas, steam, coal, oil or other suitable fuel or power. No diminution or abatement of rent or other compensation, nor any direct indirect or consequential damages shall or will be claimed by Tenant as a result of, nor shall this Lease or any of the obligations of Tenant be affected or reduced by reason of, any such interruption, curtailment, suspension or stoppage in the furnishing of the foregoing services or use, irrespective of the cause thereof. Failure or omission on the part of Landlord to furnish any of the foregoing services or use shall not be construed as an eviction of Tenant, actual or constructive, nor entitle Tenant to an abatement of rent, nor to render the Landlord liable in damages, nor release Tenant from prompt fulfillment of any of its covenants under this Lease. Notwithstanding the generality of the foregoing, Landlord shall use reasonable efforts to minimize the period of time in which such utilities and services are curtailed, suspended, interrupted, or stopped.

4. Other Services.

Landlord shall also provide throughout the Term (as the same may be extended):

A. Passenger elevator service from the existing passenger elevator system in common with Landlord and other tenants in the Building.

B. Hot water for lavatory purposes and cold water (at temperatures supplied by the municipality in which the Property is located) for drinking, lavatory and toilet purposes. If Tenant uses water for any purpose other than for ordinary lavatory, hygiene and drinking purposes, Landlord may assess a reasonable charge for the additional water so used, or install a water meter and thereby measure Tenant's water consumption for all purposes. In the latter event, Tenant shall pay the reasonable out of pocket cost of the meter and the cost of installation thereof and shall keep such meter and installation equipment in good working order and repair. Tenant agrees to pay for water consumed, as shown on such meter, together with the sewer charge based on such meter charges, as and when bills are rendered, and if Tenant defaults in making such payment, Landlord may pay such charges and collect same from Tenant as an additional charge. The foregoing payment obligations are intended to result in Tenant paying the difference between customary usage and extraordinary usage only.

C. Free access to the Premises on Business Days from 8:00a.m. to 5:30p.m., subject to restrictions based on emergency conditions and restricted access at all other times

under conditions imposed to provide security for the Building, and all other applicable provisions of this Lease including, without limitation, the provisions of Section 7.4 hereof, provided Tenant shall, subject to the terms of this Lease, have access to and use of the Premises for the Permitted Use twenty four (24) hours per day, seven (7) days per week, and three hundred sixty five (365) days per year.

D. Maintenance of the exterior of the Building, landscaping and lawn care and ice and snow removal from exterior steps, walkways, parking areas and driveways.

E. Landlord shall provide for the operation of a cafeteria food service facilityor other type food service (the "Cafeteria") in the Building. The Cafeteria will be availablefor use by Tenant and its employees, together with others, during its hours of operation andin accordance with any generally applicable and enforced rules and regulations that may be established concerning such use. Charges for food and other services provided at the Cafeteria shall be as determined by Landlord (or the operator of the Cafeteria or food vendor) from time to time in its sole discretion. It is understood and agreed that all use of the Cafeteria and its facilities, or food vendor shall be at the sole risk of Tenant and the employees using same, and, to the maximum extent this agreement may be made effective according to law (including the limitations set forth in M.G.L. c. 186, §15), but subject to Tenant's insurance requirements hereunder and Section 13.22, Tenant hereby releases Landlord, and the owner or operator of the Cafeteria for food vendor, from any liability in connection with such use and indemnifies and holds the Landlord, and the owner or operator of the Cafeteria or food vendor, harmless from and against any loss, cost, liability, damage or expense occasioned by or in any way related to or arising from the use of the Cafeteria by Tenant or Tenant's employees or by any other party allowed to use same by Tenant or any of its employees. There is expressly excluded from the foregoing indemnification, hold harmless agreement and waiver any loss, cost, liability, damage and expense arising from the gross negligence or willful misconduct of Landlord or its employees, contractors, agents or invitees. Landlord reserves the right at any time or from time to time, in its sole discretion, to alter the size, type, location or serving capacity of the Cafeteria or food vendor, or its meals or hours of operation or any other aspect thereof, provided however Landlord shall provide for some kind of food service on Business Days (Landlord reserves the right to not provide food service on Business Days that are the day before or after the holidays listed in the definition of Business Days) within or about the Building and as described below. Notwithstanding the forgoing and due to the Force Majeure Event associated with COVID-19, the Cafeteria and other type food service are not currently operating or being offered in or about the Building and shall not be offered until the Force Majeure Event has ended. Further, the Landlord reserves the right to keep the Cafeteria closed and not offer any type food service for six (6) months past the end of the present Force Majeure Event ending, as it may not be economically viable to operate. Thereafter and in the discretion of the Landlord, food service to the Building on Business Days may be the standard Cafeteria service or Avanti Micro Market or similar/better type service, and may be supplemented on certain Busines Days with third party food providers, food trucks, or similar. To the extent the Cafeteria is open or food service is being made available to the Tenant as provided herein, Tenant shall pay to Landlord, as additional rent and on a so-called net basis, Tenant's share (as computed in Article 1) of any losses, costsor subsidies incurred or paid by Landlord in operating the Cafeteria or other type food service within thirty (30) days of invoice therefor; provided Landlord may elect to collect

same in monthly estimated payments (as reasonably estimated by Landlord from time to time), due on the same date as monthly Basic Rent installment payments are due hereunder, with a periodic (not more often than annual) reconciliation

F. Landlord shall open, operate, and make available to Tenant, at least on Business Days, a fitness center facility (the "Fitness Center") in the Building. The Fitness Center shall available for use by Tenant and its employees, together with others, during its hours of operation and in accordance with any rules and regulations that may be established concerning such use, including compliance with COVID-19 regulations regarding gyms. Charges for use of and services provided at the Fitness Center shall be as determined by Landlord (or the operator of the Fitness Center, as the case may be) from time to time in its sole discretion. It is understood and agreed that all use of the Fitness Center and its facilities shall be at the sole risk of Tenant and the employees using same, and, to the maximum extent this agreement may be made effective according to law (including the limitations set forth in M.G.L. c. 186, §15), but subject to Tenant's insurance requirements hereunder, Tenant hereby releases Landlord, and the owner or operator of the Fitness Center, from any liability in connection with such use and indemnifies and holds the Landlord, and the owner or operator of the Fitness Center, harmless from and against any loss, cost, liability, damage or expense occasioned by or in any way related to or arising from the use of the in connection with such use. There is expressly excluded from the foregoing indemnification, hold harmless agreement and waiver loss, cost, liability, damage and expense arising from the gross negligence or willful misconduct of Landlord or its employees, contractors, agents or invitees. Landlord reserves the right at any time or from time to time, in its sole discretion, to limit the access to or use of the Fitness Center, or alter its size, type, location or serving capacity, or hours of operation or any other aspect thereof. As of the execution of this Lease, the Fitness Center is operating with certain additional rules and regulations of use due to the Force Majeure Event associated with COVID-19. However, Landlord may have to restrict access, partially or completely, to the Fitness Center as required to do so by any applicable government authority due to the current Force Majeure Event. To the extent the Fitness Center is open and available to the Tenant as provided herein, Tenant shall pay to Landlord, as additional rent and on a so- called net basis, Tenant's share (as computed in Article 1) of any losses, costs or subsidies incurred or paid by Landlord in operating the Fitness Center within thirty (30) days of invoice therefor; provided Landlord may elect to collect same in monthly estimated payments (as reasonably estimated by Landlord from time to time), due on the same date as monthly Basic Rent installment payments are due hereunder, with a periodic (not more often than annual) reconciliation. In the event the Premises is separately metered for any utility, Tenant shall provide the applicable utility provider with all information necessary for the Tenant to assume control of the appropriate account or meter on or before the earlier of the following, regardless of whether or not any base rent is due: (i) the Lease Commencement Date; (ii) the date of any early access to the Premises, regardless of whether said access is for Tenant to (a) conduct its business, (b) conduct or participate in any improvements to the Premises, (c) install or store any fixtures, furniture, or equipment, or (d) prepare the Premises for the Tenant's occupancy or move-in. Tenant shall maintain electrical service to the Premises throughout the Term of the Lease, regardless of whether Tenant is actually occupying the space or not. The Premises is separately metered for lights and plugs.

EXHIBIT D
OPERATING EXPENSES

Without limitation, Operating Expenses shall include:

1. All expenses incurred by Landlord or Landlord's agents which shall be directly related to employment of personnel, including amounts incurred for wages, salaries and other compensation for services, payroll, social security, unemployment and similar taxes, workman's compensation insurance, disability benefits, pensions, hospitalization, retirement plans and group insurance, uniforms and working clothes and the cleaning thereof, and expenses imposed on Landlord or Landlord's agents pursuant to any collective bargaining agreement for the services of employees of Landlord or Landlord's agents in connection with the operation, repair, maintenance, cleaning, management and protection of the Property, and its mechanical systems including, without limitation, day and night supervisors, property manager, accounts, bookkeepers, janitors, carpenters, engineers, mechanics, electricians and plumbers and personnel engaged in supervision of any of the persons mentioned above; provided that, if any such employee is also employed on other property of Landlord, such compensation shall be suitably prorated among the Property and such other properties.

2. The cost of services, utilities, materials and supplies furnished or used in the operation, repair, maintenance, cleaning, management and protection of the Property, including without limitation fees, if any, imposed upon Landlord or charged to the Property by the state or municipality in which the Property is located on account of the need of the Property for increased or augmented public safety services.

3. The cost of replacements for tools and other similar equipment used in the repair, maintenance, cleaning and protection of the Property, provided that, in the case of any such equipment used jointly on other property of Landlord, such costs shall be suitably prorated among the Property and such other properties.

4. A fee for the management of the Property, not to exceed five percent (5%) of the gross revenues of the Property, including, without limitation, all rent and other charges paid by tenants in the Building, together with the cost of reasonable legal and other professional fees relating to the Property, but excluding such fees and commissions paid in connection with services rendered for securing or renewing leases and for matters not related to the normal administration and operation of the Property.

5. Premiums for insurance against damage or loss to the Building from such hazards as shall from time to time be generally required by institutional mortgagees in the Boston area for similar properties, including, but not limited to insurance covering loss of rent attributable to any such hazards, and public liability insurance.

6. If, at any time during the term of the Lease, Landlord installs or makes an alteration, improvement, repair or replacement which is classified as a capital expenditure and anticipates to effect a reduction or saving in Operating Expenses, the cost of such expenditure amortized over its

useful life, consistently applied, with interest, shall be included in Operating Expenses.

7. Costs for electricity, water and sewer use charges, and other utilities supplied to the Property and not paid for directly by tenants or for which tenants or other occupants are obligated.

8. Amounts paid to independent contractors for services, materials and supplies furnished for the operation, repair, maintenance, cleaning and protection of the Property.

9. Costs and expenses associated with a Cafeteria and Fitness Center shall be directly allocated to each tenant based upon each tenant's pro rata share. Should the Cafeteria or Fitness Center cease operation, the payment of monies under this Exhibit for the Cafeteria or Fitness Center costs and expenses shall be prorated to reflect the closing date and thereafter no Cafeteria or Fitness Center costs and expenses shall be owed unless or until the café/cafeteria or gymnasium commenced operation.

Notwithstanding the foregoing, there shall be excluded from Operating Expenses those identified below:

1) leasing commissions, fees and costs, advertising and promotional expenses and other costs incurred in procuring tenants or in selling the Building or the Site;

2) legal fees or other expenses incurred in connection with enforcing leases with tenants in the Building;

3) costs of renovating or otherwise improving or decorating space for any tenant or other occupant of the Building or the Site, including Tenant, or relocating any tenant;

4) financing costs including interest and principal amortization of debts and the costs of providing the same;

5) except as otherwise expressly provided above, depreciation;

6) rental on ground leases or other underlying leases and the costs of providing the same;

7) wages, bonuses and other compensation of employees above the grade of General Portfolio Manager and fringe benefits other than insurance plans and tax qualified benefit plans;

8) any liabilities, costs or expenses associated with or incurred in connection with the removal, enclosure, encapsulation or other handling of Hazardous Substances and the cost of defending against claims in regard to the existence or release of Hazardous Substances at theBuilding or the Site (except with respect to those costs for which Tenant is otherwise responsible pursuant to the express terms of this Lease);

9) costs of any items for which Landlord is or is entitled to be actually paid or reimbursed by insurance;

10) increased insurance or Real Estate Taxes assessed specifically to any tenant of the Building

or the Site for which Landlord is entitled to reimbursement from any other tenant;

11) charges for electricity, water, or other utilities, services or goods and applicable taxes for which Tenant or any other tenant, occupant, person or other party is obligated to reimburse Landlord or to pay to third parties;

12) cost of any HVAC, janitorial or other services provided to tenants on an extra cost basis after regular business hours;

13) Intentionally Deleted.

14) cost of correcting defects in the design, construction or equipment of, or latent defects in, the Building or the Site;

15) cost of any work or service performed on an extra cost basis for any tenant in the Buildingor the Site to a materially greater extent or in a materially more favorable manner than furnished generally to the tenants and other occupants;

16) cost of any work or services performed for any facility other than the Building or Site;

17) any cost representing an amount paid to a person firm, corporation or other entity related to Landlord that is in excess of the amount which would have been paid in the absence of such relationship;

18) any cost of painting or decorating any interior parts of the Building or the Site other than common areas, stairwells, and loading docks;

19) Intentionally Deleted.

20) cost of initial cleaning and rubbish removal from the Building or the Site to be performed before final completion of the Building or tenant space;

21) cost of initial landscaping of the Building or the Site;

22) Intentionally Deleted.

23) Intentionally Deleted.

24) cost of the initial stock of tools and equipment for operation, repair and maintenance of the Building or the Site;

25) late fees or charges incurred by Landlord due to late payment of expenses, except to the extent attributable to Tenant’s actions or inactions;

26) cost of acquiring, securing cleaning or maintaining sculptures, paintings and other works of art;

27) real estate taxes or taxes on Landlord's business (such as income, excess profits, franchise, capital stock, estate, inheritance, etc.);

28) direct costs or allocable costs (such as real estate taxes) associated with parking operations if there is a separate charge to Tenant, other than tenants or the public for parking;

29) charitable or political contributions;

30) all other items for which another party compensates or pays so that Landlord shall not recover any item of cost more than once;

31) any cost associated with operating as an on or off-site management office for the Building, except to the extent included in the management fee permitted hereby;

32) Landlord's general overhead and any other expenses not directly attributable to the operation and management of the Building and the Site (e.g. the activities of Landlord's officers and executives or professional development expenditures), except to the extent included in the management fee permitted hereby;

33) costs and expenses incurred in connection with compliance with or contesting or settlement of any claimed violation of law or requirements of law, except to the extent attributable to Tenant's actions or inactions;

34) costs related to governmental compliance in connection with those parts of the Building or the Site that Landlord is responsible for maintaining and repairing, except to the extent attributable to Tenant's actions or inactions;

35) costs of complying with to Americans With Disabilities Act as otherwise in effect and enforceable prior to the Effective Date, whether such costs are classified as capital items or expenses under generally accepted accounting principles, except to the extent attributable to Tenant's actions or inactions;

36) costs of mitigation or impact fees or subsidies (however characterized), imposed or incurred prior to the date of the Lease or imposed or incurred solely as a result of another tenant's or tenants' use of the Site or their respective premises; and

37) costs related to public transportation, transit or vanpools.

EXHIBIT E
RULES AND REGULATIONS

1. The sidewalk, entry, passages, elevator, and stairways shall not be obstructed by the Tenant and shall not be used by them for any other purpose than for ingress and egress to and from their respective premises. Excepted from this restriction is use of these facilities for purpose of moving furniture and equipment to or from the Premises, which is permitted outside of normal office hours and on a non-interference basis with respect to other occupants of the Building.

2. No awnings or other projections shall be attached to the outside walls or windows of the Building without the prior written consent of Landlord. No curtains, blinds, shades, or screens shall be attached or hung in, or used in connection with, any window or door of the premises demised to any tenant or occupant, without the prior written consent of Landlord. Such awnings, projections, curtains, blinds, shades, screens, or other fixtures must be of a quality type, design and color, and attached in a manner, reasonably approved by Landlord in writing in advance. All non-building standard curtains, blinds, shades, etc. shall not be visible from either the exterior of the building or the interior building common areas.

3. No sign, advertisement, object, notice or other lettering shall be exhibited, inscribed, painted or affixed on any part of the outside or inside of the premises demised to any tenant or occupant of the Building without the prior written consent of Landlord. Interior signs on doors and directory tables, if any, shall be of a size, color and style approved by Landlord in writing and in advance.

4. The sashes, sash doors, skylights, windows, and doors that reflect or admit light and air into the halls, passageways or other public places in the Building shall not be covered or obstructed, nor shall any bottles, parcels, or other articles be placed on any window sills.

5. No show cases or other articles shall be put in front of or affixed to any part of the exteriorof the Building, nor placed in the halls, corridors, vestibules or other parts of the Building.

6. The water and wash closets and other plumbing fixtures shall not be used for any purposes other than those for which they were constructed, and no sweepings, rubbish, rags, or other substances shall be thrown therein.

7. No tenant or occupant shall mark, paint, drill into, or in any way deface any part of the Building or the premises demised to such tenant or occupant. No boring, cutting or stringing of wires shall be permitted, except with the prior written consent of the Landlord, and as Landlord may direct. No tenant or occupant shall install any resilient tile or similar floor covering in the premises demised to such tenant or occupant except in a manner approved by Landlord in writing and in advance.

8. No bicycles, vehicles, dogs (except for seeing eye dogs and similar animals) or other animals, birds or pets of any kind shall be brought into or kept in or about the premises demised to any tenant. Bicycles may be stored in racks, if any, furnished for such purpose by Landlord in a common area of the Property. No stove or open flame cooking shall be done or permitted in the

Building by any tenant without the approval of Landlord. No tenant shall cause or permit any unusual or objectionable odors to emanate from the premises demised to such tenant. Any open flame (candle, space heater, cooktop, etc.) is a fire hazard and is strictly prohibited in the Building. Nothing included in the Landlord's Work shall be deemed a prohibited item under this paragraphof this Lease, nor shall use thereof constitute a violation of this paragraph or this Lease.

9. Without the prior written consent of Landlord, no space in the Building shall be used for manufacturing, or for the sale of merchandise, goods or property of any kind at auction.

10. No tenant shall make, or permit to be made, any unseemly or disturbing noises or disturb or interfere with other tenants or occupants of the Building or neighboring buildings or premises whether by the use of any musical instrument, radio, television set or other audio device, unmusical noise, whistling, singing, or in any other way. Nothing shall be thrown out of any doors or windows.

11. Each tenant must, upon the termination of its tenancy, restore to Landlord all keys of stores, storage areas, offices and toilet rooms, either furnished to, or otherwise procured by, such tenant.

12. All removals from the Building or the carrying in or out of the Building or the premises demised to any tenant, of any safes, freight, furniture, or bulky matter of any description must take place at such time and in such manner as Landlord or its agents may determine, from time to time. Landlord reserves the right to inspect all freight to be brought into the Building and to exclude from the Building all freight which violates any of the Building Rules or the provisions of such tenant's lease.

13. Landlord shall have the right to prohibit any advertising by any tenant or occupant this, in Landlord's opinion, tends to impair the reputation of the Building or its desirability as a building for offices, and upon notice from Landlord, such tenant or occupant shall refrain from or discontinue such advertising.

14. Each tenant, before closing and leaving the premises demised to such tenant at any time shall see that all entrance doors are locked, lights are turned off, and windows closed. All electrical appliances including but not limited to, computers, monitors, printers, copiers, etc., shall be powered off at the close of business daily.

15. No premises shall be used, or permitted to be used, for lodging or sleeping, or for any immoral or illegal purpose.

16. There shall not be used in the Building, either by any tenant or occupant or by their agents or contractors, in the delivery or receipt of merchandise, freight or other matter, any hand trucks or other means of conveyance except those equipped with rubber tires, rubber side guards and such other safeguards as Landlord may require.

17. Canvassing, soliciting and peddling in the Building are prohibited and each tenant and occupant shall cooperate in seeking their prevention.

18. No premises shall be used, or permitted to be used, at any time, without the prior written approval of Landlord, as a store for the sale or display of goods, wires or merchandise of any kind, or as a restaurant, shop, booth, bootblack or other stand, or for the conduct of any business or occupation which predominantly involves direct patronage of the general public in the premises demised to such tenant, or for manufacturing or for other similar purpose.

19. No tenant shall move, or permit to be moved, into or out of the Building or the premises demised to such tenant, any heavy or bulky matter, without the specific approval of Landlord. If any such matter requires special handling, only a person holding a Master Rigger's license shall be employed to perform such special handling. No tenant shall place, or permit to be placed, on any part of the floor or floors of the premises demised to such tenant, a load exceeding the floor load per square foot which such floor was designed to carry and which is allowed by law. Landlord reserves the right to prescribe the weight and position of safes and other heavy matter, this must be placed so as to distribute the weight. All engineering required to verify installation method and feasibility shall be at tenant's expense.

20. The requirements of tenants will be attended to only upon application by tenant to the landlord in writing. Building employees shall not be required to perform, and shall not be requested by any tenant or occupant to perform, any work outside of their regular duties, unless under specific instructions from the office of the managing agent of the Building.

21. Tenant shall restrict parking by Tenant, its employees, service providers, agents, and visitorsto parking areas designated by Landlord and shall comply with reasonable parking rules and regulations as may be modified, posted, and distributed by Landlord from time to time. The parking spaces shall not be used for overnight parking or dead storage of vehicles or other merchandise or material. All vehicles parked or traveling through the common areas of the Building shall maintain a current registration and be properly insured. All parking shall be within the striped spaces in the parking lot. Landlord reserves the right to promulgate a system of parking stickers or passes as necessary to control parking by tenants and their visitors, and tenants shall reasonably cooperate in the implementation of such system.

22. All locks for doors in each tenant's Premises shall be building standard and no tenant shall change or install any additional lock or locks on any door in its leased area without Landlord's written consent. Tenant shall provide Landlord all access codes and any other devices necessary for Landlord's entry to Tenant's premises.

23. All Tenant entry doors, when not in use, shall be kept closed.

24. Landlord will not be responsible for lost or stolen personal property, money or jewelry from any premises demised to any tenant or occupant or public areas regardless of whether such loss occurs when the area is locked against entry or not.

25. Tenant shall not duplicate Access Keys or Access Control Cards. Tenant shall promptly report to Landlord any and all lost or stolen Access Keys or Access Control Cards. Lost or stolen Access Keys or Access Control Cards will be replaced by Landlord after notification. Replacement and any associated security system reprogramming shall be at Tenant's sole cost and expense.

26. Every reference herein to “Landlord’s Consent or Approval” means “prior written consent or approval of the Landlord in each instance”.

27. No Tenant shall smoke tobacco or marijuana in any part of the Property. Upon notice from the Landlord, Tenant shall immediately cease all activity in and around the Property which, in the reasonable discretion of the Landlord, constitutes noisy, offensive or disruptive activity. Tenant shall be responsible for the acts and omissions of their employees, agents, invitees and assigns.

28. No Tenant shall use any method of heating or cooling other than that provided by the Landlord, without the Landlord’s consent, which shall not be unreasonably withheld or delayed, or conditioned.

29. Each Tenant shall keep the Premises in a good state of cleanliness (without limiting or waiving and subject to Landlord’s obligations for cleaning under the Lease), and for such purposes shall, during the term of the Lease, make use of an approved cleaning service for the Building when supplemental cleaning is desired by Tenant. No Tenant shall employ any person or persons other than an approved cleaning service for the Building for the purpose of cleaning, or of taking charge of the Premises unless other arrangements have been approved by Landlord in writing. Each Tenant agrees that the Landlord shall not be responsible to any Tenant for any damage or loss of property within the Premises, except to the extent arising from the negligence or willful misconduct of Landlord or its employees, contractors, agents or invitees.

30. Tenant shall not install, attach or modify any appurtenances to the plumbing or HVAC systems without the Landlord’s prior written consent and Tenant shall indemnify and hold Landlord harmless from any and all loss occasioned by the installation, modification or attachments of said appurtenances.

31. Tenant shall not be permitted to use or keep in the Property any kerosene, burning fluid, or other illuminating material, inflammable, explosive, corrosive or otherwise harmful substance or materials, except as is customary in office or computer facilities, without the Landlord’s consent. Notwithstanding such consent, Tenant shall be solely liable and responsible for ensuring that such material is kept, maintained, stored, destroyed, disposed and discharged in accordance with all applicable federal, state, regulatory and local laws, regulations and ordinances as well as industry standards and practices. Tenant shall indemnify and hold Landlord harmless for its failure to comply with the above.

32. All complaints by a Tenant shall be made in writing to the Landlord. Each tenant shall giveto the Landlord’s Building superintendent prompt written notice of any damage known to Tenant or defect in pipes, wires, appliances or fixtures in or about the premises and of any damage to anypart of the premises.

33. Landlord reserves the right to rescind any of these rules and regulations and to make such other and further rules and regulations as in its reasonable judgment shall from time to time, be required for the safety, protection, care and cleanliness of the Building, the operation thereof, the

preservation of good order therein and the protection and comfort of the tenants and their agents, employees and invitees. Such rules and regulations, when made and written notice thereof is given to a tenant, shall be binding upon it in like manner as if originally herein prescribed.

EXHIBIT F
Sample Commencement Date Agreement

The Parties hereto, Prospect Fifth Ave, LLC, ("Landlord") and _____ ("Tenant"), are Parties under a certain Commercial Lease ("Lease") dated ____, for approximately ___rentable square feet + or - being a portion of the__floor at 400 Fifth Ave, Waltham, MA ("Premises"), and hereby agree for mutual consideration, the receipt of which is hereby acknowledged by both parties, as follows:

1. As used in the Lease, the term "Commencement Date" shall mean _____; and
2. As used in the Lease, the term "Rent Commencement Date" shall mean _____; and
3. As used in the Lease, the term "Expiration Date" shall mean_____; and
4. The first Lease Year shall be from_____to_____; and
5. The amount of $_____which was previously paid by the Tenant pursuant to Section 1.2 of the Lease shall be applied to the installment of monthly base rent commencing on_____*and on*_____*the Tenant shall make a partial payment to bring the Tenant's account current (strike if not applicable)*; and
6. Thereafter all payments shall be made on the first of each month pursuant to the Lease; and
7. If there are any inconsistencies between this agreement and the Lease, the terms of the Lease Agreement shall prevail; and
8. Tenant accepts the Premises in the condition required by the Lease and otherwise in "As-Is" condition. Tenant acknowledges that the all work contemplated pursuant to the Lease, has been completed to the full satisfaction of the Tenant or is subject to completion of the following punchlist items: _____.

All other terms and provisions under the Lease shall remain unchanged and are hereby ratified and affirmed.

IN WITNESS WHEREOF, the said Parties hereto set their hands and seals this day of _____, 20__.

TENANT	LANDLORD Prospect Fifth Ave LLC
Duly Authorized	Duly Authorized

EXHIBIT G

Appraisal Methodology for Extension Option Basic Rent

Within ten (10) Business Days after the expiration of the FMR Resolution Period (the "Broker Selection Deadline"), the parties shall each appoint an licensed commercial broker who has at least ten (10) years of experience and is knowledgeable in office rentals in the market where the Building is located. The two brokers shall together appoint a third licensed commercial real estate broker with the same qualifications, but the third commercial broker shall not have been hired or worked for either party for the past three (3) years. The three (3) brokers shall then each determine within twenty (20) days the then fair market value rental rate (taking into account leasehold improvements, allowances, rent abatements, commissions and other prevailing market concessions and allowances) for such space, taking into consideration the office rental market in Boston Metro West area for comparable space and the rental rates then being quoted to new tenants for comparable office space in the Building and other comparable office buildings in the Boston Metro West area. The fair market value rental rate (Basic Rent) for the extension option term shall thereafter be determined to be the amount equal to: (x) the average of the two appraisals which are closest in dollar amount to each other except that if all three appraisals are apart in equal amounts, the appraisal which falls in the middle shall be the fair market value rental rate and yearly increases on the anniversary of the commencement date of the extension term. If either party fails to selecta broker by the Broker Selection Deadline, then the broker selected by the other party, if selectedby the Broker Selection Deadline, shall be the sole broker. Landlord and Tenant shall share equallythe expense of any and all brokers. The broker(s) shall be obligated to make a determination of fair market value rental rate within thirty (30) days of the appointment of either the single broker (if only one) and within thirty (30) days of the appointment of the third broker (if three are so appointed).

In determining the fair market value rental rate for the extension term, the brokers shall consider, among other things, the then current arms' length basic rent being charged to tenants for comparable buildings in the Boston Metro West area market area.

The brokers shall not have the right to modify any provision of this Lease and shall only determine the fair market value rental rate as provided above for purposes of determination of the Basic Rent under this Lease for the extension term, subject to the limitations provided above.

The Tenant, after receiving the determination by the brokers, may decide not to exercise the option by providing notice to Landlord within ten (10) days of receiving the determination. Failure to provide timely notice shall constitute de facto exercise of the option at the fair market rental rate determined by the brokers.

EXHIBIT H

FORM LETTER OF CREDIT

IRREVOCABLE STANDBY LETTER OF CREDIT NO.

DATE:
BENEFICIARY*:* _____

APPLICANT:

Burlington, Massachusetts 01803
AS "TENANT"

AMOUNT: US $_____(_____
AND 00/100 U.S. DOLLARS)

EXPIRATION DATE: _____

LOCATION: AT OUR COUNTERS IN BOSTON, MASSACHUSETTS

DEAR SIR/MADAM:

WE HEREBY ESTABLISH OUR IRREVOCABLE STANDBY LETTER OF CREDIT NO. _____IN YOUR FAVOR AVAILABLE BY YOUR DRAFT DRAWN ON US AT SIGHT IN THE FORM OF EXHIBIT "B" ATTACHED AND ACCOMPANIED BY THE FOLLOWING DOCUMENTS:

1. THE ORIGINAL OF THIS LETTER OF CREDIT AND ALL AMENDMENT(S), IF ANY.
2. A DATED CERTIFICATION FROM THE BENEFICIARY SIGNED BY AN AUTHORIZED OFFICER OR AGENT, FOLLOWED BY ITS DESIGNATED TITLE, STATING THE FOLLOWING:

(A) "THE AMOUNT REPRESENTS FUNDS DUE AND OWING TO US FROM APPLICANT PURSUANT TO THAT CERTAIN LEASE BY AND BETWEEN BENEFICIARY, AS LANDLORD, AND APPLICANT, AS TENANT."

OR

(B) "WE HEREBY CERTIFY THAT WE HAVE RECEIVED NOTICE FROM BANK THAT LETTER OF CREDIT NO. _____WILL NOT BE RENEWED, AND THAT WE HAVE NOT RECEIVED A REPLACEMENT OF THIS LETTER OF CREDIT FROM APPLICANT SATISFACTORY TO US AT LEAST THIRTY (30) DAYS PRIOR TO THE EXPIRATION DATE OF THIS LETTER OF CREDIT."

IRREVOCABLE STANDBY LETTER OF CREDIT NO._____
DATED

THE LEASE AGREEMENT MENTIONED ABOVE IS FOR IDENTIFICATION PURPOSES ONLY AND IT IS NOT INTENDED THAT SAID LEASE AGREEMENT BE INCORPORATED HEREIN OR FORM PART OF THIS LETTER OF CREDIT.

OUR OBLIGATION UNDER THIS CREDIT SHALL NOT BE AFFECTED BY ANY CIRCUMSTANCES, CLAIM OR DEFENSE, REAL OR PERSONAL, OF ANY PARTY AS TO THE ENFORCEABILITY OF THE LEASE BETWEEN YOU AND TENANT, IT BEING UNDERSTOOD THAT OUR OBLIGATION SHALL BE THAT OF A PRIMARY OBLIGOR AND NOT THAT OF A SURETY, GUARANTOR OR ACCOMMODATION MAKER. IF YOU DELIVER THE WRITTEN CERTIFICATE REFERENCED ABOVE TO US, (I) WE SHALL HAVE NO OBLIGATION TO DETERMINE WHETHER ANY OF THE STATEMENTS THEREIN ARE TRUE, (II) OUR OBLIGATIONS HEREUNDER SHALL NOT BE AFFECTED IN ANY MANNER WHATSOEVER IF THE STATEMENTS MADE IN SUCH CERTIFICATE ARE UNTRUE IN WHOLE OR IN PART, AND (III) OUR OBLIGATIONS HEREUNDER SHALL NOT BE AFFECTED IN ANY MANNER WHATSOEVER IF TENANT DELIVERS INSTRUCTIONS OR CORRESPONDENCE TO WHICH EITHER (A) DENIES THE TRUTH OF THE STATEMENT SET FORTH IN THE CERTIFICATE REFERRED TO ABOVE, OR (B) INSTRUCTS US NOT TO PAY BENEFICIARY ON THIS CREDIT FOR ANY REASON WHATSOEVER.

PARTIAL AND MULTIPLE DRAWS ARE ALLOWED. EXCEPT AS EXPRESSLY SET FORTH HEREIN, THIS LETTER OF CREDIT MUST ACCOMPANY ANY DRAWINGS HEREUNDER FOR ENDORSEMENT OF THE DRAWING AMOUNT AND WILL BE RETURNED TO THE BENEFICIARY UNLESS IT IS FULLY UTILIZED.

DRAFT(S) AND DOCUMENTS MUST INDICATE THE NUMBER AND DATE OF THIS LETTER OF CREDIT.

THIS LETTER OF CREDIT SHALL BE AUTOMATICALLY EXTENDED FOR AN ADDITIONAL PERIOD OF ONE YEAR, WITHOUT AMENDMENT, FROM THE PRESENT OR EACH FUTURE EXPIRATION DATE UNLESS AT LEAST SIXTY (60) DAYS PRIOR TO THE THEN CURRENT EXPIRATION DATE WE NOTIFY YOU BY REGISTERED MAIL/OVERNIGHT COURIER SERVICE AT THE ABOVE ADDRESSES THAT THIS LETTER OF CREDIT WILL NOT BE EXTENDED BEYOND THE CURRENT EXPIRATION DATE. IN NO EVENT SHALL THIS LETTER OF CREDIT BE AUTOMATICALLY EXTENDED BEYOND **[SIX (6) MONTHS BEYOND LEASE EXPIRATION]**.

THIS LETTER OF CREDIT MAY BE TRANSFERRED WITHOUT COST TO THE BENEFICIARY, ONE OR MORE TIMES BUT IN EACH INSTANCE TO A SINGLE BENEFICIARY AND ONLY IN THE FULL AMOUNT AVAILABLE TO BE DRAWN UNDER THE LETTER OF CREDIT AT THE TIME OF THE TRANSFER AND ONLY BY THE ISSUING BANK UPON OUR RECEIPT OF THE ATTACHED “EXHIBIT A” DULY COMPLETED AND EXECUTED BY THE BENEFICIARY AND ACCOMPANIED BY THE ORIGINAL LETTER OF CREDIT AND ALL AMENDMENTS, IF ANY.

ALL DEMANDS FOR PAYMENT SHALL BE MADE BY PRESENTATION OF THE ORIGINAL APPROPRIATE DOCUMENTS PRIOR TO 10:00 A.M. E.S.T. TIME, ON A BUSINESS DAY AT OUR OFFICE (THE “BANK’S OFFICE”) AT: _____

BOSTON, MASSACHUSETTS _____, ATTENTION: _____ OR BY FACSIMILE TRANSMISSION AT: (617)_____-_____; AND SIMULTANEOUSLY UNDER TELEPHONE ADVICE TO: (617)_____-_____, ATTENTION: _____ WITH ORIGINALS TO FOLLOW BY OVERNIGHT COURIER SERVICE.

PAYMENT AGAINST CONFORMING PRESENTATIONS HEREUNDER SHALL BE MADE BY BANK DURING NORMAL BUSINESS HOURS OF THE BANK'S OFFICE WITHIN ONE (1) BUSINESS DAY AFTER PRESENTATION.

WE HEREBY AGREE WITH THE DRAWERS, ENDORSERS AND BONAFIDE HOLDERS THAT THE DRAFTS DRAWN UNDER AND IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THIS LETTER OF CREDIT SHALL BE DULY HONORED UPON PRESENTATION TO THE DRAWEE, IF NEGOTIATED ON OR BEFORE THE EXPIRATION DATE OF THIS CREDIT.

THIS LETTER OF CREDIT IS SUBJECT TO THE UNIFORM CUSTOMS AND PRACTICE FOR DOCUMENTARY CREDITS (1993 REVISION), INTERNATIONAL CHAMBER OF COMMERCE, PUBLICATION NO. 500.

AUTHORIZED SIGNATURE AUTHORIZED SIGNATURE

EXHIBIT “A”

DATE:

TO:

RE: STANDBY LETTER OF CREDIT

NO. ISSUED BY
ATTN: L/C
AMOUNT:

LADIES AND GENTLEMEN:

FOR VALUE RECEIVED, THE UNDERSIGNED BENEFICIARY HEREBY IRREVOCABLY TRANSFERS TO:

(NAME OF TRANSFEREE)
(ADDRESS)

ALL RIGHTS OF THE UNDERSIGNED BENEFICIARY TO DRAW UNDER THE ABOVE LETTER OF CREDIT UP TO ITS AVAILABLE AMOUNT AS SHOWN ABOVE AS OF THE DATE OF THIS TRANSFER.

BY THIS TRANSFER, ALL RIGHTS OF THE UNDERSIGNED BENEFICIARY IN SUCH LETTER OF CREDIT ARE TRANSFERRED TO THE TRANSFEREE. TRANSFEREE SHALL HAVE THE SOLE RIGHTS AS BENEFICIARY THEREOF, INCLUDING SOLE RIGHTS RELATING TO ANY AMENDMENTS, WHETHER INCREASES OR EXTENSIONS OR OTHER AMENDMENTS, AND WHETHER NOW EXISTING OR HEREAFTER MADE. ALL AMENDMENTS ARE TO BE ADVISED DIRECT TO THE TRANSFEREE WITHOUT NECESSITY OF ANY CONSENT OF OR NOTICE TO THE UNDERSIGNED BENEFICIARY.

THE ORIGINAL OF SUCH LETTER OF CREDIT IS RETURNED HEREWITH, AND WE ASK YOU TO ENDORSE THE TRANSFER ON THE REVERSE THEREOF, AND FORWARD IT DIRECTLY TO THE TRANSFEREE WITH YOUR CUSTOMARY NOTICE OF TRANSFER.

SINCERELY,

(BENEFICIARY’S NAME)

SIGNATURE OF BENEFICIARY

SIGNATURE AUTHENTICATED

(NAME OF BANK)

AUTHORIZED SIGNATURE

EXHIBIT “B”

_____

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement on Form S-8 (No. 333-197408) pertaining to the 2008 Stock Incentive Plan, as amended, the 2014 Equity Incentive Award Plan and the 2014 Employee Stock Purchase Plan of Ardelyx, Inc.

(2) Registration Statements on Form S-8 (Nos. 333-202663 and 333-230156) pertaining to the 2014 Equity Incentive Award Plan and the 2014 Employee Stock Purchase Plan of Ardelyx, Inc.

(3) Registration Statements on Form S-3 (Nos. 333-205630, 333-213085 and 333-239764) of Ardelyx, Inc.

(4) Registration Statements on Form S-8 (Nos. 333-210079, 333-216154, 333-223694 and 333-237057) pertaining to the 2014 Equity Incentive Award Plan of Ardelyx, Inc.

(5) Registration Statement on Form S-8 (No. 333-214538) pertaining to the 2016 Employment Commencement Incentive Plan of Ardelyx, Inc.

of our report dated March 8, 2021, with respect to the financial statements of Ardelyx, Inc. included in this Annual Report (Form 10-K) of Ardelyx, Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Redwood City, California
March 8, 2021

Exhibit 31.1

CERTIFICATION

I, Michael Raab, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ardelyx, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 8, 2021

By: /s/ Michael Raab

Michael Raab
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Justin Renz, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ardelyx, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 8, 2021

By: /s/ Justin Renz

Justin Renz
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Ardelyx, Inc. (the "Company") on Form 10-K for the period ending December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Michael Raab, President and Chief Executive Officer of the Company, and Justin Renz, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 8, 2021

By: /s/ Michael Raab
Michael Raab
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 8, 2021

By: /s/ Justin Renz
Justin Renz
Chief Financial Officer
(Principal Financial Officer)