UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

or

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

For the transition period from to

Commission File Number 001-40034

VALLON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**82-4369909**
(State or other jurisdiction of incorporation and organization)	(I.R.S. Employer Identification No.)
100 N. 18th Street, Suite 300, Philadelphia, PA 19103	**(267) 607-8255**
(Address of principal executive offices, including zip code)	**(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	VLON	NASDAQ Capital 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 Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

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

As of June 30, 2021 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's common stock held by non-affiliates was approximately $22.9 million based on the last reported sale price of the registrant's common stock on the Nasdaq Capital Market on June 30, 2021.

As of February 11, 2022, 6,812,836 shares of the Registrant's Common Stock were outstanding.

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VALLON PHARMACEUTICALS, INC.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this Annual Report) contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. Some of the statements in the sections captioned "Item 1. Business," "Item 1A. Risk Factors," "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations," and elsewhere in this Annual Report contain forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- the likelihood of our clinical trials and non-clinical studies demonstrating safety and efficacy of our product candidates, and other positive results;
- the timing of initiation of our future clinical trials, and the reporting of data from our completed, current and future preclinical and clinical trials;
- the size of the market opportunity for our product candidates;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- the success of competing therapies that are or may become available;
- our estimates of the number of patients in the United States who suffer from ADHD or narcolepsy and the number of patients that will enroll in our clinical trials;
- the beneficial characteristics, safety and efficacy of our product candidates;
- the timing or likelihood of regulatory filings and approval for our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to the further development and manufacturing of our product candidates, including ADMIR;
- the expected potential benefits of strategic collaborations with third parties, including MEDICE Arzneimittel Pütter GmbH & Co. KG (Medice), who is affiliated with one of our principal stockholders, SALMON Pharma GmbH (Salmon Pharma), and represented by one member of our board of directors, and our ability to attract collaborators with development, regulatory and commercialization expertise;
- existing regulations and regulatory developments in the United States, the European Union, and other geographic territories;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- the need to hire additional personnel, and our ability to attract and retain such personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;
- the impacts of the COVID-19 pandemic on our operations;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act;

- our anticipated use of our existing resources and the proceeds from this offering; and
- our ability to maintain the listing of our common stock on The Nasdaq Capital Market.

Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. You should refer to the "Risk Factors" section of this Annual Report for a discussion of other important factors that may cause actual results to differ materially from those expressed or implied by the forward-looking statements.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward- looking statements as predictions of future events. If the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this Annual Report represent our views as of the date of this Annual Report. We anticipate that subsequent events and developments will cause our views to change, however, except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this Annual Report, whether as a result of any new information, future events or otherwise. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

This Annual Report includes trademarks and registered trademarks of Vallon Pharmaceuticals, Inc. Products or service names of other companies mentioned in this Annual Report may be trademarks or registered trademarks of their respective owners.

As used in this Annual Report, unless the context requires otherwise, the "Company," "we," "us" and "our" refer to Vallon Pharmaceuticals, Inc.

RISK FACTOR SUMMARY

The following is a summary of the principal risks described below in Part I, Item 1A "Risk Factors" in this Annual Report on Form 10-K. We believe that the risks described in the "Risk Factors" section are material to investors, but other factors not presently known to us or that we currently believe are immaterial may also adversely affect us. The following summary should not be considered an exhaustive summary of the material risks facing us, and it should be read in conjunction with the "Risk Factors" section and the other information contained in this Annual Report on Form 10-K.

Risks Relating to Our Business and Industry

- We anticipate future losses and negative cash flow, and it is uncertain if or when we will become profitable.
- We are a clinical-stage company with no approved products and a lack of operating history, which makes it difficult to assess our future viability.
- As a result of our limited operating history, we may not be able to correctly estimate our future revenues, operating expenses, need for investment capital, or stability of operations, which could lead to cash shortfalls.
- We do not currently have any drug products for sale, and only one clinical stage product under development, ADAIR. Our prospects currently depend largely on the success of ADAIR, which is still in clinical development, and we may not be able to generate revenues from ADAIR.
- If serious adverse or unacceptable side effects are identified during the development of ADAIR or any potential future products, such as ADMIR, we may need to abandon or limit our development of some of such products.
- If ADAIR does not achieve broad market acceptance, the revenues that we generate from its sales will be limited.
- If we obtain approval to commercialize ADAIR, or any other future product, such as ADMIR, outside of the U.S., a variety of risks associated with international operations could materially adversely affect our business.
- If the government or third-party payors fail to provide adequate coverage and payment rates for ADAIR or any future products, such as ADMIR, we may develop, license or acquire, if any, our revenue and prospects for profitability will be limited.

- If we are unable to establish sales, marketing, and distribution capabilities or to enter into agreements with third parties to market and sell ADAIR or any other future product, such as ADMIR, we may not be successful in commercializing ADAIR or any other future product if and when they are approved.

Risk Relating to Finances and Capital Requirements

- We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.
- We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

Risks Relating to Regulatory Matters

- We may not receive regulatory approval for ADAIR or any future product, such as ADMIR, or its or their approvals may be delayed, which would have a material adverse effect on our business and financial condition.
- Even if ADAIR or any other proposed product that we develop, such as ADMIR, receives marketing approval, we will continue to face extensive regulatory requirements and the product may still face future development and regulatory difficulties.
- The abuse, misuse or off-label use of our products may harm our image in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Risks Relating to Intellectual Property

- We have filed multiple patent applications and have two issued patents by the U.S. Patent and Trademark Office (U.S. PTO) and one issued patent by the European Patent Office. These or any other patent applications may not result in issued patents, and as a result we may have limited protection of our proprietary technology in the marketplace.
- If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.
- Because it is difficult and costly to protect our proprietary rights, we may not be able to ensure their protection.

Risks Relating to Securities Markets and Our Common Stock

- If we cannot continue to satisfy the listing requirements of The Nasdaq Capital Market and other rules, including the director independence requirements, our securities may be delisted, which could negatively impact the price of our securities and stockholders' ability to sell them.
- Our stock may be subject to substantial price and volume fluctuations due to a number of factors, many of which are beyond our control and may prevent our stockholders from reselling our common stock at a profit.

MARKET, INDUSTRY AND OTHER DATA

This Annual Report on Form 10-K contains estimates, projections and other information concerning our industry, our business and the markets for our drug candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained the industry, market and similar data set forth in this report from our internal estimates and research and from independent industry publications, governmental publications, reports by market research firms or other independent sources that we believe to be reliable sources. In some cases, we do not expressly refer to the sources from which this data is derived. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our internal data and estimates are based upon information obtained from trade and business organizations and other contacts in the industry in which we operate, and our management's understanding of industry conditions. While we believe our internal research is reliable, it has not been verified by an independent source. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. We are

responsible for all of the disclosure contained in this report, and we believe these industry publications and third-party research, surveys and studies are reliable. While we are not aware of any misstatements regarding any third-party information presented in this report, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section entitled "Risk Factors" in this report, and elsewhere in this report.

PART I

Item 1. BUSINESS

Overview

We are a clinical-stage biopharmaceutical company primarily focused on the development and commercialization of proprietary biopharmaceutical products. We are developing novel medications for central nervous system (CNS) disorders with a focus on abuse-deterrent medications. Our lead investigational product candidate, ADAIR, is a proprietary, abuse-deterrent oral formulation of immediate-release dextroamphetamine (the main active ingredient in Adderall®) for the treatment of attention-deficit/hyperactivity disorder (ADHD) and narcolepsy. According to the US Department of Health and Human Services' 2018 National Survey on Drug Use and Health, over five million adolescents and adults misuse prescription stimulant medications on an annual basis. The misuse and abuse of prescription stimulants has substantial medical risk, including risk of irregular heartbeat, heart attack, seizures, hallucinations, hostile behavior and stroke, as well as increased risk of addiction. ADAIR is designed to deter attempts to crush and snort and to provide barriers to injection while still providing the expected therapeutic benefit when taken orally.

We are developing ADAIR for registration with the U.S. Food and Drug Administration (FDA) through the Section 505(b)(2) regulatory pathway, which is expected to obviate the need for large Phase 2 and Phase 3 efficacy and safety studies. In July 2018, our Investigational New Drug (IND) application for ADAIR was approved by the FDA. We have completed three Phase 1 trials of ADAIR including a proof-of-concept intranasal human abuse potential study. We have also completed a 13-week preclinical toxicology study on the final formulation of ADAIR that showed no safety findings of concern. We are currently conducting the SEAL study, a pivotal intranasal abuse study, and have completed its patient enrollment and treatment phases. The SEAL study enrolled 55 subjects who successfully passed the qualification phase with a total of 53 completing the study. We expect to report top-line results of the SEAL study in the first quarter of 2022. Additionally, we continue to conduct preclinical studies and manufacturing work and evaluate the potential for any additional studies to support the submission of a New Drug Application (NDA) for ADAIR to the FDA.

In January 2020, we entered into a license agreement (the Medice License Agreement) with Medice, which grants Medice an exclusive license to develop, use, manufacture, market and sell ADAIR throughout Europe. Under the Medice License Agreement, Medice paid us a $0.1 million upfront payment and will pay milestone payments of up to $6.3 million in aggregate upon achieving certain regulatory and sales milestones. We are also entitled to low-double digit tiered royalties on net sales of ADAIR.

In addition to ADAIR, we completed formulation development work and selected the final formulation of our second product candidate, ADMIR, an abuse deterrent formulation of methylphenidate (Ritalin®), for the treatment of ADHD. We also plan to utilize the Section 505(b)(2) regulatory pathway for registration of ADMIR.

In the future, we plan to use our abuse deterrent platform technology to develop other products that have potential for abuse in their current forms and will continue business development activities and seek partnering, licensing, merger and acquisition opportunities or other transactions to further develop our pipeline and drug-development capabilities.

The global COVID-19 pandemic continues to present uncertainty and unforeseeable new risks to our operations and business plan. We have closely monitored recent COVID-19 developments, including states' lifting COVID-19 safety measures, drops in vaccination rates, and the spread of various coronavirus strains such as the Delta and Omicron variants. In light of these developments, the full impact of the COVID-19 pandemic on our business, operations and clinical development plans remains uncertain and will vary depending on the pandemic's future impact on our clinical trial enrollment, clinical trial sites, clinical research organizations (CROs), third-party manufacturers, and other third parties with whom we do business, as well as any legal or regulatory consequences resulting therefrom. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and with most of our employees and consultants working remotely. We will continue to actively monitor the COVID-19 situation and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business.

Reverse Split

In February 2021, we filed a certificate of amendment to our amended and restated certificate of incorporation with the Secretary of State of the State of Delaware, which effected a one-for-40 reverse stock split (the reverse split) of our issued and outstanding shares of common stock. As a result of the reverse split, every 40 shares of common stock issued and outstanding were reclassified into one share of common stock. No fractional shares were issued in connection with the reverse split and any fractional shares were rounded up to the nearest whole share.

All share and per share amounts contained in this Annual Report on Form 10-K give retroactive effect to the reverse split.

Medice License Agreement

On January 6, 2020, we entered into a license agreement with Medice, who is affiliated with one of our principal stockholders, Salmon Pharma, and represented by one member of our board of directors, which grants Medice an exclusive license, with the right to grant sublicenses, to develop, use, manufacture, market and sell ADAIR throughout Europe. Medice currently markets several ADHD products in Europe and is the ADHD market leader in Europe based on branded prescription market share. Medice is responsible for obtaining regulatory approval of ADAIR in the licensed territory. Under the license agreement, Medice paid us a minimal upfront payment and will pay milestone payments of up to $6.3 million in the aggregate upon first obtaining regulatory approval to market and sell ADAIR in any country, territory or region in the licensed territory and upon achieving certain annual net sales thresholds. For the term of the license agreement, Medice will also pay tiered royalties on annual net sales of ADAIR at rates between 10% and 20%. The initial term of the license agreement will expire five years after the date on which Medice first obtains regulatory approval in any country, territory or region in the licensed territory. Medice has the option to extend the term of the license agreement for additional periods of five years each. Medice has the right to terminate the license agreement at any time upon twelve months' prior written notice to us. We have the right to terminate the license agreement immediately upon notice if Medice challenges the validity, enforceability or patentability of any patent right comprising the licensed intellectual property. Either party may terminate the license agreement if the other party materially breaches its obligations under the license agreement, provided that the terminating party gives the breaching party notice of the breach and a specified opportunity to cure the breach, or upon the other party's bankruptcy.

Intellectual Property

We strive to pursue, maintain and defend patent rights developed internally and to protect the technology, inventions and improvements that are commercially important to the development of our business. We currently have two issued U.S. patents directed to specific ADAIR formulations (i.e., composition of matter) and one pending patent application for ADAIR that is under examination with the U.S. PTO. The U.S. patents will expire in 2037. We have one issued European patent which expires in 2038. Our international PCT application has entered national phase is under examination in several foreign countries and territories, including Australia, Brazil, Canada, China, and Japan. We also rely on know-how relating to our proprietary technology and product candidates and continuing innovation to develop, strengthen and maintain our proprietary position. We also plan to rely on data exclusivity, market exclusivity and patent term extensions when available.

Employees

As of February 4, 2022, we had three full-time employee and had engaged six consultants. We have no collective bargaining agreements with our employees and none are represented by labor unions. We consider our current relations with our employees to be good.

Facilities

Our executive offices are located at 100 N. 18th Street, Suite 300, Philadelphia, PA 19103. We believe that our facilities are adequate to meet our current needs. Should we be required to obtain additional space in the future, we believe we can obtain the required facilities at competitive rates.

Legal Proceedings

We are not currently a party to any legal proceedings.

Corporate Information

We were incorporated under the laws of the State of Delaware in January 2018, and completed our organization, formation and initial capitalization activities effective in June 2018. Our telephone number is 267-607-8255, and our email address is info@vallon-pharma.com. Our website address is https://www.vallon-pharma.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act), are available through the "Investors" portion of our website after we file such material with the SEC. The information contained on, or that can be accessed through, our website is not part of this Annual Report and is not incorporated by reference. We have included our website address herein solely as an inactive textual reference. Our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at https://www.sec.gov.

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended (the Securities Act), as modified by the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies." For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenues of $1.07 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period, or (iv) the end of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act.

Item 1A. RISK FACTORS

You should consider carefully the following risks described below, together with the other information contained in this Annual Report and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risks Relating to Our Business and Industry

We anticipate future losses and negative cash flow, and it is uncertain if or when we will become profitable.

We do not expect to generate any significant revenues until we successfully complete development of our first product, including obtaining all required regulatory approvals, and we are able to successfully commercialize the product through sales and licensing. As of the date of this report, our product candidates are still in development and have not been approved by the FDA.

We have not yet demonstrated our ability to generate revenue, and we may never be able to produce revenues or operate on a profitable basis. We have incurred losses since our inception (January 11, 2018) and expect to experience operating losses and negative cash flow for the foreseeable future. ADAIR or any other future product, such as ADMIR, may never be approved or become commercially viable. Even if we and any collaborators are able to commercialize our technology, which may include licensing, we may never recover our research and development expenses.

We are a clinical-stage company with no approved products and a lack of operating history, which makes it difficult to assess our future viability.

We were incorporated on January 11, 2018, and our operations to date have been limited to organizing and staffing our company, acquiring rights to ADAIR, preparing and filing an IND application for ADAIR, conducting four Phase I studies and working on the commercial formulation and manufacturing of ADAIR. We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. For example, to execute our business plan, we will need to successfully:

- obtain adequate financing on terms that are acceptable to us;
- execute product development activities;
- obtain required regulatory approvals for the development and commercialization of ADAIR or any other future product, such as ADMIR;
- maintain, leverage, and expand our intellectual property portfolio;
- build and maintain robust sales, distribution, and marketing capabilities, either on our own or in collaboration with strategic partners;
- gain market acceptance for ADAIR or any other future product, such as ADMIR;

- develop and maintain any strategic relationships we elect to enter into; and
- manage our spending as costs and expenses increase due to clinical trials, regulatory approvals, and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop ADAIR or any other future product, such as ADMIR, raise capital, expand our business, or continue our operations.

Further, our lack of operating history makes it difficult to evaluate our business and prospects. Our prospects must be considered in light of the risks, uncertainties, expenses, and difficulties frequently encountered by companies in their early stages of development, particularly companies in the biopharmaceutical industry. As a young business, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We will need to expand our capabilities to support commercial activities. We may not be successful in adding such capabilities. The historical information in this report may not be indicative of our future financial condition and future performance. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, stockholders should not rely upon our past results of as an indication of future operating performance.

As a result of our limited operating history, we may not be able to correctly estimate our future revenues, operating expenses, need for investment capital, or stability of operations, which could lead to cash shortfalls.

We have a limited operating history from which to evaluate our business. As a result, our historical financial data is of limited value in estimating future operating expenses. In addition, although we are a clinical-stage company, we have not yet completed all of the non-clinical safety studies for ADAIR or other pivotal clinical trials. We also have not obtained regulatory approvals for any of our products, manufactured a commercial scale product, arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Therefore, our budgeted operating expense levels are based in part on our expectations concerning the FDA approval process and expenses related to development of other product candidates. Failing to reach our short-term developmental milestones within anticipated timelines due to delays caused by the COVID-19 outbreak, serious adverse or unacceptable side effects caused by our product candidates, or other events, many of which may be beyond our control, may cause our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year.

We do not currently have any drug products for sale, and only one clinical stage product under development, ADAIR. Our prospects currently depend largely on the success of ADAIR, which is still in clinical development, and we may not be able to generate revenues from ADAIR.

We do not have any prescription drug products that have been approved by the FDA, or any similar regulatory authority. Our business success depends on our ability to obtain regulatory approval for and successfully commercialize our only product currently under development, ADAIR, which will require substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from sales of ADAIR, if it is ever approved for commercialization.

We have only one other prescription drug candidate in early development today and so our business prospects currently depend primarily on the successful development, regulatory approval, and commercialization of ADAIR, which may never occur. Even though ADAIR is in the clinical development stage, it has an uncertain chance of successfully completing clinical development and gaining regulatory approval. Any significant delays in obtaining approval for and commercializing ADAIR will have a substantial adverse impact on our business and financial condition.

Even if approved, we may be unable to successfully commercialize ADAIR and we may never generate meaningful revenues. Our ability to generate revenues from ADAIR will depend on our ability to:

- hire, train, deploy, and support our sales force, including any contract sales force engaged;
- create market demand for ADAIR through our own marketing and sales activities, and any other promotional arrangements we may later establish;
- obtain sufficient quantities of ADAIR from our third-party manufacturers as required to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms; and

- maintain patent protection and regulatory exclusivity for ADAIR.

In addition, if the market for ADAIR develops less rapidly than we anticipate, we may not have the ability to shift our resources to the development of alternative products.

If serious adverse or unacceptable side effects are identified during the development of ADAIR or any potential future products, such as ADMIR, we may need to abandon or limit our development of such products.

If ADAIR or potential future products, such as ADMIR, are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective. In our industry, many compounds that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the compound. In the event that our clinical trials reveal a high and unacceptable severity and prevalence of side effects, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of ADAIR or potential future products for any or all targeted indications. The FDA could also issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve a product. The number of requests for additional data or information issued by the FDA in recent years has increased, and resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by ADAIR or potential future products could also result in the inclusion of unfavorable information in our product labeling, denial of regulatory approval by the FDA, or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating revenues from the sale of ADAIR or potential future products. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims.

Additionally, if one or more of our current or potential future products, including ADAIR or ADMIR, receive marketing approval and we or others later identify undesirable side effects caused by this product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of unfavorable labeling statements, specific warnings, or a contraindication;
- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- we may be required to change the way the product is administered, conduct additional clinical trials, or change the labeling of the product; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of ADAIR or potential future products, such as ADMIR, or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

If ADAIR does not achieve broad market acceptance, the revenues that we generate from its sales will be limited.

The commercial success of ADAIR, if approved by the FDA, will depend upon its acceptance by the medical community, our ability to ensure that the drug is included in hospital formularies, and coverage and reimbursement for ADAIR by third-party payors, including government payors. The degree of market acceptance of ADAIR or any other product we may license or acquire will depend on a number of factors, including, but not necessarily limited to:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such proposed product as well as competitive products;
- the clinical indications for which the drug is approved;
- acceptance by physicians and patients of the drug as a safe and effective treatment;
- the safety of such proposed product seen in a broader patient group, including its use outside the approved indications;
- the availability, cost, and potential advantages of alternative treatments, including less expensive generic drugs;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;

- the relative convenience and ease of administration of the proposed product for clinical practices;
- the product labeling or product insert required by the FDA or regulatory authority in other countries;
- the approval, availability, market acceptance, and reimbursement for a companion diagnostic, if any;
- the prevalence and severity of adverse side effects;
- the effectiveness of our sales and marketing efforts;
- limitations or warnings contained in the product's FDA-approved labeling;
- changes in the standard of care for the targeted indications for ADAIR or any future product, such as ADMIR, which could reduce the marketing impact of any superiority claims that we could make following FDA approval; and
- potential advantages over, and availability of, alternative treatments.

If any proposed product that we develop does not provide a treatment regimen that is as beneficial as, or is not perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that proposed product, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell ADAIR and any other product we may license or acquire will also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and achieve acceptance of the product onto hospital formularies, as well as our ability to obtain sufficient third-party coverage or reimbursement. Since many hospitals are members of group purchasing organizations, which leverage the purchasing power of a group of entities to obtain discounts based on the collective buying power of the group, our ability to attract customers will also depend on our ability to effectively promote ADAIR or any other future product to group purchasing organizations. We will also need to demonstrate acceptable evidence of safety and efficacy, as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with ADAIR or any other future product, such as ADMIR. If ADAIR or any other future product are approved but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of ADAIR or any other future product may require significant resources and may never be successful.

If we obtain approval to commercialize ADAIR, or any other future product, such as ADMIR, outside of the U.S., a variety of risks associated with international operations could materially adversely affect our business.

If ADAIR, or any other future product, such as ADMIR, is approved for commercialization outside the U.S., such as pursuant to the license agreement with Medice, who is affiliated with one of our principal stockholders, Salmon Pharma, and represented by one member of our board of directors, we will likely enter into agreements with third parties to market such product outside the U.S. We expect that we will be subject to additional risks related to entering into or maintaining international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing U.S. and foreign drug import and export rules, particularly regarding controlled substances and scheduled products, such as ADAIR;
- reduced protection for intellectual property rights in foreign countries;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- different reimbursement systems;
- 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.

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

If the government or third-party payors fail to provide adequate coverage and payment rates for ADAIR or any future products, such as ADMIR, we may develop, license or acquire, if any, our revenue and prospects for profitability will be limited.

In both domestic and foreign markets, our sales of any future products, such as ADMIR, will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare, Medicaid, managed care providers, private health insurers and other organizations. Accordingly, ADAIR or any other future product that we may develop, in-license or acquire, if approved, will face competition from other therapies and drugs for these limited payor financial resources. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of insurers, hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Any of our future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

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

Other than the license agreement with Medice, we currently do not have a marketing or sales organization for the marketing, sales and distribution of biopharmaceutical products. In order to commercialize any product that receives marketing approval, we would need to build marketing, sales, distribution, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In the event of successful development and regulatory approval of ADAIR or another future product, such as ADMIR, we expect to build a targeted specialist sales force to market or co-promote the product. There are risks involved with establishing our own sales, marketing, and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products, if any, on our own include, but are not necessarily limited to:

- our inability to recruit, train, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary or other products to be offered by sales personnel, which may put us at a competitive disadvantage from the perspective of sales efficiency relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

As an alternative to establishing our own sales force, we may choose to partner with third parties that have well-established direct sales forces to sell, market, and distribute our products.

We rely on a limited number of suppliers and manufacturers for ADAIR and expect to continue to do so for any future product that we may develop, including ADMIR, and for commercialization of our products. This reliance on a limited number of third parties increases the risk that we will not have sufficient quantities of ADAIR or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

The manufacture of biopharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls and the use of specialized processing equipment. We

have entered into an agreement to complete pre-commercial manufacturing development activities with one contract manufacturer and expect to contract with them for the commercial manufacture of ADAIR. However, we have not yet negotiated and signed a commercial supply agreement. The inability of a third-party manufacturer to successfully manufacture ADAIR may materially harm our business and financial condition, and frustrate future development and any commercialization efforts for this product.

We do not have any of our own manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacture of ADAIR or any other future product, such as ADMIR, for clinical testing, as well as for commercial manufacture if any of ADAIR or any other future product receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of ADAIR or any other future product or such quantities at an acceptable cost or quality, which could delay, prevent, or impair our development or commercialization efforts.

We also expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of any product for which our collaborators or we obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including, but not necessarily limited to:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over ADAIR or any other future product, such as ADMIR, or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

All of our contract manufacturers must comply with strictly enforced federal, state, and foreign regulations, including current Good Manufacturing Practice (cGMP) requirements enforced by the FDA through its facilities inspection program. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations for manufacture of ADAIR or any other future product, such as ADMIR. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations or similar regulatory requirements outside the U.S. could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, suspension of production, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation, and potential for product liability claims.

ADAIR and any products that we may develop may compete with other products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any replacement manufacturers. The DEA restricts the importation of a controlled substance finished drug product when the same substance is commercially available in the United States, which could reduce the number of potential alternative manufacturers for ADAIR.

Our current and anticipated future dependence upon others for the manufacture of ADAIR or any other future products, such as ADMIR, may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of ADAIR or any other future product, such as ADMIR, or commercialization of any of our products, producing additional losses and depriving us of potential product revenue.

Public health crises such as pandemics or similar outbreaks could materially and adversely affect our preclinical and clinical trials, business, financial condition and results of operations.

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. The COVID-19 pandemic continues to affect the U.S. and global economies and may affect our operations and certain other third parties on which we rely, including by causing disruptions in the supply of our product candidates and the conduct of future clinical trials. Moreover, the COVID-19 pandemic may adversely affect the operations of the FDA and other health authorities, resulting in delays of reviews and approvals with respect to our product candidates. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. In addition, the loss of any of our employees as a result of COVID-19, or another pandemic, may adversely affect our operations. The ultimate impact of the COVID-19 pandemic is highly uncertain, and we do not yet know the full extent of potential delays or impacts that COVID-19 may have on our business, financing or clinical trial activities.

Some examples of potential disruptions that may result from the COVID-19 pandemic, include, but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;
- delays or disruptions in preclinical experiments and IND-enabling studies due to restrictions of on-site staff and unforeseen circumstances at CROs and vendors, including any delays caused by the COVID-19 pandemic;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and pre-clinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions or the refusal of employees to comply with COVID-19 vaccine mandates;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

The COVID-19 global pandemic remains a public health threat and its ultimate impact on our business and the global economy is uncertain. The extent to which the pandemic may affect our clinical trials, business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions, actions to contain the pandemic 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, and the ongoing worldwide vaccine rollout and implementation of vaccine mandates. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition and results of operations.

Our future growth may depend on our ability to identify and acquire or in-license products and if we do not successfully identify and acquire or in-license related product candidates and products or integrate them into our operations, we may have limited growth opportunities.

An important part of our business strategy is to continue to develop a pipeline of product candidates and products by acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our business. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- difficulty or inability to secure financing to fund development activities for such acquired or in-licensed technologies in the current economic environment;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- 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.

We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger biopharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

Expanding our product offerings may not be profitable.

We may choose to develop new products to offer. We are currently developing an abuse deterrent formulation of Ritalin, ADMIR, another commonly prescribed product for the treatment of ADHD. Developing new products involves inherent risks, including our inability to estimate demand for the new offerings, competition from more established market participants, and a lack of market understanding. In addition, expanding into new geographic areas and/or expanding product offerings will be challenging and may require integrating new employees into our culture as well as assessing the demand in the applicable market.

We may expend our limited resources to pursue a particular proposed product or indication, and fail to capitalize on a different proposed product or indication that may have been more profitable or for which there would have been a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and proposed products that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other proposed products, or for other indications, that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and proposed products for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular proposed product, we may relinquish valuable rights to that proposed product through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such proposed product.

If we fail to effectively manage our growth, our business and reputation, results of operations, and financial condition may be adversely affected.

We may experience a rapid growth in operations, which may place significant demands on our management team and our operational and financial infrastructure. As we continue to grow, we must effectively identify, integrate, develop and motivate new employees, and maintain the beneficial aspects of our corporate culture. To attract top talent, we believe we will have to offer attractive compensation packages. The risks of over-hiring or overcompensating and the challenges of integrating a rapidly growing employee base may impact profitability.

Additionally, if we do not effectively manage our growth, the quality of our services could suffer, which could adversely affect our business and reputation, results of operations, and financial condition. If operational, technology, and infrastructure improvements are not implemented successfully, our ability to manage our growth will be impaired and we may have to make significant additional expenditures to address these issues. To effectively manage our growth, we will need to continue to improve our operational, financial, and management controls and our reporting systems and procedures. This will require that we refine our information technology systems to maintain effective online services and enhance information and communication systems to ensure that our employees effectively communicate with each other and our growing base of customers. These system enhancements and improvements will require significant incremental and ongoing capital expenditures and allocation of valuable management and employee resources. If we fail to implement these improvements and maintenance programs effectively, our ability to manage our expected growth and comply with the rules and regulations that are applicable to publicly reporting companies will be impaired and we may incur additional expenses.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

Our key employees currently include Mr. David Baker, our President and Chief Executive Officer, Ms. Leanne Kelly, our Chief Financial Officer and Ms. Penny Toren, our Senior Vice President, Regulatory Affairs & Program Management, who is responsible for regulatory affairs, and consulting arrangements with individuals such as our Chief Medical Officer, Dr. Timothy Whitaker, who is responsible for overseeing clinical development of our product candidates. Our future growth and success depend on our ability to recruit, retain, manage, and motivate our employees and key consultants. The loss of the services of our Chief Executive Officer, or any of our key employees or the inability to hire or retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results. Although we have employment agreements in place with management, these agreements are terminable at will with minimal notice.

Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific and technical consultants. We may not be able to attract or retain qualified management and commercial, scientific, and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical, and other businesses. In addition, the loss of one or more of our senior executive officers or key consultants could be detrimental to us if we cannot recruit suitable replacements in a timely manner.

We do not currently carry "key person" insurance on the lives of members of senior management. The competition for qualified personnel in the biopharmaceutical field is intense.

If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our directors, consultants and advisors are not obligated to commit their time and attention exclusively to our business and therefore they may encounter conflicts of interest with respect to the allocation of time and business opportunities between our operations and those of other businesses.

Our directors are not obligated to commit their time and attention exclusively to our business and, accordingly, they may encounter conflicts of interest in allocating their own time, or any business opportunities which they may encounter, between our operations and those of other businesses.

Currently, our full-time employees consist of David Baker, our President and Chief Executive Officer, Leanne Kelly, our Chief Financial Officer, and Penny Toren, our Senior Vice President, Regulatory Affairs. Our key consultants consist of Dr. Timothy Whitaker, our Chief Medical Officer, as well as consultants for bookkeeping, pre-clinical and formulation development, chemistry manufacturing and controls (CMC), and clinical operations. Currently, consulting arrangements with individuals, such as Dr. Whitaker, only require them to devote an average of approximately 10 to 20 hours per week to our business. In addition, our consultants and advisors may have other clients or projects that grow in scope or they may acquire new clients and projects that require more of their time that may come at our expense. We also currently rely on consultants for clinical

operations, statistical support, and preclinical development. If the execution of our business plan demands more time than is currently committed by any of our officers, directors, consultants or advisors, they will be under no obligation to commit such additional time, and their failure to do so may adversely affect our ability to carry on our business and successfully execute our business plan.

Additionally, all of our officers and directors, in the course of their other business activities, may become aware of investments, business opportunities, or information which may be appropriate for presentation to us as well as to other entities to which they owe a fiduciary duty. They may also in the future become affiliated with entities that are engaged in business or other activities similar to those we intend to conduct. As a result, they may have conflicts of interest in determining to which entity particular opportunities or information should be presented. If, as a result of such conflict, we are deprived of investment, business or information, the execution of our business plan and our ability to effectively compete in the marketplace may be adversely affected.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us under the Federal Physician Payments Sunshine Act and similar state laws. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, making or contributing to the making of a false claim for reimbursement to federal, state or private payors, 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. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. 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. 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 and results of operations, including the imposition of significant fines or other sanctions.

Our market is subject to intense competition. If we are unable to compete effectively, ADAIR or any other proposed product that we develop may be rendered noncompetitive or obsolete.

There are a number of existing treatments for ADHD currently on the market, all of which are marketed by pharmaceutical companies that are far larger and more experienced than we are. Patients and doctors are often unwilling to change medications, and this factor will make it difficult for ADAIR or any other proposed product to penetrate the market. Further, our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. All of these competitors currently engage in, have engaged in or may engage in the future in the development, manufacturing, marketing and commercialization of new pharmaceuticals, some of which may compete with ADAIR or other proposed product we may have in the future. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. These companies may have products in development that are superior to ADAIR or any other future product, such as ADMIR. Key competitive factors affecting the commercial success of ADAIR and any other proposed product that we may develop in the future are likely to be efficacy, time of onset, safety and tolerability profile, reliability, convenience of dosing, price, and reimbursement.

Many of our potential competitors have substantially greater financial, technical, and human resources than we do and significantly greater experience in the discovery and development of drug candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Established competitors may invest heavily to quickly discover and develop novel compounds that could make ADAIR or other proposed product we may develop obsolete. Other companies may be developing abuse deterrent formulations of ADHD treatments that may be approved and marketed before ADAIR, limiting the commercial potential of ADAIR. Accordingly, our competitors may be more successful than us in obtaining FDA and other marketing approvals, or more favorable language in the prescription information, for their drugs, and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render ADAIR or any other proposed product that we develop obsolete or non-competitive before we can recover the expenses of developing and commercializing the product. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the

development of new treatment methods for the diseases we are targeting could render ADAIR or any other proposed product that we develop non-competitive or obsolete.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for ADAIR or other proposed product we may license or acquire and may have to limit their commercialization.

The use of ADAIR and any other proposed product we may license or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical 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, or a breach of warranties. Product liability claims might be brought against us by consumers, health care providers, or others using, administering, or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- decreased demand for any proposed product or products that we may develop;
- initiation of investigations by regulators;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- reduced resources of our management to pursue our business strategy.

We will obtain limited product liability insurance coverage for any and all of our clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, 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 due to liability. When needed, we intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for ADAIR or any other future product in development, such as ADMIR, but we may be unable to obtain commercially reasonable product liability insurance for any product approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

Despite the implementation of security measures, our internal computer systems and those of our future CROs, manufacturers, and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information (such as individually identifiable health information), we could incur significant liabilities and the further development and commercialization of ADAIR or any other future product, including ADMIR, could be delayed.

Medice may not successfully develop or commercialize ADAIR in Europe.

On January 6, 2020, Vallon entered into a license agreement with Medice, who is affiliated with one of our principal stockholders, Salmon Pharma, and represented by one member of our board of directors, which grants Medice an exclusive license, with the right to grant sublicenses, to develop, use, manufacture, market and sell ADAIR throughout Europe. Medice may be unsuccessful with the development program for ADAIR as required to gain regulatory approval in European countries.

The requirements for approval by European regulatory agencies may be deemed too onerous and expensive to continue the development of ADAIR in Europe. Even if Medice is successful in gaining approval of ADAIR in European countries, it may be unsuccessful in gaining favorable reimbursement of ADAIR by national payors of prescription medications in Europe. Medice may not generate sufficient sales of ADAIR in Europe to support continued commercialization. All of the commercial risks for ADAIR in the United States may also apply to Europe. In addition, Medice may not devote adequate marketing and sales efforts to generate meaningful sales of ADAIR in Europe. The ADHD market in Europe is substantially smaller than in the United States, estimated to be approximately $700 million annually as compared to $9 billion in the United States. Dextroamphetamine products as a class capture much lower market share in Europe as compared to the United States. If European regulatory authorities reject the approval of ADAIR in Europe, this may reflect poorly on ADAIR and diminish sales growth or overall sales in the United States.

Increased scrutiny of our environmental, social or governance responsibilities have and will likely continue to result in additional costs and risks and may adversely impact our reputation, employee retention and willingness of customers and suppliers to do business with us.

There is an increasing focus from certain customers, consumers, employees and other stakeholders concerning environmental, social and governance (ESG) matters, including corporate citizenship and sustainability. Additionally, public interest and legislative pressure related to public companies' ESG practices continues to grow. If our ESG practices fail to meet regulatory requirements or stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, Board of Director and employee diversity, human capital management, employee health and safety practices, corporate governance and transparency and employing ESG strategies in our operations, our brand, reputation and employee retention may be negatively impacted, and customers and suppliers may be unwilling to do business with us.

If we fail to adopt ESG standards or practices as quickly as stakeholders desire, fail, or be perceived to fail, in our achievement of such initiatives or goals, or fail in fully and accurately reporting our progress on such initiatives and goals, our reputation, business, financial performance and growth may be adversely impacted. In addition, we could be criticized for the scope of such initiatives or goals or perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. Any such matters, or related corporate citizenship and sustainability matters, could have a material adverse effect on our business.

Risks Relating to Finances and Capital Requirements

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

Our operations have consumed substantial amounts of cash since our inception. As of December 31, 2021, we had an accumulated deficit of $21.9 million and our net loss was $9.3 million for the year ended December 31, 2021. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our business will require additional capital for implementation of our long-term business plan and product development and commercialization.

Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. As we require additional funds, we may seek to fund our operations through the sale of additional equity securities, debt financing and/or strategic collaboration agreements. We cannot be sure that additional financing from any of these sources will be available when needed or that, if available, the additional financing will be obtained on favorable terms.

Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, timing, scope, and costs of our clinical trials, including the ability to timely enroll patients in our potential future clinical trials;
- the outcome, timing, and cost of regulatory approvals by the FDA and comparable regulatory authorities, including the potential that the FDA or comparable regulatory authorities may require that we perform more studies than those that we currently expect;
- the number and characteristics of ADAIR or any other future product, such as ADMIR, that we may in-license and develop;
- our ability to successfully commercialize ADAIR or any other future product, such as ADMIR;

- the amount of sales and other revenues from ADAIR or any other future product, such as ADMIR, that we may commercialize, if any, including the selling prices for such potential product and the availability of adequate third-party reimbursement;
- selling and marketing costs associated with our potential products, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions and/or the development of other products;
- the costs of operating as a public company;
- the cost and timing of completion of commercial-scale, outsourced manufacturing activities;
- the time and cost necessary to respond to technological and market developments;
- any disputes which may occur between us and Arcturus, employees, collaborators or other prospective business partners; and
- the costs of filing, prosecuting, defending, and enforcing any patent claims and other intellectual property rights.

If we raise additional funds by selling shares of our common stock or other equity-linked securities, the ownership interest of our current stockholders will be diluted. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or products or to grant licenses on terms that may not be acceptable to us. If we raise additional funds through debt financing, we may have to grant a security interest on our assets to the future lenders, our debt service costs may be substantial, and the lenders may have a preferential position in connection with any future bankruptcy or liquidation involving the company.

If we are unable to raise additional capital when needed, we may be required to curtail the development of our technology or materially curtail or reduce our operations. We could be forced to sell or dispose of our rights or assets. Any inability to raise adequate funds on commercially reasonable terms could have a material adverse effect on our business, results of operations, and financial condition, including the possibility that a lack of funds could cause our business to fail and our company to dissolve and liquidate with little or no return to investors.

We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting, and other expenses under the Securities Exchange Act of 1934, as amended (Exchange Act), the Sarbanes-Oxley Act, and other applicable securities rules and regulations. In addition, we are subject to the requirements of The Nasdaq Capital Market.

These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. In addition, the listing requirements of The Nasdaq Capital Market require that we satisfy certain corporate governance requirements relating to director independence, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel need to devote a substantial amount of time to ensure that we comply with all of these requirements. As a result, it may be difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal controls over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. Additionally, our independent auditors may be required to perform a similar evaluation and report on the effectiveness of our internal controls over financial reporting. These efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources.

While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by the U.S. Securities and Exchange Commission (the SEC), or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock. See the risk factor entitled "Financial reporting obligations of being a public company in the United States require well defined disclosure and financial controls and procedures that we did not have as a private company and that are expensive and time-consuming requiring our management to devote substantial time to compliance matters." in this report for more information on our internal controls over financial reporting.

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our securities less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. As an emerging growth company, we are not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, we have reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and we are exempt from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Additionally, as an emerging growth company, we have elected to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As such, our financial statements may not be comparable to companies that comply with public company effective dates. We cannot predict if investors will find our stock less attractive because we may rely on these provisions. If some investors find our stock less attractive as a result, there may be a less active trading market for our shares and our stock price may be more volatile.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. We have elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, will not adopt the new or revised standard until the time private companies are required to adopt the new or revised standard. This may make comparison of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accountant standards used.

After we become a reporting company under the Exchange Act, we will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenues of $1.07 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period, or (iv) the end of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act.

Our ability to utilize our net operating loss (NOL) carryforwards may be limited.

As of December 31, 2021, we had NOL carryforwards available to reduce future taxable income, if any, for federal and state income tax purposes of $20.1 million and $20.4 million, respectively. The federal net operating loss carryforwards do not expire. If not utilized, the state and local losses begin to expire in the year ending December 31, 2038. Our ability to utilize NOL carryforward amounts to reduce taxable income in future years may be limited for various reasons, including if future taxable income is insufficient to recognize the full benefit of such NOL carryforward amounts prior to their expiration. Additionally, our ability to fully utilize these U.S. tax assets can also be adversely affected by "ownership changes" within the meaning of Section 382 of the Internal Revenue Code of 1986, as amended (the Code), in a three-year period. Any ownership change is generally defined as a greater than 50% increase in equity ownership by "5% stockholders," as that term is defined for purposes of Section 382 of the Code in any three-year period. Further, we may experience an ownership change in the future as a result of further shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Changes in tax laws and regulations or in our operations may impact our effective tax rate and may adversely affect our business, financial condition and operating results.

Changes in tax laws in any jurisdiction in which we operate, or adverse outcomes from any tax audits that we may be subject to in any such jurisdictions, could result in an unfavorable change in our effective tax rate in the future, which could adversely affect our business, financial condition, and operating results.

The report of our independent registered public accounting firm included a "going concern" explanatory paragraph.

The report of our independent registered public accounting firm on our financial statements as of and for the year ended December 31, 2021 included an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. We have financed our working capital requirements to date by raising capital through private placements of shares of our common stock, issuing of short-term and convertible notes, and the proceeds from our initial public offering (IPO) completed in February 2021. If we are unable to raise sufficient capital as and when needed, our business, financial condition and results of operations will be materially and adversely affected, and we will need to significantly modify our operational plans to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The inclusion of a going concern explanatory paragraph by our independent registered public accounting firm, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into critical contractual relations with third parties and otherwise execute our development strategy.

Risks Relating to Regulatory Matters

We may not receive regulatory approval for ADAIR or any future product, such as ADMIR, or its or their approvals may be delayed, which would have a material adverse effect on our business and financial condition.

ADAIR and any other future product, such as ADMIR, as well as the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency, and similar regulatory authorities outside the U.S. Failure to obtain marketing approval for ADAIR or any future product will prevent us from commercializing such products. We have not received approval to market ADAIR from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations and regulatory consultants to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the proposed product's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. ADAIR or any future product may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If ADAIR or any future product receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product. We may never succeed in convincing regulatory agencies to allow us to promote the abuse deterrent properties of ADAIR, even if we are successful in demonstrating these characteristics in studies.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if approval is granted at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the proposed product involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical studies and/or clinical trials. In addition, varying interpretations of the data obtained from preclinical studies and/or clinical testing could delay, limit, or prevent marketing approval of a proposed product. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our proposed product or any future product, the commercial prospects for our proposed product may be harmed and our ability to generate revenue will be materially impaired.

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

Separately, in response to the global pandemic of COVID-19, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. The FDA reiterated its stance to Congress on June 2, 2020 stating, "only inspections deemed mission-critical will be considered on a case-by-case basis as this outbreak continues to unfold." On August 20, 2020, and subsequently updated on January 29, 2021, the FDA's Guidance for Industry against stated, "foreign pre-approval and for-cause inspection assignments that are not deemed mission-critical remain temporarily postponed, while those deemed mission-critical will still be considered for inspection on a case-by-case basis."

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. If the FDA becomes unable to continue its current level of performance, we could experience delays and setbacks for our product candidates, including ADAIR and ADMIR, and for any approvals we may seek which could adversely affect our business.

Even if ADAIR or any other proposed product that we develop, such as ADMIR, receives marketing approval, we will continue to face extensive regulatory requirements and the product may still face future development and regulatory difficulties.

ADAIR and any other proposed product we may develop, such as ADMIR, or license or acquire, will also be subject to ongoing requirements and review of the FDA and other regulatory authorities. These requirements include labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping of the drug.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market ADAIR or any other future product for only their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDCA, relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, false claims acts, as well as state consumer protection laws.

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

- restrictions on such products, operations, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;

- fines, restitution, or disgorgement of profits;
- suspension or withdrawal of marketing or regulatory approvals;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of ADAIR or any other future product, such as ADMIR;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP and other regulations.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our proposed product. 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.

The abuse, misuse or off-label use of our products may harm our image in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

The products we market will be approved by the FDA for specific treatments. We will train our marketing and direct sales force to not promote our products for uses outside of the FDA-approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgement, he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those approved by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. In addition, although ADAIR is very difficult to manipulate into a form that can be snorted, it is not impossible to do so, as was shown by a third-party drug laboratory, hired by us in preparation for human abuse studies, that was able to develop a time-consuming and laborious process to convert ADAIR into a form that could be insufflated. In addition, although ADAIR is difficult to solubilize into a form that can be injected, sophisticated drug abusers may be able to develop methods to manipulate ADAIR into a form that can be injected. We cannot assure stockholders that users of ADAIR or such other products we may develop in the future will not manipulate our products with the intention of abusing our products. Such abuse of our products may harm our image in the marketplace and damage our reputation.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations.

In addition, physicians may misuse our products if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described elsewhere, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market, and distribute any product for which we

obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state, and foreign healthcare laws and regulations that may affect our ability to operate include, but are not necessarily limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, 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 and state healthcare programs, such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members. Data collection began on August 1, 2013 with requirements for manufacturers to submit reports to CMS by March 31, 2014 and 90 days after the end each subsequent calendar year. Disclosure of such information was made by CMS on a publicly available website beginning in September 2014; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thereby complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for ADAIR or

any other future product, such as ADMIR, our ability to effectively market and sell ADAIR or any other future product may be reduced, and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to send a Warning Letter to the Company (which becomes public) alleging violations of the FDCA and subjecting the Company to other potential enforcement such as to suspend or withdraw an approved product from the market, require a recall or institute fines, or could diminish our reputation and result in disgorgement of money, operating restrictions, injunctions, or criminal prosecution, any of which could harm our business.

Public concern regarding the safety of drug products such as ADAIR could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs. The Food and Drug Administration Amendments Act of 2007 (FDAAA) grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, this law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of this law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our preclinical studies and clinical trials. Data from preclinical studies and clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies and/or clinical trials. If the FDA requires us to conduct additional preclinical studies or clinical trials prior to approving ADAIR, our ability to obtain approval of this proposed product will be delayed. If the FDA requires us to provide additional preclinical studies and/or clinical data following the approval of ADAIR, the indications for which this proposed product is approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize ADAIR may be otherwise adversely impacted.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to continue existing clinical trials, or initiate new clinical trials, for our proposed product if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S. Some of our competitors have ongoing clinical trials for proposed products that treat the same indications as our proposed product, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' proposed products. Available therapies for the indications we are pursuing can also affect enrollment in our clinical trials. Patient enrollment is affected by other factors including, but not necessarily limited to:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the proposed product under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and

- the availability of other approved drugs to treat the same condition, thereby creating competition for our clinical trial enrollment and reducing the incentive for prospective patients to participate in our trials.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for ADAIR or any future product, such as ADMIR, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize ADAIR or any other proposed product that we develop and affect the prices we may set.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for ADAIR or any other proposed product that we develop, restrict or regulate post-approval activities and affect our ability to profitably sell ADAIR or any other proposed product for which we obtain marketing approval.

Legislative and regulatory proposals have been made to expand post-approval requirements, restrict sales and promotional activities for pharmaceutical products, and regulate pricing. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our proposed product, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize ADAIR and for any future product, such as ADMIR, and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell ADAIR and for any future product, such as ADMIR, for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs, restrict or regulate post-approval activities and improve the quality of healthcare.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

For example, in March 2010, the Affordable Care Act, was enacted in the United States. Among the provisions of the Affordable Care Act of importance to ADAIR and for any future product, the Affordable Care Act: establishes an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extends manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expands eligibility criteria for Medicaid programs; expands the entities eligible for discounts under the Public Health program; increases the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; creates a new Medicare Part D coverage gap discount program; establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and establishes a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

At this time, we are unsure of the full impact that the Affordable Care Act will have on our business. There have been judicial and political challenges to certain aspects of the Affordable Care Act. For example, since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements of the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the

Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 (Tax Act) included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act 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 January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share. The Bipartisan Budget Act of 2018 (the BBA) among other things, amends the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole," by increasing from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In July 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas (Texas District Court Judge) 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 Act, the remaining provisions of the ACA are invalid as well. While the Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. The Coronavirus Aid, Relief, and Economic Security Act, which was signed into law on March 27, 2020, designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended these reductions from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices through proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has begun the process of soliciting feedback on some of these measures and, at the same time, is implementing others under its existing authority. Although some of these, and other, proposals will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for ADAIR and for any future product, such as ADMIR, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We expect that the Affordable Care Act, these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private

payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize ADAIR and for any future product, such as ADMIR, if approved.

We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or complying with applicable regulatory requirements.

We rely on third-party contract research organizations and clinical research organizations to conduct our clinical trials for ADAIR and for any future product, such as ADMIR. We expect to continue to rely on third parties, such as contract research organizations, clinical research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct all of our clinical trials. The agreements with these third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that could delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and in accordance with good laboratory practice, as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices (GCPs) for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our clinical research organizations fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure investors that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies 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. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

The third parties with whom we have contracted to help perform our clinical trials may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our proposed product and will not be able to, or may be delayed in our efforts to, successfully commercialize our proposed product.

If any of our relationships with these third-party contract research organizations or clinical research organizations terminates, we may not be able to enter into arrangements with alternative contract research organizations or clinical research organizations or to do so on commercially reasonable terms. Switching or adding additional contract research organizations or clinical research organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new contract research organization or clinical research organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our contract research organizations or clinical research organizations, there can be no assurance that we will not encounter similar challenges or delays in the future.

We rely on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable.

As part of our strategy to mitigate development risk, we seek to develop proposed products with validated mechanisms of action, and we utilize biomarkers to assess potential clinical efficacy early in the development process. This strategy necessarily relies upon clinical data and other results obtained by third parties that may ultimately prove to be inaccurate or unreliable. Further, such clinical data and results may be based on products or proposed products that are significantly different from ADAIR or any future product, such as ADMIR. If the third-party data and results we rely upon prove to be inaccurate, unreliable or not applicable to ADAIR or any future product, we could make inaccurate assumptions and conclusions about our proposed product and our research and development efforts could be compromised.

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

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. Our operations involve

the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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

If the FDA does not conclude that ADAIR is sufficiently bioequivalent, or demonstrate comparable bioavailability to its reference listed drug (RLD), or if the FDA otherwise does not conclude that ADAIR satisfies the requirements of Section 505(b)(2) of the FDCA, approval pathway, the approval pathway for this proposed product will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and the FDA may not approve this proposed product.

A key element of our strategy is to seek FDA approval for ADAIR through Section 505(b)(2) approval pathway. Section 505(b)(2) of the FDCA permits the filing of an NDA that contains full safety and efficacy reports but where at least some of the information required for approval comes from studies not conducted by or for the applicant. Such information could include the FDA's findings of safety and efficacy in the approval of a similar drug, and for which the applicant has not obtained a right of reference and/or published literature. Such reliance is typically predicated on a showing of bioequivalence or comparable bioavailability to an approved drug.

If the FDA does not allow us to pursue the Section 505(b)(2) approval pathway for ADAIR, or if we cannot demonstrate bioequivalence or comparable bioavailability of ADAIR to an approved product, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for ADAIR would increase. Moreover, our inability to pursue the Section 505(b)(2) approval pathway could result in new competitive products reaching the market sooner than ADAIR, which could have a material adverse effect on our competitive position and our business prospects. Even if we are allowed to pursue the Section 505(b)(2) approval pathway, we cannot assure investors that ADAIR will receive the requisite approval for commercialization on a timely basis, if at all.

In addition, notwithstanding the approval of a number of products by the FDA under the Section 505(b)(2) approval pathway over the last few years, pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its policies and practices with respect to the Section 505(b)(2) approval pathway, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Even if ADAIR is approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the product may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, including additional clinical trials.

ADAIR contains a controlled substance, the manufacture, use, sale, importation, exportation, and distribution of which are subject to regulation by state, federal, and foreign law enforcement and other regulatory agencies.

ADAIR contains, and any future product, such as ADMIR, if any, may contain, controlled substances which are subject to state, federal, and foreign laws and other regulations regarding their manufacturing, use, sale, importation, exportation, and distribution. ADAIR's active ingredient, dextroamphetamine, is classified as a controlled substance under the CSA, and regulations of the DEA. A number of states also independently regulate these drugs as controlled substances. Controlled substances are classified by the DEA as Schedule I, II, III, IV, or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredient in ADAIR, dextroamphetamine, is listed by the DEA as a Schedule II controlled substance under the CSA. For our current proposed

product, and any potential future product, such as ADMIR, containing a controlled substance, we and our suppliers, manufacturers, contractors, customers, and distributors are required to obtain and maintain applicable registrations from state, federal, and foreign law enforcement and regulatory agencies and comply with their laws and regulations regarding the manufacturing, use, sale, importation, exportation, and distribution of controlled substances. An example of such practice is that all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the CSA and DEA regulations. We may not be able to obtain sufficient quantities of these controlled substances in order to complete our clinical trials or meet commercial demand, even if ADAIR is approved for marketing.

In addition, controlled substances are subject to regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment, and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of proposed products that include controlled substances. The DEA and some states conduct periodic inspections of registered establishments that handle controlled substances.

Failure to obtain and maintain required registrations or to comply with any applicable regulations, including quotas imposed by the DEA, could delay or preclude us from developing and commercializing our proposed product that contains a controlled substance and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of our proposed product containing controlled substances.

If we, our drug products or the manufacturing facilities for our drug products fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products or request that we initiate a product recall; or
- refuse to allow us to enter into supply contracts, including government contracts.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

The FDA may not approve product labeling for ADAIR that would permit us to market and promote our product in the United States by describing its abuse-deterrent features.

We have invested resources conducting Laboratory Manipulation and Extraction Studies (Category 1), and may spend substantial additional resources conducting Pharmacokinetic Studies (Category 2) and Clinical Abuse Potential Studies (Category 3) to support ADAIR's abuse-deterrence characteristics, and we believe such studies are consistent with the April 2015 final FDA guidance on opioid medications (the 2015 FDA Guidance), as no guidance exists on stimulants. However, we have not yet received regulatory approval to market ADAIR and additional data may emerge that could change the FDA's position on the proposed product label, and there can be no assurance that ADAIR or our other current or any future product, such as ADMIR, will receive FDA-approved product labeling that describes abuse-deterrent features of such product given the current absence of specific FDA guidance on development of abuse-deterrent amphetamines. Our failure to achieve FDA approval of product labeling containing information on abuse-deterrence characteristics of ADAIR will prevent or substantially limit our promotion of the abuse-deterrent features of ADAIR. This type of limitation would make it difficult for us to differentiate ADAIR from other amphetamine-containing products, may cause us to lower the price of our product to the

extent that there are competing products with abuse-deterrent claims on their product labels and as a result, our product would be less competitive in the market. The FDA closely regulates promotional materials and other promotional activities, even if the FDA initially approves product labeling that includes a description of the abuse- deterrent characteristics of ADAIR and therefore the FDA may object to our marketing claims and product advertising campaigns. This could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of our product from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions, and civil or criminal prosecution. Any of these consequences would harm the commercial success of ADAIR or any other future product.

Even if any other proposed products are approved for marketing with certain abuse-deterrence claims, the 2015 FDA Guidance may not apply to such proposed product, as the said guidance is not binding law and may be superseded or modified at any time. Also, if the FDA determines that our post-marketing data do not demonstrate that the abuse-deterrent properties result in reduction of abuse, or demonstrate a shift to routes of abuse that present a greater risk, the FDA may find that product labeling revisions are needed, and may require the removal of our abuse-deterrence claims. Although ADAIR is very difficult to manipulate into a form that can be snorted, it is not impossible to do so, as was shown by a third-party drug laboratory, hired by us in preparation for human abuse studies, that was able to develop a time-consuming and laborious process to convert ADAIR into a form that could be insufflated. In addition, although ADAIR is difficult to solubilize into a form that can be injected, sophisticated drug abusers may be able to develop methods to manipulate ADAIR into a form that can be injected.

Further, in October 2020, an FDA advisory committee reviewed another abuse deterrent stimulant which relied on different delivery technology and a different active molecule than ADAIR. The advisory committee recommended against the approval of the other product, voting that the benefits did not outweigh the risks. In particular, the advisory committee determined that the other product had not established that it could deter the risk of intranasal abuse based on the results of its human abuse liability study because it failed the study's primary endpoint. Further the advisory committee voted that the safety of the other product had not been adequately characterized because of safety concerns with two inactive ingredients contained in the other product. ADAIR does not contain either of these inactive ingredients. Nevertheless, we may not be able to conduct a successful pivotal human abuse trial and an FDA advisory committee could vote that the benefits of ADAIR or ADMIR do not outweigh the risks.

We may need to comply with the requirements of the Drug Supply Chain Security Act, which outlines critical steps required to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

We may need to comply with the requirements of the Drug Supply Chain Security Act, including those related to product tracing, verification, and authorized trading partners. Signed into law in 2013, the Drug Supply Chain Security Act, amended the FDCA, and is being implemented over a 10-year period. The law's requirements include the ability to quarantine and promptly investigate a suspect product, such as a potentially counterfeit, diverted or stolen product, to determine if it is illegitimate, and notify our trading partners and the FDA of any illegitimate product. Such compliance may be time consuming and expensive to implement. Also, in the event that we fail to comply with these requirements, we may face regulatory actions that could affect our ability to commercialize ADAIR.

Even if ADAIR or any other future product, such as ADMIR, we may develop receives marketing approval, there could be adverse effects not discovered during development.

Even if any of our proposed products receive marketing approval, we or others may later identify undesirable side-effects caused by the product or problems with our third-party manufacturers or manufacturing processes, and in either event a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications or distribution and use restrictions;
- regulatory authorities may require us to issue specific communications to healthcare professionals, such as "Dear Doctor" letters;
- regulatory authorities may issue negative publicity regarding the affected product, including safety communications;
- we may be required to change the way the product is administered, conduct additional clinical trials or restrict the distribution or use of the product;
- we could be sued and held liable for harm caused to patients; and

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase commercialization costs or even force us to cease operations.

Our products may cause or contribute to adverse medical events that we are required to report to the FDA and if we fail to do so, we would be subject to sanctions that would materially harm our business.

Post-marketing safety data collection and adverse event reporting (ADR) are critical elements of FDA's oversight of drugs and therapeutic biologics available to the American public. The testing that helps to establish the safety of products, such as drugs and therapeutic biologics, is typically conducted on small groups before FDA approves the products for sale. Some problems can remain unknown, only to be discovered when a product is used by a large number of people. An adverse event is any unanticipated experience or side effect associated with the use of a drug or therapeutic biologic in humans, whether or not it is considered related to the product. An adverse event could occur:

- with use in professional practice;
- from overdose whether accidental or intentional;
- from abuse;
- from withdrawal; and
- due to lack of expected effectiveness.

During inspections, FDA investigators will review a company's post-marketing adverse event information to ensure compliance with federal laws and regulations.

Our marketed products are subject to ADR which require that we report to the FDA events related to our products. The timing of our obligation to report under the ADR regulations is 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 of which we become aware within the prescribed timeframe. We may also fail to recognize 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 could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearances or approvals, seizure of our products, or delay in clearance or approval of future products.

Our products may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in their design or manufacture. A government-mandated or voluntary recall could occur as a result of an unacceptable risk to health, contaminated product, manufacturing errors, or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits.

Changes in regulatory requirements and guidance or unanticipated events during our clinical trials may occur, which may result in necessary changes to clinical trial protocols, which could result in increased costs to us, delay our development timeline or reduce the likelihood of successful completion of our clinical trials.

Changes in regulatory requirements and guidance or unanticipated events during our clinical trials may occur, as a result of which we may need to amend clinical trial protocols. Amendments may require us to resubmit our clinical trial protocols to IRBs for review and approval, which may impact the cost, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our proposed product would be harmed and our ability to generate product revenue would be delayed, possibly materially.

Our amended and restated certificate of incorporation designate specific courts as the exclusive forum for certain litigation that may be initiated by the Company's stockholders, which could limit its stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated certificate of incorporation, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of or based on a breach of a fiduciary duty owed by any director, officer or other employee of ours to us or our stockholders; (3) any action asserting a claim pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation; or (4) any action asserting a claim governed by the internal affairs doctrine (Delaware Forum Provision). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated certificate of incorporation further provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (Federal Forum Provision). In addition, our amended and restated certificate of incorporation provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

We recognize that the Delaware Forum Provision in our amended and restated certificate of incorporation may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the forum selection clauses in our amended and restated certificate of incorporation may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Risks Relating to Intellectual Property

We have filed multiple patent applications and have two issued patents by the U.S. PTO and one issued patent by the European Patent Office. These or any other patent applications may not result in issued patents, and as a result we may have limited protection of our proprietary technology in the marketplace.

We have had two patents granted and one additional patent application directed to ADAIR for ADHD and narcolepsy filed in the United States, have had one patent granted in Europe, and we are seeking patent protection for ADAIR internationally in several foreign countries and territories, including Australia, Brazil, Canada, China, and Japan. The U.S. patents will expire in 2037 and the European patent will expire in 2038. It is impossible to predict whether or how our PCT application will result in any issued patent. Even if the pending application issues, it may issue with claims significantly narrower than those we currently seek.

The patent position of biotechnology and biopharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the U.S. PTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and biopharmaceutical patents. Consequently, a patent may not issue from our pending patent applications. Therefore, we do not know the degree of future protection that we will have on any proprietary product or technology that we have or may develop.

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection in the United States and other countries with respect to ADAIR or any other future product, such as ADMIR, that we may license or

acquire and the methods we use to manufacture them, as well as successfully defending these patents and trade secrets against third-party challenges. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our proposed products. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. If our licensors or we fail to obtain or maintain patent protection or trade secret protection for ADAIR or any other future product, such as ADMIR, we may license or acquire, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability. Moreover, should we enter into other collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance, and enforcement of our patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. In addition, no consistent policy regarding the breadth of claims allowed in biopharmaceutical or biotechnology patents has emerged to date in the United States. The patent situation outside the U.S. is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until eighteen (18) months after a first filing, or in some cases at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or whether we were the first to file for patent protection of such inventions. In the event that a third party has also filed a U.S. patent application relating to our proposed products or a similar invention, we may have to participate in interference proceedings declared by the U.S. PTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. PTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. PTO, or become involved in opposition, derivation, reexamination, inter parties review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing, and regulatory review of new proposed products, patents protecting such proposed products might expire before or shortly after such proposed products are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Because it is difficult and costly to protect our proprietary rights, we may not be able to ensure their protection.

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

- our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate ADAIR or any future product, such as ADMIR;
- it is possible that none of the pending patent applications licensed to us will result in issued patents;
- the issued patents covering ADAIR or any future product, such as ADMIR, may not provide a basis for market exclusivity for active products, may not provide us with any competitive advantages, or may be challenged by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- patents of others may have an adverse effect on our business.

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

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, rendered unenforceable, or interpreted narrowly.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.

Our ability to develop, manufacture, market and sell ADAIR or any other future product, such as ADMIR, that we may license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general fields of ADHD and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims by third parties, which could have a material adverse effect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that ADAIR may infringe. There could also be existing patents of which we are not aware that ADAIR may inadvertently infringe

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we infringe on their patents or misappropriated their technology, we could face a number of issues, including:

- infringement and other intellectual property claims, which, with or without merit, can be expensive and time consuming to litigate and can divert management's attention from our core business;

- substantial damages for past infringement which we may have to pay if a court decides that our product infringes on a competitor's patent;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of ADAIR or any other future product, such as ADMIR. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize ADAIR or any other future product. If we are unable to obtain a license from these third parties, or unable to obtain a license, on commercially reasonable terms, our business could be harmed.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

In the future, we may become party to licenses that are important for product development and commercialization. If we fail to comply with our obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product or utilize any technology that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could materially and adversely affect the value of a proposed product being developed under any such agreement or could restrict our drug discovery activities. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and biopharmaceutical industry, we employ individuals who were previously employed at other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

In addition to seeking patent protection for ADAIR or any future product, such as ADMIR, we also rely on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain our competitive position, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We limit disclosure of such trade secrets where possible, but we also seek to protect these trade secrets, in part, by

entering into non-disclosure and confidentiality agreements with parties who do have access to them, such as our employees, our licensors, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and may unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Relating to Securities Markets and Our Common Stock

An active, liquid and orderly market for our common stock may not be maintained.

Prior to our February 2021 IPO, there had been no public market for our common stock. Our common stock only recently began trading on The Nasdaq Capital Market, but we can provide no assurance that we will be able to develop and sustain an active trading market for our common stock. Even if an active trading market is developed, it may not be sustained. The lack of an active market may impair stockholders' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

If we cannot continue to satisfy the listing requirements of The Nasdaq Capital Market and other rules, including the director independence requirements, our securities may be delisted, which could negatively impact the price of our securities and stockholders' ability to sell them.

Although common stock is listed on The Nasdaq Capital Market, we may be unable to continue to satisfy the listing requirements and rules, including the director independence requirements and certain financial metrics for our stockholders' equity and market value of listed securities or net income from continuing operations. If we are unable to satisfy The Nasdaq Capital Market criteria for maintaining our listing, our securities could be subject to delisting. If The Nasdaq Capital Market delists our securities, we could face significant consequences, including:

- a limited availability for market quotations for our securities;
- reduced liquidity with respect to our securities;
- a determination that our common stock is a "penny stock," which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in reduced trading;
- activity in the secondary trading market for our common stock;
- limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

In addition, we would no longer be subject to The Nasdaq Capital Market rules, including rules requiring us to have a certain number of independent directors and to meet other corporate governance standards.

Our stock may be subject to substantial price and volume fluctuations due to a number of factors, many of which are beyond our control and may prevent our stockholders from reselling our common stock at a profit.

The market prices for securities of biotechnology and biopharmaceutical companies have historically been highly volatile, and the market has from time-to-time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. In particular, the trading prices for pharmaceutical, biopharmaceutical and biotechnology companies have been highly volatile as a result of the COVID-19 pandemic.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- results from, and any delays in, our clinical trials for our product candidates, including ADAIR and ADMIR, or any other future clinical development programs, including any delays related to the COVID-19 pandemic;
- announcements concerning the progress of our efforts to obtain regulatory approval for and commercialize ADAIR or any future product, including ADMIR, including any requests we receive from the FDA for additional studies or data that result in delays in obtaining regulatory approval or launching such proposed product, if approved;
- market conditions in the biopharmaceutical and biotechnology sectors or the economy as a whole;
- price and volume fluctuations in the overall stock market;
- the failure of ADAIR or any future product, such as ADMIR, if approved, to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- actual fluctuations in our quarterly operating results, and concerns by investors that such fluctuations may occur in the future;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- health care reform legislation, including measures directed at controlling the pricing of biopharmaceutical products, and third-party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our common stock, a liquid trading market, if any, for our common stock may not develop, and if it does, our share price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts and analysts may not provide favorable coverage, or any coverage at all. If any of the analysts that do cover us make an adverse recommendation regarding our stock, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

Because we do not intend to declare cash dividends on our common stock in the foreseeable future, stockholders must rely on appreciation of the value of our common stock for any return on their investment.

We have never declared or paid cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future.

Our significant stockholders may exert a substantial influence on actions requiring a stockholder vote, potentially in a manner that you do not support.

As of January 31, 2022, our executive officers, directors, beneficial owners of 5% of more of our capital stock and their respective affiliates will, in the aggregate, beneficially own approximately 54.4% of our outstanding common stock, including Medice, through its affiliated entity, Salmon Pharma, and Arcturus Therapeutics, Ltd. (Arcturus), our largest stockholders, assuming no exercise of the underwriters' option to purchase additional shares.

If Salmon Pharma, Arcturus or any member of our board or management acquires additional shares of common stock in the aftermarket or in privately negotiated transactions, this would increase their control. Factors that would be considered in making such additional purchases would include consideration of the current trading price of our common stock.

Salmon Pharma and Arcturus's large ownership stake may allow it to exert a substantial influence on actions requiring a stockholder vote, potentially in a manner that stockholders' do not support, including amendments to our amended and restated certificate of incorporation, election of our board of directors, removal of any of our directors, adoption of measures that could delay or prevent a change in control or impede a merger, takeover, or other business combination involving us, and approval of other major corporate transactions. In addition, Salmon Pharma and Arcturus's stock ownership may discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, which in turn could reduce our stock price or prevent our stockholders from realizing a premium over our stock price. Accordingly, our stockholders other than Salmon Pharma and Arcturus may be unable to influence management and exercise control over our business.

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.

Certain provisions of our amended and restated certificate of incorporation and our amended and restated bylaws and applicable provisions of Delaware law may delay or discourage transactions involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. The provisions in our amended and restated certificate of incorporation and amended and restated bylaws:

- limit who may call stockholder meetings;
- do not provide for cumulative voting rights;
- provide that all vacancies may be filled only by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain legal claims; and
- provide that the federal district courts of the United States of American will be the exclusive forum for legal claims under the Securities Act.

In addition, once we become a publicly traded corporation, Section 203 of the Delaware General Corporation Law may limit our ability to engage in any business combination with a person who beneficially owns 15% or more of our outstanding voting stock unless certain conditions are satisfied. This restriction lasts for a period of three years following the share acquisition. These provisions may have the effect of entrenching our management team and may deprive stockholders' of the opportunity to sell their shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock. See Exhibit 4.5 "Description of Capital Stock" for additional information.

Financial reporting obligations of being a public company in the United States require well defined disclosure and financial controls and procedures that are expensive and time-consuming requiring our management to devote substantial time to compliance matters.

As a publicly traded company, we incur significant legal, accounting and other expenses that we did not incur as a privately held company prior to the completion of our IPO in February 2021. These reporting obligations associated with being a public company in the United States require significant expenditures and place significant demands on our management and other personnel, including costs resulting from our reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, as amended, and the listing requirements of The Nasdaq Capital Market. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations may make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." In addition, we expect these rules and regulations to make it more difficult and more expensive for us to maintain director and officer liability insurance. Our management and other personnel need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

If we fail to comply with the rules under the Sarbanes-Oxley Act related to accounting controls and procedures in the future, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting after a transition period ending with our second annual report on Form 10-K filed under Section 13(a) of the Exchange Act. If we fail to comply with the rules under the Sarbanes-Oxley Act related to disclosure controls and procedures in the future, or, if in the future we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our executive offices are located at 100 N. 18th Street, Suite 300, Philadelphia, PA 19103. We believe that our facilities are adequate to meet our current needs. Should we be required to obtain additional space in the future, we believe we can obtain the required facilities at competitive rates.

Item 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Our common stock is traded on The Nasdaq Capital Market under the symbol "VLON". As of February 4, 2022, there were 7 holders of record of our common stock. As of such date, there were 6,812,836 shares of our common stock outstanding. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Securities Authorized for Issuance Under Equity Compensation Plans

See Part III, Item 12. "Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters" for information relating to our equity compensation plans.

Recent Sales of Unregistered Securities

2021 Convertible Note Financing

On January 11, 2021, we entered into a Convertible Promissory Note Purchase Agreement with certain existing stockholders, including Salmon Pharma, an affiliate of Medice, and David Baker, our Chief Executive Officer, pursuant to which we issued convertible promissory notes (the 2021 Convertible Notes) for cash proceeds of $350,000. The 2021 Convertible Notes bear an interest rate of 7.0% per annum, non-compounding, and had a maturity date of September 30, 2021. The 2021 Convertible Notes were convertible into shares of our capital stock offered to investors in any subsequent equity financing after the date of their issuance in which we issued any of our equity securities (a Qualified Financing), and were convertible at a twenty percent (20%) discount to the price per share offered in such Qualified Financing. Such Qualified Financing included the IPO of our common stock, consummated on February 12, 2021; therefore, the 2021 Convertible Notes converted into an aggregate of 54,906 shares of our common stock immediately prior to the closing of the IPO, as agreed upon among the parties thereto.

Based in part upon the representations of Salmon Pharma and David Baker, the offering and sale of the 2021 Convertible Notes and the shares of our common stock issued upon conversion thereof were exempt from registration under Section 4(a)(2) of the Securities Act. The sales of our common stock issued upon conversion of the 2021 Convertible Notes will not be registered under the Securities Act or any state securities laws and may not be offered or sold in the United States absent registration with the SEC or an applicable exemption from the registration requirements.

Use of Proceeds from Registered Securities

On February 9, 2021, our Registration Statement on Form S-1 (File No. 333-249636) relating to the IPO of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 2,250,000 shares of our common stock at a price of $8.00 per share for aggregate cash proceeds of approximately $15.5 million, which amount is net of $1.6 million in underwriter's discounts, commissions and expenses, and $0.9 million of other expenses incurred in connection with the offering.

There has been no material change in the expected use of the net proceeds from our IPO, as described in our final prospectus filed with the SEC on February 11, 2021 pursuant to Rule 424(b) under the Securities Act.

Purchases of Equity Securities By the Issuer and Affiliated Purchasers

Neither we nor any affiliated purchaser or anyone acting on our behalf or on behalf of an affiliated purchaser made any purchases of shares of our common stock during the year ended December 31, 2021.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes beginning on page F-1 of this Annual Report. Some of the information contained in this

discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Item 1A. Risk Factors" and "Special Note Regarding Forward-Looking Statements" of this Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company primarily focused on the development and commercialization of proprietary biopharmaceutical products. We are developing novel medications for central nervous system (CNS) disorders with a focus on abuse-deterrent medications. Our lead investigational product candidate, ADAIR, is a proprietary, abuse-deterrent oral formulation of immediate-release dextroamphetamine (the main active ingredient in Adderall®) for the treatment of attention-deficit/hyperactivity disorder (ADHD) and narcolepsy. According to the US Department of Health and Human Services' 2018 National Survey on Drug Use and Health, over 5 million adolescents and adults misuse prescription stimulant medications on an annual basis. The misuse and abuse of prescription stimulants has substantial medical risk, including risk of irregular heartbeat, heart attack, seizures, hallucinations, hostile behavior and stroke, as well as increased risk of addiction. ADAIR is designed to deter attempts to crush and snort and to provide barriers to injection while still providing the expected therapeutic benefit when taken orally.

We are developing ADAIR for registration with the U.S. Food and Drug Administration (the FDA) through the Section 505(b)(2) regulatory pathway, which is expected to obviate the need for large Phase 2 and Phase 3 efficacy and safety studies. In July 2018, our Investigational New Drug (IND) application for ADAIR was approved by the FDA. We have completed three Phase 1 trials of ADAIR including a proof-of-concept intranasal human abuse potential study. In the second quarter of 2021, we completed a 13-week preclinical toxicology study on the final formulation of ADAIR that showed no safety findings of concern. We are currently conducting the SEAL study, a pivotal intranasal abuse study, and have recently completed its patient enrollment and treatment phases. The SEAL study enrolled 55 subjects who successfully passed the qualification phase with a total of 53 completing the study. We expect to report top-line results of the SEAL study in the first quarter of 2022. Additionally, we continue to conduct preclinical studies and manufacturing work and continue to evaluate the potential for any additional studies to support the submission of a New Drug Application (NDA) for ADAIR to the FDA.

In January 2020, we entered into the Medice License Agreement, which grants Medice an exclusive license to develop, use, manufacture, market and sell ADAIR throughout Europe. Under the license agreement, Medice paid us a $0.1 million upfront payment and will pay milestone payments of up to $6.3 million in aggregate upon achieving certain regulatory and sales milestones. We are also entitled to low-double digit tiered royalties on net sales of ADAIR.

In addition to ADAIR, we completed formulation development work and selected the final formulation of our second product candidate, ADMIR, an abuse deterrent formulation of methylphenidate (Ritalin®), for the treatment of ADHD. We also plan to utilize the Section 505(b)(2) regulatory pathway for registration of ADMIR.

In the future, we plan to use our abuse deterrent platform technology to develop other products that have potential for abuse in their current forms and will continue business development activities and seek partnering, licensing, merger and acquisition opportunities or other transactions to further develop our pipeline and drug-development capabilities.

The global COVID-19 pandemic continues to present uncertainty and unforeseeable new risks to our operations and business plan. We have closely monitored recent COVID-19 developments, including states' lifting COVID-19 safety measures, drops in vaccination rates, and the spread of various coronavirus strains such as the Delta and Omicron variants. In light of these developments, the full impact of the COVID-19 pandemic on our business, operations and clinical development plans remains uncertain and will vary depending on the pandemic's future impact on our clinical trial enrollment, clinical trial sites, clinical research organizations (CROs), third-party manufacturers, and other third parties with whom we do business, as well as any legal or regulatory consequences resulting therefrom. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and with most of our employees and consultants working remotely. We will continue to actively monitor the COVID-19 situation and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business.

Critical Accounting Policies

Our financial statements are prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be

reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Marketable Securities

Marketable securities consist of debt securities that are designated as available-for-sale. Marketable debt securities are recorded at fair value and unrealized holding gains or losses are reported as a component of accumulated other comprehensive income (loss). The amortization of discounts and premiums on marketable securities is included in interest expense, net on the statements of operations and comprehensive loss.

Realized gains or losses resulting from the sale of these securities are determined based on the specific identification of the securities sold. An impairment charge is recognized when the decline in the fair value of a debt security below the amortized cost basis is determined to be other-than-temporary. We consider various factors in determining whether to recognize an impairment charge, including the duration and severity of any decline in fair value below the amortized cost basis, any adverse changes in the financial condition of the issuers and our intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

Revenue Recognition

We account for revenue in accordance with Financial Accounting Standards Board Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers*. This standard applies to all contracts with customers with the exception of contracts that are within the scope of other standards, such as leases, insurance and financial instruments. Under ASC Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to be entitled in exchange for those goods or services.

We perform the following five steps to recognize revenue under ASC Topic 606: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only recognize revenue when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services that will be transferred to the customer.

To date, our revenues have been generated by a single license agreement (the Medice License Agreement) with Medice (Note 13). The Medice License Agreement included an exclusive license to develop, use, manufacture, market and sell ADAIR throughout Europe, a non-refundable up-front payment, regulatory and sales milestones and royalty payments.

Stock-based Compensation

We recognize expense for employee and non-employee stock-based compensation in accordance with ASC Topic 718, *Compensation - Stock Compensation*. ASC Topic 718 requires that such transactions be accounted for using a fair value-based method. The estimated fair value of the options is amortized over the vesting period, based on the fair value of the options on the date granted, and is calculated using the Black-Scholes option-pricing model. We account for forfeitures as incurred.

Estimating the fair value of option shares issued under the employee stock purchase plan requires the input of subjective assumptions, including the estimated fair value of our common stock, the expected life of the option, stock price volatility, the risk-free interest rate and expected dividends. The assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future.

These assumptions used in our Black-Scholes option-pricing model are estimated as follows:

- *Expected Term.* Due to the lack of sufficient company-specific historical data, the expected term of employee options is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option. The expected term of nonemployee options is equal to the contractual term.

- *Expected Volatility*. The expected volatility is based on historical volatilities of similar entities within our industry which were commensurate with the expected term assumption as described in SAB No. 107.
- *Risk-Free Interest Rate*. The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.
- *Expected Dividends*. The expected dividend yield is 0% because we have not historically paid, and do not expect for the foreseeable future to pay, a dividend on our common stock.

Leases

We account for leases in accordance with Accounting Standards Update (ASU) 2016-02, *Leases (Topic 842)* and ASU 2018-10, *Codification Improvements to Topic 842, Leases*, and ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, both of which clarify and enhance the certain amendments made in ASU 2016-02. The ASUs increase transparency and comparability among entities by recognizing for all leases lease assets and lease liabilities on the balance sheet and disclosing key information about lease arrangements. We entered into one lease for manufacturing equipment for ADAIR which we determined was a finance lease.

Financial Operations Overview

Revenue

To date, we have not generated any revenues from product sales. All of our revenue to date has been derived from the Medice License Agreement. We do not expect to generate significant product revenue until we obtain approval and commercialize ADAIR. Under the terms of the Medice License Agreement, we received $0.1 million in licensing revenues in connection with the initial signing of the license agreement in the first quarter of 2020.

Research and Development Expenses

Research and development expenses include personnel costs associated with research and development activities, including third party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. We accrue for costs incurred by external service providers, including contract research organizations and clinical investigators, based on its estimates of service performed and costs incurred.

Our research and development expenses have consisted primarily of in-process research and development expenses, costs incurred in preparing for and conducting the development program for ADAIR, working on commercial manufacturing of ADAIR and developing formulations for ADMIR. Research and development costs are expensed as incurred. These expenses include:

- employee -related expenses, such as salaries, bonuses and benefits, consultant-related expenses such as consultant fees and bonuses, stock-based compensation, overhead related expenses and travel related expenses for our research and development personnel;
- expenses incurred under agreements with contract research organizations (CROs), as well as consultants that support the implementation of our clinical and non-clinical studies;
- manufacturing and packaging costs in connection with conducting clinical trials and for stability and other studies required to support the NDA filing as well as manufacturing drug product for commercial launch;
- formulation, research and development expenses related to ADMIR; and other products we may choose to develop; and
- costs for sponsored research.

We typically use our employee, consultant and infrastructure resources across our research and development programs. Although we track certain outsourced development costs by product candidate, we do not allocate personnel costs or other internal costs to specific product candidates.

We plan to incur research and development expenses for the foreseeable future as we expect to continue the development of ADAIR and our other product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development and the early stage of our other product candidates, we are unable to estimate with any certainty the costs we will incur and the timelines we will require in our continued development efforts.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and consulting related expenses for executives and other administrative personnel, professional fees and other corporate expenses, including legal and accounting fees, travel expenses, facilities-related expenses, and consulting services relating to our formation and corporate matters.

We anticipate that our general and administrative expenses will increase in the future as we support our continued research and development activities and operate as a public company. These increases will likely include increased costs related to the hiring of personnel, including compensation and employee-related expenses, including stock-based compensation, and fees to outside consultants, lawyers and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with The Nasdaq Capital Market and SEC requirements, directors and officers insurance, increased legal and accounting costs and investor relations costs. In addition, if ADAIR obtains regulatory approval for marketing, we expect that we would incur expenses associated with building a commercialization team if we have not sold or licensed the rights to commercialize ADAIR to a third party in territories not under the license agreement with Medice.

Other Income

Other income consists of income recognized as a result of the extinguishment of the promissory note issued to us under the Paycheck Protection Program (PPP) as a result of the forgiveness of the note.

Revaluation of Derivative Instruments

In January 2021, we entered into a Convertible Promissory Note Purchase Agreement pursuant to which we issued $350,000 in convertible promissory notes (the 2021 Convertible Notes). The 2021 Convertible Notes automatically converted into 54,906 shares of our common stock concurrently with the closing of the IPO. We identified the mandatory conversion into shares our common stock as a redemption feature, which requires bifurcation from the 2021 Convertible Notes and treated it as a derivative liability under ASC 815 as the redemption feature was not clearly and closely related to the debt. We evaluated the fair value of the derivative liability at issuance. Upon the conversion of the 2021 Convertible Notes to common stock at the closing of the IPO, the embedded derivative liability was remeasured and removed from the balance sheet.

Interest Expense, net

Interest expense, net, consists of interest earned on our cash, cash equivalents and marketable securities held with institutional banks, the amortization of discounts and premiums on marketable securities and interest expense on our finance lease of equipment utilized in the commercial scale manufacturing of ADAIR.

Recently Issued Accounting Pronouncements

We consider the applicability and impact of all ASUs. ASUs not discussed below were assessed and determined to be either not applicable or are expected to have minimal impact on the financial statements.

On January 1, 2021, we adopted ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions to the general principals in Topic 740. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending the existing guidance. The adoption of this standard did not have a material impact on our financial statements.

JOBS Act

We are an "emerging growth company," as defined in Section 2(a) the Securities Act, as modified by the JOBS Act. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies." For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). After we become a reporting company under the Exchange Act, we will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of

the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenues of $1.07 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (iv) the end of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

The following table sets forth our results of operations for the year ended December 31, 2021 compared to the year ended December 31, 2020 (in thousands):

	Year Ended December 31,	
	2021	**2020**
License revenue – from related party	$ —	$ 100
Operating expenses:		
Research and development	5,187	3,707
General and administrative	4,072	1,181
Total operating expenses	9,259	4,888
Loss from operations	(9,259)	(4,788)
Other income	61	—
Change in fair value of derivative liability	(89)	—
Interest expense, net	(16)	(34)
Net loss	$ (9,303)	$ (4,822)

License Revenue – From Related Party

Licensing revenues were $0.1 million for the year ended December 31, 2020 as a result of the upfront payment received under the terms of the Medice License Agreement. No licensing revenues were recognized during the year ended December 31, 2021.

Research and Development Expenses

Research and development expenses were $5.2 million and $3.7 million for the years ended December 31, 2021 and 2020, respectively. The $1.5 million increase in research and development expenses was primarily due to increases of $1.5 million in expenses related to the registration development program of ADAIR and $0.1 million in consulting fees, offset by a decrease of $0.1 million in expenses related to the formulation work for ADMIR.

General and Administrative Expenses

General and administrative expenses were $4.1 million and $1.2 million for the years ended December 31, 2021 and 2020, respectively. The $2.9 million increase was primarily related to increased costs for directors and officers insurance of $1.3 million, personnel expense, including non-cash stock compensation, of $1.0 million, and public company expenses of $0.5 million.

Other Income

In May 2020, we issued a promissory note under the PPP totaling $61,000. As of December 31, 2020, we had utilized the entire proceeds from such note for payroll costs (greater than 75%), costs related to health care benefits and rent payments. In January 2021, we were notified that the note along with accumulated interest had been forgiven. As a result, we recorded income from the extinguishment of the obligation in accordance with ASC 405-20-40-1.

Revaluation of Derivative Liability

During the year ended December 31, 2021, pursuant to ASC 815, we revalued the embedded derivative liability associated with the 2021 Convertible Notes, resulting in an $89,000 decrease in the fair value of the derivative liability associated with the 2021 Convertible Notes.

Interest Expense, net

Interest expense, net, was $16,000 and $34,000 for the years ended December 31, 2021 and 2020, respectively.

Liquidity and Capital Resources

Since inception, we have incurred losses and expect to continue to incur losses for the foreseeable future. We incurred net losses of $9.3 million and $4.8 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $21.9 million.

We have financed our working capital requirements to date through the issuance of common stock, convertible notes, short-term promissory notes, and a PPP promissory note. As of December 31, 2021, we had $3.7 million in cash and cash equivalents.

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

	Year Ended December 31,	
	2021	2020
Net cash provided by (used in):		
Operating activities	(8,312)	$ (3,706)
Investing activities	(3,842)	(2)
Financing activities	15,747	(4)
Net increase (decrease) in cash and cash equivalents	$ 3,593	$ (3,712)

Cash Flows from Operating Activities

For the years ended December 31, 2021 and 2020, $8.3 million and $3.7 million were used in operating activities, respectively. The $4.6 million increase was primarily due to a $4.5 million increase in our net loss, a $0.5 million increase in non-cash stock compensation expense, as well as increases in accrued and prepaid expenses of $0.1 million, offset by a $0.3 million decrease in accounts payable.

Cash Flows from Investing Activities

Net cash used in investing activities was $3.8 million for the year ended December 31, 2021, which was related to the purchase of marketable securities. Net cash used in investing activities was $2,000 for the year ended December 31, 2020, which was related to the purchase of computer equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was $4,000 during the year ended December 31, 2020, which was related to proceeds received from a PPP note of $61,000, offset by payments related to our finance lease of $65,000. Net cash provided by financing activities was $15.8 million for the year ended December 31, 2021 and was primarily related to the net proceeds from our IPO and 2021 Convertible Notes financings.

2021 Convertible Note Financing

In January 2021, we entered into a Convertible Promissory Note Purchase Agreement with certain existing stockholders, including Salmon Pharma, an affiliate of Medice, and David Baker, our Chief Executive Officer, pursuant to which we issued convertible promissory notes (the 2021 Convertible Notes) for cash proceeds of $350,000. The 2021 Convertible Notes bear an interest rate of 7.0% per annum, non-compounding, and had a maturity date of September 30, 2021. The 2021 Convertible Notes were convertible into shares of our capital stock offered to investors in any subsequent equity financing after the date of their issuance in which we issued any of our equity securities (a Qualified Financing) and were convertible at a twenty percent discount to the price per share offered in such Qualified Financing. Such Qualified Financing included the IPO of our common stock, consummated on February 12, 2021; therefore, the 2021 Convertible Notes converted into an aggregate of 54,906 shares of our common stock immediately prior to the closing of the IPO, as agreed upon among the parties thereto.

Future Funding Requirements

Although it is difficult to predict future liquidity requirements, we expect that our existing cash and cash equivalents will provide funding for our ongoing business activities into the third quarter of 2022. We will require substantial additional financing to fund our research and development activities. No assurance can be given that any such financing will be available when needed or that our research and development efforts will be successful. If the we are not able to obtain additional financing on acceptable terms and in the amounts necessary to fully fund our future operating requirements, we may be forced

to reduce or discontinue our operations entirely. Therefore, there is substantial doubt about our ability to continue as a going concern. We expect to continue to incur significant and increasing operating losses at least for the foreseeable future. We do not expect to generate product revenue unless and until we successfully complete development, obtain regulatory approval for, and successfully commercialize ADAIR, or any other future products, including ADMIR. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of planned clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will increase substantially as we:

- conduct clinical trials and non-clinical studies;
- scale up manufacturing capabilities with third-party contract manufacturer(s);
- conduct ongoing stability studies of ADAIR;
- seek to identify, acquire, develop and commercialize additional products, such as ADMIR;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand and protect our intellectual property portfolio;
- hire scientific, clinical, quality control and administrative personnel;
- add operational, financial and management information systems and personnel, including personnel to support our drug development efforts;
- seek regulatory approvals for any products that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any drug candidates for which we may obtain regulatory approval, including through the license agreement with Medice; and
- operate as a public company.

Contractual Obligations and Other Commitments

We enter into contracts in the normal course of business with third-party contract organizations for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice and therefore we believe that our non-cancelable obligations under these agreements are not material.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable to a smaller reporting company.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required pursuant to this item are incorporated by reference herein from the applicable information included in Item 15 of this annual report and are presented beginning on page F-1.

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

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to

ensure that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer) evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a 15(e) and 15d 15(e) under the Exchange Act, as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2021.

Management's 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 to provide reasonable assurance of the reliability of financial reporting and of the preparation of financial statements for external reporting purposes, in accordance with U.S. generally accepted accounting principles.

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

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

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. In making this assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework (2013). These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. Management's assessment included documentation, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on management's processes and assessment, as described above, management has concluded that, as of December 31, 2021, our internal control over financial reporting was effective.

Remediation of Material Weakness in Internal Control Over Financial Reporting

The closing of our IPO occurred on February 12, 2021. As a newly public company under the Exchange Act, we were not required to evaluate the effectiveness of our internal controls over financial reporting until the end of the fiscal year after we file our Annual Report on Form 10-K for the year ended December 31, 2020. Although our management did not conduct an evaluation of our internal control over financial reporting, in connection with the audit of our financial statements for the years ended December 31, 2020, 2019 and 2018, we became aware of material weaknesses in our internal controls over financial reporting for those periods.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses related to a lack of segregation of duties in the financial reporting process due to the small size of our accounting and finance department, lack of sufficient documentation of various accounting processes, and the design over controls related to recording certain transactions.

We have remediated the material weaknesses by hiring additional accounting and finance staff, and implementing new controls, processes and technologies to formalize internal controls frameworks and procedures.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption provided by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

We have taken actions and remediated the material weaknesses relating to our internal controls over financial reporting as described above. Except as otherwise disclosed herein, there have been no changes in our internal control over financial reporting during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE MANAGEMENT

The following table sets forth certain information about our directors, director nominees, our executive officers, and a key consultant.

Name	Age	Position
Executive Officers		
David Baker	58	President, Chief Executive Officer and Director *(Principal Executive Officer)*
Leanne Kelly	45	Chief Financial Officer *(Principal Financial and Accounting Officer)*
Penny S. Toren	55	Senior Vice President, Regulatory Affairs & Program Management
Non-Employee Directors and Director Nominee		
Ofir Levi[1][3]	47	Director, Chairman of the Board
Joseph Payne[1][2][3]	50	Director
Richard Ammer	51	Director
Marella Thorell[1][2]	54	Director
Key Consultant		
Timothy Whitaker, M.D.	63	Chief Medical Officer

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Executive Officers

David Baker has served as our President and Chief Executive Officer since January 15, 2019, and as a member of the board of directors from that time until August 23, 2019, and upon the consummation of the IPO of our common stock on February 12, 2021, he was again appointed as a director. Prior to being appointed our President and Chief Executive Officer, he served as a consultant to our company since January 15, 2018. He previously served as the Interim Chief Executive Officer and Chief Commercial Officer of Alcobra Ltd (now known as Arcturus), where he oversaw the development of ADAIR. Prior to joining Alcobra Ltd., he worked at Shire Pharmaceuticals for 10 years, including as Vice President of Commercial Strategy and New Business in the Neuroscience Business Unit. In that role, Mr. Baker led the commercial assessment of neuroscience licensing opportunities, managed commercial efforts on pipeline CNS products, and led the long-term strategic planning process. Previously, he served as Global General Manager for Shire's Vyvanse® where he led the launch of Vyvanse and led global expansion efforts including successful establishment of a partnership in Japan and launches in Canada and Brazil. Prior to that, Mr. Baker served as Vice President of Marketing for all of Shire's ADHD products. From 1990 through 2004, Mr. Baker worked at Merck & Co., where he held positions of increasing responsibility in marketing, sales, market research, and business development. In addition to his knowledge and experience with CNS medications, Mr. Baker's expertise includes therapeutics for osteoporosis, migraine, and hyperlipidemia. He has been directly involved with the marketing of five medications with annual sales in excess of $1 billion each. Mr. Baker graduated Magna Cum Laude with a bachelor's degree in Economics and Computer Science from Duke University. He earned a Master of Business Administration in Marketing from Duke's Fuqua School of Business. Mr. Baker also serves on the board of directors of Benchworks, Inc., a private healthcare advertising agency.

We believe Mr. Baker's extensive experience in the biopharmaceuticals industry and his in-depth understanding of our business, strategy and management team qualifies him to serve on our board of directors.

Leanne M. Kelly has served as our Chief Financial Officer since May 2021. She brings over 20 years of experience leading private and publicly traded companies across life science, technology and e-Commerce sectors with a foundation in public accounting. Prior to joining Vallon, she most recently served as the Controller and Executive Director, Global Financial Reporting at OptiNose, Inc, a $50 million revenue specialty pharmaceutical company. Over the course of her career, she has held Senior Vice President of Finance, Controller and Chief Financial Officer positions in private and public companies such as

Flower Orthopedics, Iroko Pharmaceuticals, LLC, and Genaera Corporation. Ms. Kelly began her career as an auditor with KPMG LLP. While serving in those roles, Ms. Kelly's work included multi-million dollar financings, M&A diligence and support. She also has experience in financial oversight, internal and external financial reporting, forecasting, and financial analysis, as well as investor and public relations. Ms. Kelly received her Bachelor of Science degree in Business Economics with a concentration in Accounting from Lehigh University, and is a licensed CPA (inactive status) in the state of Pennsylvania.

Penny S. Toren has served as our Senior Vice President, Regulatory Affairs, since April 2018. She brings over 25 years of Regulatory and Clinical Development experience in the pharmaceutical industry from Glaxo SmithKline, AstraZeneca, Cephalon, and Teva. At Vallon, Ms. Toren heads the Regulatory Affairs & Program Management function, providing regulatory strategies to optimize the most efficient and effective outcomes for Vallon's drug products as well as ensuring full compliance with FDA and DEA regulations for products in development through post approval. From 2003 until April 2018, Ms. Toren developed the Global Regulatory Policy & Intelligence function for Teva's Specialty, Generic, & Biosimilar portfolio. In this role, Ms. Toren participated in several FDA, PhRMA, and BIO cross company working groups to address regulatory policy for abuse deterrent products. Prior to that, Ms. Toren led the successful registration of Fentora®, negotiated approval of the first RiskMap for opioids, and was a driver of the initial development of the Fentora® and Actiq® REMS programs. Ms. Toren earned her bachelor's degree in Chemistry and Biology from Florida Atlantic University, an MS in Biostatistics and Epidemiology from New York Medical College.

Non-Executive Directors

Ofir Levi has served as a member of our board of directors since inception and has served as the Chairman of the board of directors since our inception. He is an accomplished biotech entrepreneur with over 16 years of experience establishing, managing and investing in early to late stage life science companies. He was a research consultant for Adamas Health Care Fund from its inception in 2014 until January 2020 where he led a research team that conducts deep scientific analysis of publicly traded pharmaceutical and biotechnology companies. Prior to his engagement with Adamas Health Care Fund, Dr. Levi was the founder and CEO at Bioassociate Ltd., an expertise-based consulting, research and analysis company focused on the pharmaceutical, biotechnology and life science sectors. Until 2011, Dr. Levi was the CEO of Radmor Biocap LLC, a company that invested and managed seed and early stage companies, pharmaceutical development, clinical diagnostics and medical devices. Led by Dr. Levi, Radmor signed several license agreements with leading universities around the world for novel technologies, and established companies developing these technologies. Dr. Levi completed his Ph.D. studies in Prof. Daniel Michaelson's neurobiology lab at Tel-Aviv University. During the four years of his Ph.D. studies, he led a research group in both in-house research and several international collaborations. Dr. Levi's PhD thesis focused on neurogenesis processes in Alzheimer's Disease.

We believe Dr. Levi's extensive experience as an investor and entrepreneur in the biopharmaceuticals industry and his in-depth understanding of our business, strategy and management team qualifies him to serve on our board of directors.

Joseph Payne joined our board of directors on June 22, 2018 in connection with the Asset Purchase Agreement, as the designated director nominee of Arcturus pursuant to the terms of the 2018 Voting Agreement (as hereinafter defined), which agreement terminated upon the filing of the registration statement in connection with the IPO of our common stock. He also serves on the board of directors of Arcturus since November 2017. Mr. Payne previously served as President and Chief Executive Officer of Arcturus and on its board of directors from March 2013 to February 2018. Prior to joining Arcturus, Mr. Payne served as Senior Manager of Nitto Denko Corporation, a life sciences research company, from June 2009 until February 2013. Mr. Payne's background includes over 20 years of drug discovery experience at Arcturus, Nitto Denko Corporation, Kalypsys Inc., Merck Research Labs, Bristol-Myers Squibb Co. and DuPont Pharmaceuticals Co. Mr. Payne received a bachelor's degree in Chemistry, magna cum laude from Brigham Young University, a Master of Science in Synthetic Organic Chemistry from the University of Calgary and an Executive Training Certificate from MIT Sloan School of Management.

We believe Mr. Payne's extensive experience in the biopharmaceuticals industry and as a chief executive officer of a biopharmaceutical company qualifies him to serve on our board of directors.

Richard Ammer, M.D., Ph.D. joined our board of directors in July 2019 in connection with the July 2019 private placement. Since 2003, Dr. Ammer served as general manager and since 2012 as managing owner of MEDICE Arzneimittel Pütter GmbH & Co. KG, a family-owned mid-sized pharmaceutical enterprise, where he is responsible for search and development, medical and regulatory affairs, manufacturing, market access and international marketing and distribution. Since 2008, Dr. Ammer has served as a board member and Vice President of the German Pharmaceutical Association with a focus on research and development. Dr. Ammer graduated with a degree in medicine from Technical University, Munich, and internship at Harvard Medical School, Boston. Dr. Ammer pursued his clinical and scientific education in internal medicine at Massachusetts General Hospital in Boston from 1996 until 2000, the German Heart Center from 2000 until 2001, and the University Hospital in

Muenster 2001, where he has been responsible for patients undergoing cardiac and renal care. He also established a nation-wide network of excellence and competence on cardiac arrhythmias, sponsored by the federal ministry of science (BMBF), for which he served as its general manager from 2002 to 2004. His research on atrial fibrillation, for which he obtained his PhD in 2000 from Technical University, Munich, was awarded by the European Society in Cardiology with the Young Investigator Award in Basic Science in 2001. Dr. Ammer also studied business administration and economics at University St. Gallen from 1992 until 1996, and at Harvard Extension School from 1996 until 1998 and obtained a PhD in 2005 from University St. Gallen. Since 2001, Dr. Ammer has also served as lecturer at University St. Gallen, Switzerland.

We believe Dr. Ammer's extensive experience in the biopharmaceuticals industry and as a chief executive officer of a biopharmaceutical company qualifies him to serve on our board of directors.

Marella Thorell has served as a director and as the chairperson of our audit committee since February 12, 2021. Ms. Thorell has more than 30 years of accomplishments in finance and operations having successfully led multiple M&A, licensing, and fundraising transactions. She currently serves as the Chief Accounting Officer of Centessa Pharmaceuticals plc (Nasdaq: CNTA) and previously served as Head of Finance. Prior to that, Ms. Thorell was the Chief Financial Officer of Palladio Biosciences, leading their finance operations and capital strategy and execution. Before joining Palladio, she served in various capacities at Realm Therapeutics, PLC, (Nasdaq: RLM), including Chief Financial Officer, Chief Operating Officer and Executive Director. In this role, she led accounting and financial reporting operations and helped transition Realm's focus to drug development following a strategic overhaul. She was also responsible for divesting domestic and international operating businesses and in-licensing and out-licensing assets. Earlier in her career Ms. Thorell worked for Campbell Soup Company (NYSE: CPB) in finance and operational roles of increasing responsibility and at Ernst & Young, LLP where she earned a C.P.A. Ms. Thorell also serves on the Board of Essa Pharm (Nasdaq: EPIX) and on the Board of Living Beyond Breast Cancer (lbbc.org). Ms. Thorell earned a B.S. in Business from Lehigh University, magna cum laude.

We believe Ms. Thorell's extensive experience and education in finance and accounting in the biopharmaceuticals industry qualifies her to serve on our board of directors.

Key Consultant

Timothy Whitaker, M.D. is a part-time consultant that has served as our Chief Medical Officer since April 2018. He brings over 20 years of experience in the pharmaceutical industry and nearly a decade in academic medicine. His pharmaceutical industry experience involves extensive leadership and management of many global clinical development programs, achieving numerous global regulatory approvals. The majority of this work has been in neuroscience and includes leading the development and approval of multiple ADHD medications. Most recently, Dr. Whitaker served as the Chief Medical Officer at Alder Biopharmaceuticals leading a positive Phase III study in the development of a CGRP antagonist for migraine. Prior to that, Dr. Whitaker worked at Shire for more than 10 years, most recently as VP and Neuroscience Therapeutic Area Head, Global Clinical Development. Prior to Shire, Dr. Whitaker served as a Senior Director — Neuroscience at Wyeth Research with a focus on sleep disorders and life cycle management for Effexor®. Prior to joining industry, Dr. Whitaker held a variety of clinical and teaching positions at the University of Vermont (UVM) College of Medicine and the Medical Center Hospital of Vermont, including Associate Professor of Psychiatry, Director of the Inpatient Services, Executive Committee of the Vermont Regional Sleep Disorders Center, and Director of the Psychopharmacology Clinic. He earned his bachelor's degree from Duke University, and his medical degree from Wake Forest University School of Medicine. He completed a residency training program in psychiatry and a fellowship in clinical psychopharmacology at UVM/Medical Center Hospital of Vermont in Burlington.

Family Relationships

There is no family relationship between any director, executive officer or person nominated to become a director or executive officer.

Composition of Our Board of Directors

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the number of directors on our board shall be determined from time to time by resolution of the Board or our stockholders, and the current size of our Board is five members.

Our amended and restated bylaws also provide that our directors may be removed from office with or without cause by vote of the holders of a majority of the shares of stock entitled to vote in the election of directors.

Our current and future executive officers and significant employees serve at the discretion of our board of directors. Our board of directors may also choose to form certain committees, such as a compensation and an audit committee.

Our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the directors whose terms then expire will be subject to re-election to serve until the third annual meeting following re-election. As a result, 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. Our directors are divided among the three classes as follows:

- the Class I directors are David Baker and Ofir Levi, and their term expires at the annual meeting of stockholders to be held in 2022;
- the Class II directors are Richard Ammer and Marella Thorell, and their term expires at the annual meeting of stockholders to be held in 2022; and
- the Class III directors are Joseph Payne, and his term expires at the annual meeting of stockholders to be held in 2023.

With respect to the Class I directors, their terms were originally scheduled to expire at last year's annual meeting. Because we did not hold an annual meeting of stockholders in 2021, the Class I directors will continue to serve as directors through this year's annual meeting, whereby both Class I and Class II directors will be subject to re-election. Upon re-election, each Class I director will serve a term expiring at our annual meeting of stockholders in 2024, while each Class II director will serve the full three-year term.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that only our board of directors can fill vacancies on the board, including due to increases in the size of the board. Any additional directorships resulting from an increase in the authorized number of directors would be placed among the three classes so that, as nearly as possible, each class consists of one-third of the authorized number of directors.

The classification of our board of directors may have the effect of delaying or preventing changes in our control or management. See Exhibit 4.5 "Description of Capital Stock — Anti-Takeover Effects of our Certificate of Incorporation and Bylaws and Delaware Law."

Director Independence

Under the listing requirements of The Nasdaq Capital Market, independent directors must comprise a majority of a listed company's board of directors within twelve months from the date of listing. In addition, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees must be independent within twelve months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended (the Exchange Act), and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. A director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (2) be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board of directors must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

Our board of directors has determined that all members of the board of directors and our director nominees, except Richard Ammer and David Baker, are independent directors, including for purposes of the rules of The Nasdaq Capital Market and the SEC. In making such independence determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. The composition and functioning of our board of directors and each of our committees comply with all applicable requirements of The Nasdaq Capital Market and the rules and regulations of the SEC.

Board Oversight of Risk

One of the key functions of our board of directors is informed oversight of our risk management process. In particular our board of directors is responsible for monitoring and assessing strategic risk exposure. Our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its oversight function directly as a whole. Our board of directors also administers its oversight through various standing committees, which address risks inherent in their respective areas of oversight. For example, our audit committee is responsible for overseeing the management of risks associated with financial reporting, accounting and auditing matters; our compensation committee oversees the management of risks associated with our compensation policies and programs; and our nominating and corporate governance committee oversees the management of risks associated with director independence, conflicts of interest, composition and organization of our board of directors and director succession planning.

Board Committees

Our board of directors established an audit committee, a compensation committee and a nominating and corporate governance committee and may establish other committees to facilitate the management of our business. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Our board of directors and its committees set meeting schedules throughout the year and can also hold special meetings and act by written consent from time to time, as appropriate.

Our board of directors expects to delegate various responsibilities and authority to committees as generally described below. The committees regularly report on their activities and actions to the full board of directors. Each member of each committee of our board of directors qualifies as an independent director in accordance with the listing standards of The Nasdaq Capital Market. Each committee of our board of directors has a written charter that was approved by our board of directors.

Copies of each charter are posted on our website at www.vallon-pharma.com under the Investor Relations section. Information contained on our website is not incorporated by reference into this Annual Report.

Audit Committee

The members of our audit committee are Ofir Levi, Joseph Payne and Marella Thorell, who is the chair of the audit committee.

Our audit committee assists our board of directors with its oversight of the integrity of our financial statements; our compliance with legal and regulatory requirements; the qualifications, independence and performance of the independent registered public accounting firm; the design and implementation of our financial risk assessment and risk management. Among other things, our audit committee is responsible for reviewing and discussing with our management the adequacy and effectiveness of our disclosure controls and procedures. Our audit committee also discusses with our management and independent registered public accounting firm the annual audit plan and scope of audit activities, scope and timing of the annual audit of our financial statements, and the results of the audit, quarterly reviews of our financial statements and, as appropriate, initiates inquiries into certain aspects of our financial affairs.

Our audit committee is responsible for establishing and overseeing procedures for the receipt, retention and treatment of any complaints regarding accounting, internal accounting controls or auditing matters, as well as for the confidential and anonymous submissions by our employees of concerns regarding questionable accounting or auditing matters. In addition, our audit committee has direct responsibility for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm. Our audit committee has sole authority to approve the hiring and discharging of our independent registered public accounting firm, all audit engagement terms and fees and all permissible non-audit engagements with the independent auditor. Our audit committee reviews and oversees all related person transactions in accordance with our policies and procedures.

Each member of our audit committee is independent under the rules and regulations of the SEC and the listing standards of The Nasdaq Capital Market applicable to audit committee members. Our board of directors has determined that Marella Thorell qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of The Nasdaq Capital Market listing standards. In making this determination, our board has considered Ms. Thorell's prior experience, business acumen and independence. Both our independent registered public accounting firm and management periodically meets privately with our audit committee.

We believe that the composition and functioning of our audit committee complies with all applicable requirements of Section 404 of the Sarbanes-Oxley Act of 2002, and all applicable SEC and The Nasdaq Capital Market rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee

The members of our compensation committee are Marella Thorell and Joseph Payne, who is the chair of the compensation committee.

Each member of our compensation committee is independent under the rules and regulations of the SEC and the listing standards of The Nasdaq Capital Market applicable to compensation committee members. Our compensation committee assists our board of directors with its oversight of the forms and amount of compensation for our executive officers (including officers reporting under Section 16 of the Exchange Act), the administration of our equity and non-equity incentive plans for employees and other service providers and certain other matters related to our compensation programs. Our compensation committee, among other responsibilities, evaluates the performance of our chief executive officer and, in consultation with him, evaluates the performance of our other executive officers (including officers reporting under Section 16 of the Exchange Act).

Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are Joseph Payne and Ofir Levi, who is the chair of the nominating and corporate governance committee.

Each member of our nominating and governance committee is independent under the rules and regulations of the SEC and the listing standards of The Nasdaq Capital Market, applicable to nominating and governance committee members. Our nominating and corporate governance committee assists our board of directors with its oversight of and identification of individuals qualified to become members of our board of directors, consistent with criteria approved by our board of directors, and selects, or recommends that our board of directors selects, director nominees; develops and recommends to our board of directors a set of corporate governance guidelines and oversees the evaluation of our board of directors.

Communicating with Our Board of Directors

You may communicate with our board of directors as a group, or to specific directors, by writing to the Chairman of our board of directors at our offices located at 100 N. 18th Street, Suite 300, Philadelphia, PA 19103, or board@vallon-pharma.com, who will then forward all such correspondence to the Chairman. The Chairman will review all such correspondence and regularly forward to our full board of directors such correspondence and copies of all correspondence that, in the opinion of the Chairman, deals with the functions of our board of directors or committees thereof or that he otherwise determines requires their attention. Directors may at any time review a log of all correspondence we receive that is addressed to members of our board of directors and request copies of any such correspondence. Concerns relating to accounting, internal controls, or auditing matters may be communicated in this manner. These concerns will be immediately brought to the attention of our board of directors and handled in accordance with procedures established by our board of directors. Notwithstanding the foregoing, the non-management directors have requested that the Chairman not forward to them advertisements, solicitations for periodicals or other subscriptions, and other similar communications.

Compensation Committee Interlocks and Insider Participation

None of our current or former executive officers serve as a member of the compensation committee. None of our officers serve, or have served during the last completed fiscal year, on the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee. For a description of transactions between us and members of our compensation committee and affiliates of such members, see the section entitled "Certain Relationships and Related Party Transactions."

Code of Business Conduct and Ethics

We adopted a Code of Business Conduct and Ethics that applies to all directors, officers and employees. Our Code of Business Conduct and Ethics is available on our website at https://www.vallon-pharma.com/. A copy of our code of ethics will also be provided to any person without charge, upon written request sent to us at our offices located at 100 N. 18th Street, Suite 300, Philadelphia, PA 19103.

Item 11. EXECUTIVE COMPENSATION

Summary Compensation Table

As an emerging growth company, we are required to disclose the compensation earned by or paid to our named executive officers for the last two completed fiscal years.

Name and Principal Position	Year	Salary ($)	Option Awards ($)[1]	Non-Equity Incentive Compensation[2]	All Other Compensation ($)[3]	Total ($)
David Baker	2021	391,553	259,136	150,000	12,000	812,689
President and Chief Executive Officer	2020	330,000	122,999	206,250	9,900	669,149
Leanne M. Kelly	2021	177,604	259,136	55,772	6,347	498,859
Chief Financial Officer						
Penny S. Toren	2021	256,871	64,784	30,174	7,544	359,373
Senior Vice President, Regulatory Affairs & Program Management	2020	235,000	57,399	58,750	7,050	358,199

(1) Reflects the aggregate grant date fair value of stock options granted during the fiscal year calculated in accordance with FASB ASC Topic 718. These amounts do not necessarily correspond to the actual value that may be realized by the executive in connection with the option awards. The assumptions made in valuing the option awards reported in this column are described in our audited financial statements (Note B. *Summary of Significant Accounting Policies - [3] Stock-based compensation* and *Note F, Equity incentive plan*).
(2) The amounts in this column represent performance bonuses earned by the named executive officers in the year shown based upon the achievement of pre-established performance objectives. See "—Non-Equity Incentive Plan Compensation" below.
(3) The amounts reflect matching contributions to the named executive officers' accounts under our SIMPLE IRA plan.

Elements of Compensation

2021 Base Salaries

Effective as of April 1, 2021, Mr. Baker's annual salary was increased to $400,000. Effective as of March 1, 2021, Ms. Toren's annual salary was increased to $251,450. Ms. Kelly's base salary, which was negotiated in connection with her appointment as Chief Financial Officer on May 10, 2021, was set at $275,000.

Non-Equity Incentive Plan Compensation

Each of our named executive officers is eligible to receive an annual performance bonus based on the achievement of corporate and personal objectives as determined by our board of directors or compensation committee. Each executive officer is assigned a target bonus expressed as a percentage of base salary. For 2021, the target bonus opportunities for Mr. Baker, Ms. Kelly (prorated to her May 10, 2021 start date) and Ms. Toren, expressed as a percentage of base salary, were 50%, 35% and 20%, respectively. Actual performance bonus payments depend on the extent to which we achieve pre-established corporate objectives for the year, along with an overall assessment of each officer's personal performance, as determined by our board of directors or compensation committee. For 2021, the corporate objectives, consisted primarily of: (i) IPO completion; (ii) execution of the SEAL study; (iii) determination of ADMIR ; (iv) execution of key non-clinical studies; and (v) manufacture of ADAIR. In the first quarter of 2022, our compensation committee assessed our level of achievement of these objectives. Based on this assessment, our compensation committee determined that our performance relative to the corporate objectives warranted a payout of 75% of the target bonus opportunity, subject to adjustments for personal performance. Actual bonus amounts paid with respect to 2021 are reflected in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table above.

In addition, pursuant to her employment agreement, Ms. Toren is entitled to receive a one-time performance bonus of $130,000 related to the development and commercialization of ADAIR, which will vest in installments on the following dates: (i) $25,000 on the date the FDA completes its 30-day review period of our IND application for ADAIR , which occurred in July 2018 (ii) $25,000 on the date that we successfully complete the human abuse liability study for ADAIR , (iii) $30,000 on the date that we submit an NDA filing for ADAIR , and (iv) $50,000 on the later of the date when the FDA approves the NDA and the date we engage in exclusive collaboration for commercialization of the product.

Option Awards Granted During 2021

On May 14, 2021, each of Mr. Baker and Ms. Toren was granted a non-qualified stock option to purchase 100,000 and 25,000 shares of our common stock, respectively, with an exercise price of $3.66 per share, which was equal to the closing price of our common stock on the date of grant. Subject to the executive's continued employment on each applicable vesting date, 25% of the shares underlying these options vest on May 14, 2022, with the remainder vesting in equal quarterly installments thereafter through May 14, 2025.

Additionally, on May 14, 2021, in conjunction with the commencement of her employment with the Company, Ms. Kelly was granted non-qualified options to purchase 100,000 shares of our common stock, with an exercise price of $3.66 per share, which was equal to the closing price of our common stock on the date of grant. Subject to Ms. Kelly's continued employment on each applicable vesting date, 70,000 shares underlying these options will vest as follows: (i) 17,500 shares on May 14, 2022, and (ii) the remainder vesting in equal quarterly installments thereafter through May 14, 2025. An additional 30,000 shares underlying these options will vest, if at all, following the achievement of certain performance conditions related to regulatory submissions to the FDA for ADAIR, subject to Ms. Kelly’s continued employment.

Qualified Retirement Plan

We offer our employees, including our named executive officers, retirement and certain other benefits, including participation in the tax-qualified SIMPLE IRA retirement plan sponsored by the Company in the same manner as all of our other employees. Pursuant to the SIMPLE IRA program, employees are eligible to contribute to an individual SIMPLE IRA account on a tax-deferred basis. If an employee participates in the SIMPLE IRA plan, we make a matching contribution to the employee’s SIMPLE IRA account in an amount up to 3% of the employee’s base salary (subject to applicable IRS compensation limits). In 2021, Mr. Baker, Ms. Kelly and Ms. Toren contributed to the SIMPLE IRA and received a related matching contribution. Participants are fully vested in both their own contribution and the matching contributions at all times.

We do not maintain any deferred compensation, pension, or profit-sharing plans.

Employment Agreements

We have entered into an employment agreement with each of our named executive officers. The employment agreements provide that the executive will receive a base salary and be eligible to receive an annual cash bonus contingent upon the attainment of certain company milestones and/or individual objectives. Pursuant to the employment agreements, each executive's base salary and target bonus will be reviewed periodically by our compensation committee or board of directors. The employment agreements also provide for certain termination benefits, which are described below in the section entitled "Potential Payments Upon a Termination or Change in Control."

Our named executive officers are also entitled to participate in all of our retirement and group welfare plans available to our senior level executives as a group or our employees generally, subject to the terms and conditions applicable to such plans. Further, each such executive's employment agreement contains restrictive covenants relating to non-disclosure of confidential information, mutual non-disparagement, assignment of inventions, non-competition and non-solicitation provisions.

Potential Payments Upon a Termination or Change in Control

David Baker

Pursuant to his employment agreement with us, if Mr. Baker’s employment were terminated by us without cause or terminated by Mr. Baker for good reason, in either case not in connection with a change in control, then Mr. Baker is entitled to the following severance benefits:

- continued base salary for a period of 12 months, plus a pro-rated bonus for the year of termination, based on actual performance results for the entire year, and provided he was employed for at least six months during that year; and
- subsidized premiums for COBRA continuation coverage for a period of 12 months (or such earlier date that he obtains alternative coverage).

Pursuant to his employment agreement with us, if Mr. Baker’s employment were terminated by us without cause or terminated by Mr. Baker for good reason,in either case withing the one-year period following a change in control, then Mr. Baker would be entitled to the following severance benefits:

- continued base salary for a period of 18 months, plus a lump sum payment equal to 150% of his target bonus, without proration, for the fiscal year of termination;

- subsidized premiums for COBRA continuation coverage for a period of 18 months (or such earlier date that he obtains alternative coverage); and
- accelerated vesting of all outstanding stock-based awards held by the executive as of the date of termination, with any performance awards deemed satisfied at the "target" performance level, and any stock options remaining outstanding for their full term.

Leanne M. Kelly

Pursuant to her employment agreement with us, if Ms. Kelly's employment were terminated by us without cause or terminated by Ms. Kelly for good reason, in either case not in connection with a change in control, then Ms. Kelly would be entitled to the following severance benefits:

- continued base salary for a period of nine months, plus a pro-rated bonus for the year of termination, based on actual performance results for the entire year, and provided she was employed for at least six months during that year; and
- subsidized premiums for COBRA continuation coverage for a period of nine months (or such earlier date that she obtains alternative coverage).

Pursuant to her employment agreement with us, if Ms.Kelly's employment were terminated by us without cause or terminated by Ms. Kelly for good reason, in ether case within the one-year period following a change in control transaction, then Ms. Kelly would be entitled to the following severance benefits:

- continued base salary for a period of 12 months, plus a lump sum payment equal to 100% of her target bonus, without proration, for the fiscal year of termination;
- subsidized premiums for COBRA continuation coverage for a period of 12 months (or such earlier date that she obtains alternative coverage); and
- accelerated vesting of all outstanding stock-based awards held by the executive as of the date of termination, with any performance awards deemed satisfied at the "target" performance level, and any stock options remaining outstanding for their full term.

Penny S. Toren

Pursuant to her employment agreement with us, if Ms. Toren's employment were terminated by us without cause or terminated by Ms. Toren for good reason, then Ms. Toren would be entitled to the following severance benefits:

- continued base salary for a period equal to two months, plus an additional one month for every whole year of service performance by Ms. Toren for the Company and its affiliates, up to a maximum of six months.

Outstanding Equity Awards at Fiscal Year-End

Stock Option Awards

The following table sets forth the outstanding stock option awards as of December 31, 2021 held by our named executive officers, on an award-by-award basis, setting forth the total number of shares underlying each stock option award that are (i)

exercisable, but not yet exercised, (ii) unexercisable and not yet exercised, and (iii) total aggregate amount underlying each award.

Name	Number of securities underlying unexercised, but vested stock options [1]	Number of securities underlying unexercised, but unvested stock options (time based) [1]	Number of securities underlying unexercised, but unvested stock options (performance based) [1][2]	Total securities underlying the stock options	Option exercise price	Option expiration date
David Baker	46,875	—	—	46,875 [3]	$ 1.84	10/1/2028
Chief Executive Officer	61,250	—	—	61,250 [3]	$ 2.20	2/5/2029
	—		37,500	37,500	$ 4.72	5/22/2030
	—	100	—	100,000 [4]	$ 3.66	5/14/2031
Leanne Kelly	—	70	30,000	100,000 [5]	$ 3.66	5/14/2031
Chief Financial Officer						
Penny Toren	7,813	—	39,062	46,875 [6]	$ 1.84	10/1/2028
SVP, Regulatory Affairs and Project Management	3,334	2	—	5,000 [7]	$ 3.82	10/11/2029
	—		17,500	17,500	$ 4.72	5/22/2030
	—	25	—	25,000 [4]	$ 3.66	5/14/2031

(1) All stock option awards were granted under our 2018 Equity Incentive Plan.
(2) The stock option award will vest upon satisfaction of certain performance milestones.
(3) The stock option award is fully vested.
(4) The stock options award will vest 25% on the first anniversary of the vesting start date (May 14, 2021) and 6.25% (1/16th of such shares) for each subsequent full quarter that the executive remains employed with us.
(5) 70% of the stock option award will vest 25% on the first anniversary of the vesting start date (May 14, 2021) and 6.25% (1/16th of such shares) for each subsequent full quarter that the executive remains employed with us. The remaining 30% of the stock option award will vest upon the satisfaction of certain performance milestones.
(6) The stock option award vests as to one-sixth of the underlying shares of common stock upon the date of grant, then upon satisfaction of certain performance milestones.
(7) The stock option award vests as to one-third of the underlying shares of common stock on each of October 11, 2020, October 11, 2021 and October 11, 2022.

Stock Awards

We have not granted any stock awards to any of our named executive officers.

Director Compensation and Compensation Table

Our director compensation program is designed to enhance our ability to attract and retain highly qualified directors and to align their interests with the long-term interests of our shareholders. The program generally includes a cash component, which is designed to compensate non-employee directors for their service on our board of directors and an equity component, which is designed to align the interests of non-employee directors and shareholders. Directors who are employees of the Company receive no additional compensation for their service on our board of directors.

The compensation committee annually reviews compensation paid to our non-employee directors and makes recommendations for adjustments, as appropriate, to the full board of directors. As part of this annual review, the committee considers the significant time commitment and skill level required by each non-employee director in serving on our board of directors and its various committees. The compensation committee seeks to maintain a market competitive director compensation program and benchmarks our director compensation program against those maintained by our peer group.

For 2021, each of our non-employee directors was eligible to receive an annual retainer of $25,000, and the chair of the audit committee was eligible to receive an additional retainer of $10,000. The annual retainer was payable in cash, or at the election of a director, in the form of an equivalent amount of stock options. In addition, each non-employee director serving in 2021 received an initial stock option grant to purchase 15,000 shares, which generally vests in quarterly or monthly installments over two years.

In January 2022, the board of directors, upon recommendation of the compensation committee, increased the annual retainer for each non-employee director to $30,000, increased the annual retainer for the chair of the audit committee to $15,000, and provided an annual retainer for the chair of the compensation committee of $10,000 and for the chair of the nominating and governance committee of $5,000. Going forward, non-employee directors who are first appointed or elected to the board will receive an initial stock option grant to purchase 15,000 shares, which generally will vest in quarterly installments over two years.

The following table provides information on compensation paid to our non-employee directors in 2021:

Name	Fees Earned or Paid in Cash (US$)	Option Awards ($)(1)(7)	Total
Richard Ammer	$ —	$ 62,607 (2)(3)	$ 62,607
Ofir Levi	—	111,964 (4)	111,964
Joseph Payne	—	72,609 (2)(5)	72,609
Marella Thorell	30,973	80,235 (6)	111,208

(1) Reflects the aggregate grant date fair value of stock options granted during the fiscal year calculated in accordance with FASB ASC Topic 718. These amounts do not necessarily correspond to the actual value that may be realized by the executive in connection with the option awards. The assumptions made in valuing the option awards reported in this column are described in our audited financial statements (Note B. *Summary of Significant Accounting Policies - [3] Stock-based compensation* and *Note F, Equity incentive plan*).
(2) Options to purchase 15,000 shares of common stock were granted on May 14, 2021 and vest monthly over a 24-month period.
(3) Options to purchase 10,204 shares of common stock were granted on May 14, 2021 of which 25% vested immediately and an additional 25% vested on each of June 30, 2021, September 30, 2021 and December 31, 2021.
(4) Options to purchase 30,000 shares of common stock were granted on May 14, 2021 which vest monthly over a 24-month period. An additional 15,000 options to purchase common stock were grantedon May 14, 2021 of which 25% vested immediately and an additional 25% vested on each of June 30, 2021, September 30, 2021 and December 31, 2021.
(5) Options to purchase 14,286 were granted on May 14, 2021 of which 25% vested immediately and an additional 25% vested on each of June 30, 2021, September 30, 2021 and December 31, 2021.
(6) Ms. Thorell joined our board of directors effective February 12, 2021 and was granted 15,000 options which vest monthly over a period of 24 months.
(7) The following table shows the aggregate number of outstanding shares of common stock underlying outstanding options held by our non-employee directors as of December 31, 2021:

Name	Outstanding Option Awards
Richard Ammer	45,000
Ofir Levi	25,204
Joseph Payne	29,286
Marella Thorell	15,000

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

The following table sets forth certain information known to us regarding beneficial ownership of our capital stock as of December 31, 2021, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each person or group of affiliated persons known by us to be the beneficial owner of more than five percent of our capital stock;
- each of our named executive officers;
- each of our directors and our director nominees; and
- all of our executive officers, and directors and director nominees as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power, and includes securities that the individual or entity has the right to acquire, such as through the exercise of stock options, within 60 days of December 31, 2021. Except as noted by footnote, and subject to community property laws where applicable, we believe, based on the information provided to us, that the persons and entities named in the table below have sole voting and investment power with respect to all common stock shown as beneficially owned by them.

The percentage of beneficial ownership in the table below is based on 6,812,836 shares of common stock deemed to be outstanding as of December 31, 2021.

Unless otherwise indicated, the address for each beneficial owner is c/o Vallon Pharmaceuticals, Inc., 100 N. 18th Street, Suite 300, Philadelphia, PA 19103.

	Common Stock Beneficially Owned	
Name and Address of Beneficial Owner	**Number of Shares and Nature of Beneficial Ownership**	**Percentage of Total Common Stock**
Greater than 5% Stockholders		
SALMON Pharma GmbH[1]	1,523,797	22.4 %
Arcturus Therapeutics, Inc. (fka successor to Arcturus Therapeutics Ltd.)[2]	843,750	12.4 %
Tomer Feingold[4][11][12]	509,781	7.5 %
Dov Malnik[3][4][11][12]	509,781	7.5 %
Directors, Director Nominees and Named Executive Officers[5]		
David Baker[6]	128,468	1.9 %
Leanne Kelly[7]	6,250	*
Ofir Levi[8]	223,125	3.3 %
Richard Ammer[9]	1,539,626	22.6 %
Joseph Payne[10]	881,161	12.9 %
Marella Thorell[11]	7,500	*
All directors, director nominees, and executive officers as a group (6 persons)	2,786,130	39.8 %

* Represents beneficial ownership of less than one percent of our outstanding common stock.
(1) SALMON Pharma GmbH's address is Sankt-Jakobs-Strasse 90, CH-9002 Basel, Switzerland.
(2) Arcturus Therapeutics Ltd.'s address is 10628 Science Center Drive, Suite 250, San Diego, California 92121.
(3) Mr. Malnik has granted Ariel Malnik a power of attorney to vote and dispose of the shares held individually by Mr. Malnik.
(4) On March 3, 2020, the Securities and Exchange Commission filed an action against Tomer Feingold and Dov Malnik in the U.S. District Court for the Southern District of New York (SEC v. Feingold, et al., Civ. Action No. 20-cv-01881) alleging violations of Section 10(b) of the Exchange Act and Rule 10b-5 thereunder, Section 14(e) of the Exchange Act and Rule 14e-3 thereunder and requesting other equitable relief. Adamas is named as a relief defendant in the action. As of November 23, 2021, the action has been settled with regard to Mr. Malnik. Vallon Pharmaceuticals, Inc. is not a named party or identified in this action.
(5) The address for each of our executive officers, directors and director nominees is c/o Vallon Pharmaceuticals, 100 N. 18th Street, Suite 300, Philadelphia, PA 19103.
(6) Consists of (i)7,843 shares of common stock and (ii) 120,625 shares of common stock issuable pursuant to stock options exercisable within 60 days of December 31, 2021.
(7) Consists of 6,250 shares of common stock.
(8) Consists of (i) 196,875 shares of common stock and (ii) 26,250 shares of common stock issuable pursuant to stock options exercisable within 60 days of December 31, 2021.
(9) Consists of (i) 1,523,797 shares of common stock held by SALMON Pharma GmbH ("Salmon Pharma"), of which Dr. Ammer is an affiliate and may be deemed to have shared voting and dispositive power over the shares beneficially owned by Salmon Pharma but disclaims such beneficial ownership except to the extent of his pecuniary interest therein, if any, and (ii) 15,829 shares of common stock issuable pursuant to stock options exercisable within 60 days of December 31, 2021.
(10) Consists of 843,750 shares of common stock held by Arcturus, of which Mr. Payne is an affiliate and may be deemed to have shared voting and dispositive power over the shares beneficially owned by Arcturus but disclaims such beneficial ownership except to the extent of his pecuniary interest therein, if any, (ii) 17,500 shares of common stock and (iii) 19,911 shares of common stock issuable pursuant to stock options exercisable within 60 days of December 31, 2021.
(11) Includes 7,500 shares of common stock issuable pursuant to stock options exercisable within 60 days of December 31, 2021.
(12) On December 30, 2020, we entered into the 2020 Voting Agreement with Dov Malnik and Tomer Feingold, pursuant to which, following the date of effectiveness of this registration statement, at every meeting of our stockholders, and at every adjournment or postponement thereof, Messrs. Malnik and Feingold (in their capacity as stockholders) shall have the right to vote all common stock held by them collectively constituting no more than 9.99% of the total number of shares of common stock issued and outstanding as of the record date for voting on the matters presented at such meeting or taking action by written consent. The common stock held or otherwise beneficially owned by Messrs. Malnik and Feingold in excess of the Share Voting Cap shall be voted at every meeting of the stockholders of the Company, and at every adjournment or postponement thereof, and on every action or approval by written consent of the stockholders, in a manner that is proportionate to the manner in which all other holders of the issued and outstanding shares of Common Stock vote in respect of each matter presented at any such meeting and in respect of each action taken by written consent. See the section entitled "Certain Relationships and Related Party Transactions—2020 Voting Agreement".

Equity Compensation Information

Our 2018 Equity Incentive Plan is our sole equity incentive plan approved and adopted by our stockholders, and provides for the issuance of shares of our common stock to our officers and other employees, directors and consultants.

The following table presents information as of December 31, 2021 with respect to compensation plans or arrangements under which shares of our common stock may be issued.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders (1)	690,365	$ 3.57	657 (3)
Equity compensation plans not approved by security holders	18,125 (2)	$ 4.72	—
Total	708,490	$ 3.60	

(1) Includes shares of our common stock under our 2018 Equity Incentive Plan. For a description of this plan, refer to Note F to the financial statements included in this Annual Report on Form 10-K.
(2) The 18,125 stock options referenced above were granted to an advisor in January 2020 and May 2020 outside of the 2018 Equity Incentive Plan, and are subject to separate stock option award agreements.
(3) Excludes 70,000 shares of common stock issuable upon the exercise of options for which the Company can, at its discretion, issue cash in lieu of shares to the extent the authorized option pool is depleted when exercised.

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

The following is a summary of each transaction or series of similar transactions since January 1, 2019, to which we have been a party that:

- The amount involved exceeded or exceeds $120,000 or is greater than 1% of our total assets as of December 31, 2020 and 2019; and
- any of our directors or executive officers, any holder of 5% of our capital stock or any member of their immediate family had or will have a direct or indirect material interest.

Ofir Levi

Beginning in June 2020 and ending in October 2020, Dr. Levi, a member of our board of directors, received a consulting fee of $6,000 per month for his advisory services.

Medice

Medice, through its affiliated entity, Salmon Pharma, owns approximately 22.4% of our issued and outstanding shares of common stock, and accordingly controls approximately 22.4% of our voting power. On January 6, 2020, we entered into a license agreement with Medice, which grants Medice an exclusive license, with the right to grant sublicenses, to develop, use, manufacture, market and sell ADAIR throughout Europe. Medice currently markets several ADHD products in Europe and is the ADHD market leader in Europe based on branded prescription market share. Medice is responsible for obtaining regulatory approval of ADAIR in the licensed territory. Under the license agreement, Medice paid Vallon a minimal upfront payment and will pay milestone payments of up to $6.3 million in the aggregate upon first obtaining regulatory approval to market and sell ADAIR in any country, territory or region in the licensed territory and upon achieving certain annual net sales thresholds.

2020 Voting Agreement

On December 30, 2020, we entered into the 2020 Voting Agreement with Dov Malnik and Tomer Feingold, pursuant to which at every meeting of our stockholders and at every adjournment or postponement thereof, Messrs. Malnik and Feingold (in their capacity as stockholders) shall have the right to vote all common stock held by them collectively constituting no more than 9.99% of the total number of shares of common stock issued and outstanding as of the record date for voting on the matters presented at such meeting or taking action by written consent (Share Voting Cap). The common stock held or otherwise beneficially owned by Messrs. Malnik and Feingold in excess of the Share Voting Cap (Excess Shares) shall be voted at every meeting of the stockholders of the Company, and at every adjournment or postponement thereof, and on every action or approval by written consent of the stockholders, in a manner that is proportionate to the manner in which all other holders of the issued and outstanding shares of common stock vote in respect of each matter presented at any such meeting and in respect of each action taken by written consent. Furthermore, each of Messrs. Malnik and Feingold executed an irrevocable proxy for the voting of the Excess Shares in accordance with the 2020 Voting Agreement. The 2020 Voting Agreement terminates on the earliest to occur of (i) the date following the effective date of the 2020 Voting Agreement on which Messrs. Malnik and Feingold collective beneficial ownership of our common stock falls below 9.99%, (ii)the third anniversary of the effectiveness

of our registration statement relating to the IPO, or (iii) with respect to either Messrs. Malnik or Feingold, the date on which any proceeding before or brought by the SEC against such stockholder has been terminated or otherwise concluded.

Equity Financings

2019 Convertible Note Financing

In April 2019, we entered into a Convertible Promissory Note Purchase Agreement (the 2019 Contrvertible Notes) with certain existing stockholders and Salmon Pharma, an affiliate of Medice, pursuant to which we issued the 2019 Convertible Notes for cash proceeds of $1,150,000. The 2019 Convertible Notes bore an interest rate of 7.0% per annum, non-compounding, and had a maturity date of January 1, 2020. The terms of the 2019 Convertible Notes included a mandatory conversion upon a qualified financing, such as the July 2019 Financing discussed below, and were convertible into shares of our capital stock that are offered to investors in a subsequent equity financing at a discount to the price per share offered in such subsequent financing.

In July 2019, upon the closing of the July 2019 Financing, the 2019 Convertible Notes converted into an aggregate of 383,849 shares of our common stock at a conversion price of $3.04 per share.

2019 Private Placement

In July 2019, we entered into a Stock Purchase Agreement with Salmon Pharma (the July 2019 Financing), pursuant to which we sold and issued 1,309,861 shares of our common stock for aggregate cash proceeds of $5.0 million.

2021 Convertible Note Financing

In January 2021, we entered into a Convertible Promissory Note Purchase Agreement with certain existing stockholders, including Salmon Pharma and David Baker, our Chief Executive Officer, pursuant to which we issued convertible promissory notes for cash proceeds of $350,000. The 2021 Convertible Notes bear an interest rate of 7.0% per annum, non-compounding, and had a maturity date of September 30, 2021. The 2021 Convertible Notes were convertible into shares of our capital stock offered to investors in any subsequent equity financing, or Qualified Financing, after the date of their issuance in which we issued any of our equity securities and were convertible at a 20.0% discount to the price per share offered in such Qualified Financing.

On February 12, 2021, we consummated the IPO of our common stock, which was considered a Qualified Financing. Accordingly, the 2021 Convertible Notes converted into an aggregate of 54,906 shares of our common stock immediately prior to the closing of the IPO at a conversion price of $6.40 per share.

The following table sets forth the principal amounts under the 2019 Convertible Notes and 2021 Convertible Notes, or the Convertible Notes, acquired by 5% holders in the financing transaction described above, and the number of shares of common stock such Convertible Notes converted into in connection with the July 2019 Financing and IPO.

Participants	Principal Amount under the Convertible Notes	Shares of Common Stock upon Conversion of Convertible Notes
Greater than 5% Stockholders[1]		
Tomer Feingold	$ 200,000	66,812
Dov Malnik	$ 200,000	66,812
SALMON Pharma GmbH[2]	$ 800,000	213,936

(1) Additional details regarding these stockholders and their equity holdings are provided in this report under the caption "Principal Stockholders."
(2) Dr. Ammer is affiliated with Salmon Pharma.

Review, Approval or Ratification of Transactions with Related Parties

Our written related party transactions policy states that our employees, officers and directors, and any members of the immediate family of and any entity affiliated with any of the foregoing persons are not permitted to enter into a material related party transaction with us without the review and approval of our Audit Committee. The policy provides that the our general counsel, or, if we do not then have a general counsel, our principal executive, financial, or accounting officer (each a Designated Officer), must be notified of any request for us to enter into a transaction with such parties in which the amount involved exceeds $120,000 as well as of the facts and circumstances of the proposed transaction. Should an employee of the Company become aware of a related party transaction, regardless of whether such employee is a party to such transaction, such

employee will report the Related Party Transaction to the Designated Officer. The Designated Officer shall report such Related Party Transaction to the Committee for review. In approving or rejecting any such proposal, our Audit Committee considers the relevant facts and circumstances available and deemed relevant to the committee, including, but not limited to, (i) whether the transaction was undertaken in the ordinary course of business; (ii) whether the related party transaction was initiated by us, a subsidiary, or the related party; (iii) whether the transaction with the related party is proposed to be, or was, entered into on terms no less favorable to the company than terms that could have been reached with an unrelated third party; (iv) the purpose of, and the potential benefits to us of, the Related Party Transaction; (v) the approximate dollar value of the amount involved in the related party transaction, particularly as it relates to the related party; (vi) the related party's interest in the related party transaction; (vii) whether the related party transaction would impair the independence of an otherwise independent director; and (viii) any other information regarding the related party transaction or the related party that would be material to investors in light of the circumstances of the particular transaction.

Employment Agreements

We have entered into employment agreements with certain of our executive officers. See "Item 11-Executive Compensation."

Equity Grants

We have granted stock options to certain of our executive officers and members of our board of directors. See "Item 11-Executive Compensation."

Indemnification and Limitation on Liability

Section 145 of the Delaware General Corporation Law (DGCL) authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our amended and restated certificate of incorporation and our amended and restated bylaws that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for 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;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors, and intend to enter into such agreements with our executive officers. These agreements provide that we will indemnify each of our directors, our executive officers and, at times,

their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

Insurance

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended, or the Securities Act.

Director Independence

See "Item 10. Directors, Executive Officers and Corporate Governance Management—Director Independence."

Committees of our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates pursuant to a written charter adopted by our board of directors. See "Item 10. Directors, Executive Officers and Corporate Governance Management—Board Committees."

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Our independent registered public accounting firm is EisnerAmper LLP, Iselin, New Jersey, Auditor Firm ID: 274.

The following table represents aggregate fees incurred for EisnerAmper LLP services during the years ended December 31, 2021 and 2020 by us.

	December 31,	
	2021	2020
Audit Fees [1]	$ 180,760	$ 171,984
Audit Related Fees [2]	—	—
Tax Fees [3]	—	—
All Other Fees [4]	—	—
Total	$ 180,760	$ 171,984

(1) *Audit Fees* represent the aggregate fees billed for professional services rendered by our independent registered public accounting firm for the audit of our annual financial statements, review of financial statements included in our quarterly reports or services that are normally provided in connection with statutory and regulatory filings or engagements for those fiscal years as well as the issuance of consents in connection with registration statement filings with the SEC and comfort letters in connection with securities offerings.
(2) *Audit Related Fees* represent the aggregate fees billed for assurance and related professional services rendered by our independent registered public accounting firm that are reasonably related to the performance of the audit or review of our financial statements and are not reported under "Audit Fees" .
(3) *Tax Fees* represent the aggregate fees billed for professional services rendered by our independent registered public accounting firm for tax compliance, tax advice and tax planning services.
(4) *All Other Fees* represent the aggregate fees billed for all other products and services rendered by our independent registered public accounting firm other than the services reported in the other categories

The Audit Committee will approve in advance the engagement and fees of the independent registered public accounting firm for all audit services and non-audit services, based upon independence, qualifications and, if applicable, performance. The Audit Committee may form and delegate to subcommittees of one or more members of the Audit Committee the authority to grant pre-approvals for audit and permitted non-audit services, up to specific amounts. All audit services provided by EisnerAmper LLP for the periods presented were ratified by our board of directors.

Pre-Approval of Audit and Non-Audit Services

Our audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our registered public accounting firm. These policies and procedures generally provide that we will not engage our registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by our audit committee or the engagement is entered into pursuant to one of the pre-approval procedures described below.

From time to time, our audit committee may pre-approve specified types of services that are expected to be provided to us by our registered public accounting firm during the next twelve months. Any such pre-approval is detailed as to the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

Consistent with requirements of the SEC and the Public Company Accounting Oversight Board regarding auditor independence, our Audit Committee is responsible for the appointment, compensation and oversight of the work of our independent registered public accounting firm. In recognition of this responsibility, our Audit Committee, or the chair if such approval is needed between meetings of the audit committee, pre-approves all audit and permissible non-audit services provided by the independent registered public accounting firm. These services may include audit services, audit-related services, tax services and other services.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

(1) Financial Statements. The financial statements of the Company, together with the report thereon of EisnerAmper LLP, an independent registered public accounting firm, are included in this Annual Report beginning on page F-1.

(2) Financial Statement Schedules. All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

(3) Exhibits. See (b) below.

(b) Exhibits

The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this Annual Report.

		Incorporated by Reference		
Exhibit No.	**Description**	**Form**	**Date**	**Number**
1.1	Underwriting Agreement	8-K	2/16/21	1.1
3.1	Amended and Restated Certificate of Incorporation of Vallon Pharmaceuticals, Inc.	8-K	2/16/21	3.1
3.2	Amended and Restated Bylaws of Vallon Pharmaceuticals, Inc.	8-K	2/16/21	3.3
4.1	Specimen certificate evidencing shares of common stock	S-1	10/23/20	4.1
4.2	Convertible Promissory Note Purchase Agreement, dated as of April 11, 2019	S-1	10/23/20	4.2
4.3	Form of Convertible Promissory Note	S-1	10/23/20	4.3
4.4	Form of Representative's Warrant	8-K	2/16/21	4.1
4.5	Description of the Securities of Vallon Pharmaceuticals, Inc.	10-K	3/29/21	4.5
9.1	Voting Agreement, dated as of December 30, 2020, by and among Vallon Pharmaceuticals, Inc. and certain of its stockholders	S-1/A	1/14/21	10.17
10.1	Amended and Restated Asset Purchase Agreement, dated as of June 22, 2017, by and among Arcturus Therapeutics, Ltd. (and its subsidiary, Arcturus Therapeutics, Inc.), Amiservice Development Ltd. and Vallon Pharmaceuticals, Inc.	S-1/A	1/14/21	10.1
10.2#	Consulting Agreement with Whitaker Biopharmaceutical Consulting LLC, dated April 2, 2018	S-1/A	1/14/21	10.2
10.3#	Employment Agreement between Vallon Pharmaceuticals, Inc. and Penny S. Toren, dated April 2, 2018	S-1/A	1/14/21	10.3
10.4#	Employment Agreement between Vallon Pharmaceuticals, Inc. and David Baker, dated January 15, 2019	S-1/A	1/14/21	10.4
10.5#	Vallon Pharmaceuticals, Inc. 2018 Equity Incentive Plan	S-1	10/23/20	10.5
10.6#	Form of Stock Option Agreement under Vallon Pharmaceuticals, Inc. 2018 Equity Incentive Plan	S-1	10/23/20	10.6
10.7#	Form of Incentive Stock Option Agreement under Vallon Pharmaceuticals, Inc. 2018 Equity Incentive Plan	S-1	10/23/20	10.7
10.8#	Form of Nonqualified Stock Option Agreement under Vallon Pharmaceuticals, Inc. 2018 Equity Incentive Plan	S-1/A	1/14/21	10.8
10.9#	Form of Directors' and Officers' Indemnity Agreement	S-1/A	1/14/21	10.9
10.10	Patent and Patent Application Assignment Agreement between Arcturus Therapeutics, Ltd. and Vallon Pharmaceuticals, Inc., dated June 22, 2018	S-1/A	1/14/21	10.10
10.11	Form of Subscription Agreement	S-1/A	1/14/21	10.11
10.12	Form of Stock Purchase Agreement, dated June 7, 2018, among Vallon Pharmaceuticals, Inc. and the investors listed therein	S-1/A	1/14/21	10.12
10.13	Form of Stock Purchase Agreement, dated July 25, 2019, between Vallon Pharmaceuticals, Inc. and SALMON Pharma GmbH	S-1/A	1/14/21	10.13
10.14	Investor's Rights Agreement, dated as of July 25, 2019, by and between Vallon Pharmaceuticals, Inc. and SALMON Pharma GmbH	S-1/A	1/14/21	10.14
10.15†	License Agreement, effective as of January 6, 2020, by and between Vallon Pharmaceuticals, Inc. and MEDICE Arzneimittel Putter GmbH & Co. KG	S-1/A	11/16/20	10.15
10.16	Form of Lock Up Agreement	S-1/A	1/14/21	10.16

10.17	Form of Convertible Promissory Note Purchase Agreement, dated as of January 11, 2021, by and among Vallon Pharmaceuticals and the investors named therein	S-1/A	1/14/21	10.18
10.18	Form of Convertible Promissory Note	S-1/A	1/14/21	10.19
10.19	Employment Agreement between Vallon Pharmaceuticals, Inc. and David Baker, dated April 20, 2021	10-Q	5/13/21	10.1
10.20	Employment Agreement between Vallon Pharmaceuticals, Inc. and Leanne M. Kelly, dated May 10, 2021	10-Q	5/13/21	10.2
21.1	List of subsidiaries	S-1	10/23/20	21.1
23.1	Consent of Independent Registered Public Accounting Firm			
24.1	Powers of Attorney for directors and certain executive officers (contained on the signature page)			
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.			
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.			
32.1+	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
32.2+	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
101 INS	XBRL Instance Document			
101 SCH	XBRL Taxonomy Extension Schema Linkbase Document			
101 CAL	XBRL Taxonomy Extension Calculation Linkbase Document			
101 DEF	XBRL Taxonomy Extension Definition Linkbase Document			
101 LAB	XBRL Taxonomy Extension Label Linkbase Document			
101 PRE	XBRL Taxonomy Extension Presentation Linkbase Document			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101			

Unless otherwise indicated, exhibits are filed herewith.

Indicates a management contract or any compensatory plan, contract or arrangement.

† Indicates that portions of this exhibit (indicated by bracketed asterisks) are omitted in accordance with the rules of the Securities and Exchange Commission because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.

+ The certification attached as Exhibit 32.1 that accompany this Annual Report on Form 10-K is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

VALLON PHARMACEUTICALS, INC.

Date: February 14, 2022

By: /s/ David Baker

Name: David Baker

Title: President and Chief Executive Officer

SIGNATURES AND POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David Baker as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and all documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that such attorneys-in-fact and agents or any of them, or his or her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual 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/ David Baker David Baker	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 14, 2022
/s/ Leanne Kelly Leanne Kelly	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 14, 2022
/s/ Ofir Levi Ofir Levi	Director, Chairman of the Board	February 14, 2022
/s/ Joseph Payne Joseph Payne	Director	February 14, 2022
/s/ Richard Ammer Richard Ammer	Director	February 14, 2022
/s/ Marella Thorell Marella Thorell	Director	February 14, 2022

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Vallon Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Vallon Pharmaceuticals, Inc. (the "Company") as of December 31, 2021 and 2020, and the related statements of operations and comprehensive loss, changes in stockholders' equity (deficit), and cash flows for each of the years then ended, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has sustained a net loss and has experienced cash outflows from operations since inception that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits 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.

/s/ EisnerAmper LLP

We have served as the Company's auditors since 2018.

EISNERAMPER LLP

Iselin, New Jersey

February 14, 2022

Vallon Pharmaceuticals, Inc.
Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 3,702	$ 109
Marketable securities, available-for-sale	3,808	—
Prepaid expenses and other current assets	619	565
Total current assets	8,129	674
Other assets	206	279
Property and equipment, net	—	2
Total assets	$ 8,335	$ 955
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 918	$ 1,226
Accrued expenses	1,430	847
Note payable, current	—	47
Other current liabilities	97	105
Total current liabilities	2,445	2,225
Note payable, non-current	—	14
Other liabilities	72	170
Total liabilities	2,517	2,409
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 250,000,000 shares authorized; 6,812,836 and 4,506,216 shares issued and outstanding as of December 31, 2021 and 2020, respectively	—	—
Additional paid-in-capital	27,722	11,145
Accumulated other comprehensive loss	(2)	—
Accumulated deficit	(21,902)	(12,599)
Total stockholders' equity (deficit)	5,818	(1,454)
Total liabilities and stockholders' equity (deficit)	$ 8,335	$ 955

See accompanying notes to financial statements.

Vallon Pharmaceuticals, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2021	**2020**
Licensing revenue – related party	$ —	$ 100
Operating expenses:		
Research and development	5,187	3,707
General and administrative	4,072	1,181
Total operating expenses	9,259	4,888
Loss from operations	(9,259)	(4,788)
Other income	61	—
Revaluation of derivative liability	(89)	—
Interest expense, net	(16)	(34)
Net loss	$ (9,303)	$ (4,822)
Other comprehensive loss:		
Unrealized loss on marketable securities, available-for-sale	$ (2)	$ —
Total comprehensive loss	$ (9,305)	$ (4,822)
Net loss per share of common stock, basic and diluted	$ (1.42)	$ (1.07)
Weighted-average common shares outstanding, basic and diluted	6,541,097	4,506,216

See accompanying notes to financial statements.

Vallon Pharmaceuticals, Inc.
Statements of Changes in Stockholders' Equity (Deficit)
(in thousands, except shares)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount				
Balance, December 31, 2019	4,506,216	$ —	$ 10,991	$ —	$ (7,777)	$ 3,214
Stock-based compensation expense	—	—	154	—	—	154
Net loss	—	—	—	—	(4,822)	(4,822)
Balance, December 31, 2020	4,506,216	—	11,145	—	(12,599)	(1,454)
Issuance of common stock for convertible notes	54,906	—	439	—	—	439
Issuance of common stock for IPO, net of issuance expenses	2,250,000	—	15,104	—	—	15,104
Issuance of common stock for services	1,714	—	9	—	—	9
Issuance of Underwriters Warrants	—		399	—	—	399
Stock-based compensation expense	—	—	626	—	—	626
Unrealized loss on marketable securities, available-for sale	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	(9,303)	(9,303)
Balance, December 31, 2021	6,812,836	$ —	$ 27,722	$ (2)	$ (21,902)	$ 5,818

See accompanying notes to financial statements.

Vallon Pharmaceuticals, Inc.
Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (9,303)	$ (4,822)
Adjustments to reconcile net loss to cash used in operating activities:		
Amortization of finance lease right-of-use asset	73	74
Amortization of marketable securities premiums	32	—
Revaluation of derivative liability	89	—
Stock-based compensation expense	626	154
Forgiveness of PPP note	(61)	—
Non-cash interest, depreciation and other expense	12	1
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(55)	(464)
Accounts payable	(308)	980
Accrued expenses	583	371
Cash used in operating activities	(8,312)	(3,706)
Investing activities:		
Purchase of marketable securities	(3,842)	—
Purchase of property and equipment	—	(2)
Cash used in investing activities	(3,842)	(2)
Financing activities:		
Proceeds from common stock issuance, net of offering expenses	15,104	—
Proceeds from issuance of warrants	399	—
Proceeds from PPP loan	—	61
Proceeds from convertible notes	350	—
Payment of finance lease liability	(106)	(65)
Cash provided by (used in) financing activities	15,747	(4)
Net increase (decrease) in cash and cash equivalents	3,593	(3,712)
Cash and cash equivalents at beginning of period	109	3,821
Cash and cash equivalents at end of period	$ 3,702	$ 109
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 29	$ 41
Non-cash financing activities:		
Conversion of convertible notes to common stock	$ 350	$ —

See accompanying notes to financial statements

Vallon Pharmaceuticals, Inc.
Notes to Financial Statements
(in thousands, except share and per share data)

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Vallon Pharmaceuticals, Inc. (Vallon or the Company) was incorporated in Delaware in January 2018 (inception) and is based in Philadelphia, PA.

The Company is a biopharmaceutical company focused on the development and commercialization of novel abuse-deterrent medications for central nervous system (CNS) disorders. The Company's lead investigational product candidate, ADAIR, is a proprietary, abuse-deterrent oral formulation of immediate-release dextroamphetamine (the main active ingredient in Adderall®) for the treatment of attention-deficit/hyperactivity disorder (ADHD) and narcolepsy. The Company plans to develop other abuse-deterrent products, which have potential for abuse in their current forms, beginning with the development of ADMIR, an abuse deterrent formulation of Ritalin, for which the Company has completed formulation development work.

LIQUIDITY

These financial statements have been prepared on the basis that the Company is a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any significant revenues from operations since inception, and does not expect to do so in the foreseeable future. The Company has incurred operating losses since inception and has incurred $21,902 in accumulated deficit through December 31, 2021. The Company has financed its working capital requirements to date through the issuance of common stock, convertible notes, short-term promissory notes, and a Paycheck Protection Program (PPP) note.

In January 2021, the Company completed a $350 convertible note financing and in February 2021, the Company closed on its initial public offering (IPO) raising net proceeds of approximately $15,500. As of December 31, 2021, the Company had cash, cash equivalents and marketable securities of approximately $7,510, which management expects will provide funding for its ongoing business activities into the third quarter of 2022.

The Company's ability to continue as a going concern is dependent on its ability to raise substantial additional capital to fund its business activities, including its research and development program. The Company intends to raise capital through additional issuances of common stock and /or short-term notes, but there can be no assurances any such financing will be available when needed or that the Company's research and development efforts will be successful. If the Company is not able to obtain additional financing on acceptable terms and in the amounts necessary to fully fund its future operating requirements, it may be forced to reduce or discontinue its operations entirely. Therefore, there is substantial doubt about the Company's ability to continue as a going concern. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might result from this uncertainty.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

References in this Annual Report on Form 10-K to "authoritative guidance" is meant to refer to accounting principles generally accepted in the United States of America (GAAP) as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

Recapitalization

Immediately prior to the closing of the IPO (Note 10), the Company effected a one-for-40 reverse stock split of its common stock. All share and per share amounts, excluding the number of authorized shares and par value, contained in these financial statements and accompanying notes, and this Annual Report on Form 10-K give retroactive effect to the reverse split.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Estimates and assumptions are primarily made in relation to the valuation of share options, the embedded derivative of convertible notes, warrant issuance, valuation allowances relating to deferred tax assets, revenue recognition, accrued expenses and estimation of the incremental borrowing rate for the finance lease. If actual results differ from the Company's estimates, or to the extent these estimates are adjusted in future periods, the Company's results of operations could either benefit from, or be adversely affected by, any such change in estimate.

Concentration of credit risk

The Company from time to time during the period covered by these financial statements may have had bank account balances in excess of federally insured limits. The Company has not experienced losses in such accounts. The Company believes that it is not subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Cash equivalents

Cash equivalents are highly-liquid investments that are readily convertible into cash with original maturities of three months or less when purchased and as of December 31, 2021 and 2020 included investment in money market funds.

Marketable Securities

Marketable securities consist of debt securities that are designated as available-for-sale. Marketable debt securities are recorded at fair value and unrealized holding gains or losses are reported as a component of accumulated other comprehensive income (loss). Amortization of premiums and discounts on marketable securities are included in interest expense, net on the statements of operations and comprehensive loss.

Realized gains or losses resulting from the sale of these securities are determined based on the specific identification of the securities sold. An impairment charge is recognized when the decline in the fair value of a debt security below the amortized cost basis is determined to be other-than-temporary. The Company considers various factors in determining whether to recognize an impairment charge, including the duration and severity of any decline in fair value below the amortized cost basis, any adverse changes in the financial condition of the issuers and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

Fair value of financial instruments

The Company follows ASC 820, *Fair Value Measurements and Disclosures* (ASC 820), to measure the fair value of its financial statements and disclosures about fair value of its financial instruments. ASC 820 establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase consistency and comparability in fair value measurements and related disclosures, ASC 820 establishes a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The three levels of fair value hierarchy defined by ASC 820 are described below:

Level 1: Quoted market prices available in active markets for identical assets or liabilities as of the reporting date.

Level 2: Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date.

Level 3: Pricing inputs that are generally unobservable inputs and not corroborated by market data.

The fair value hierarchy gives the highest priority to quoted prices (unadjusted) in active markets for identical assets or liabilities and the lower priority to unobservable inputs. If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument. The Company uses this framework for measuring fair value and disclosures about fair value measurement. The Company uses fair value measurements in areas that include derivative instruments.

The Company recognizes transfers between levels of the fair value hierarchy on the date of the event or change in circumstances that caused the transfer. The carrying amounts reported in the balance sheets for cash and cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses, and note payable approximate their fair value based on the short-term maturity of these instruments.

Property and equipment

Property and equipment are stated at cost. The Company commences depreciation when the asset is placed in service. Computers and peripheral equipment are depreciated on a straight-line method over useful lives of three years.

Vallon Pharmaceuticals, Inc.
Notes to Financial Statements
(in thousands, except share and per share data)

Leases

The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to use, or control the use of, identified property, plant, or equipment for a period of time in exchange for consideration. Leases may be classified as finance leases or operating leases. Lease right-of-use (ROU) assets and lease liabilities recognized in the accompanying balance sheet represent the right to use an underlying asset for the lease term and an obligation to make lease payments arising from the lease respectively.

At each reporting date, the finance lease liabilities are increased by interest and reduced by repayments made under the lease agreements. The ROU asset is subsequently measured at the amount of the remeasured lease liability (i.e. the present value of the remaining lease payments), any cumulative prepaid or accrued rent if the lease payments are uneven throughout the lease term, and any unamortized initial direct costs.

Licensing revenues

The Company has a license agreement (the Medice License Agreement) with MEDICE Arzneimittel Pütter GmbH & Co. KG (Medice), a related party (Note 13). The license agreement provides for an exclusive license to develop, use, manufacture, market and sell ADAIR throughout Europe, a non-refundable up-front payment, potential regulatory and sales milestones and potential royalty payments. The Company analyzed the performance obligations under the license agreements, the consideration received to date and the consideration the Company could receive in the future as part of its analysis in accordance with ASC 606– *Revenue from Contracts with Customers* (ASC 606). The Company recognized $100 as licensing revenue during the year ended December 31, 2020. No licensing revenue was recognized during the year ended December 31, 2021.

Research and development

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including third party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. The Company accrues for costs incurred by external service providers, including contract research organizations and clinical investigators, based on its estimates of service performed and costs incurred.

Stock-based compensation

The Company recognizes expense for employee and non-employee stock-based compensation in accordance with ASC Topic 718, *Stock-Based Compensation* (ASC 718). ASC 718 requires that such transactions be accounted for using a fair value-based method. The estimated fair value of the options is amortized over the vesting period, based on the fair value of the options on the date granted, and is calculated using the Black-Scholes option-pricing model. The Company accounts for forfeitures as incurred. In considering the fair value of the underlying stock when the Company granted options, the Company considered several factors including the fair values established by market transactions. Stock option-based compensation includes estimates and judgments of when stock options might be exercised and stock price volatility. The timing of option exercises is out of the Company's control and depends upon a number of factors including the Company's market value and the financial objectives of the option holders. These estimates can have a material impact on the stock compensation expense but will have no impact on the cash flows. The estimation of share-based awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from original estimates, such amounts are recorded as a cumulative adjustment in the period the estimates are revised. The Company uses the expected term, rather than the contractual term, for both employee and consultant options issued.

Derivative instruments

The Company evaluated its convertible notes to determine if those contracts or embedded components of those contracts qualified as derivatives to be separately accounted for in accordance with ASC 815, *Derivatives and Hedging*. The result of this accounting treatment is that the fair value of the embedded derivative is marked to market each balance sheet date and recorded as a liability. In the event that the fair value is recorded as a liability, the change in fair value is recorded in the statements of operations as other income or expense. Upon conversion or exercise of a derivative instrument, the instrument is marked to fair value at the conversion date and then that fair value is reclassified to equity.

In circumstances where the embedded conversion option in a convertible instrument is required to be bifurcated and there are also other embedded derivative instruments in the convertible instrument that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument.

(in thousands, except share and per share data)

Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities are classified in the balance sheets as current or non-current to correspond with its host instrument.

Income taxes

Income taxes are accounted for under the asset and liability method. The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities and the expected benefits of net operating loss carryforwards. The impact of changes in tax rates and laws on deferred taxes, if any, applied during the period in which temporary differences are expected to be settled, is reflected in the Company's financial statements in the period of enactment. The measurement of deferred tax assets is reduced, if necessary, if, based on the weight of the evidence, it is more likely than not that some, or all, of the deferred tax assets will not be realized. As of December 31, 2021 and 2020, the Company concluded that a full valuation allowance was necessary for all of its net deferred tax assets. The Company had no amounts recorded for uncertain tax positions, interest or penalties in the accompanying consolidated financial statements.

Net loss per common share

Basic net loss per common share is computed based on the weighted average number of shares of common stock outstanding during each year. Diluted net loss per common share is computed based on the weighted average number of shares of common stock outstanding during each year, plus the dilutive effect of options considered to be outstanding during each year, in accordance with ASC 260, *Earnings Per Share*.

Recent accounting pronouncements

The Company considers the applicability and impact of all ASUs. ASUs not discussed below were assessed and determined to be either not applicable or are expected to have minimal impact on the financial statements.

On January 1, 2021, the Company adopted ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions to the general principals in Topic 740. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending the existing guidance. The adoption of this standard did not have a material impact on the Company's financial statements.

4. MARKETABLE SECURITIES AND FAIR VALUE MEASUREMENTS

Marketable Securities

The following is a summary of the Company's available-for-sale securities as of the dates indicated:

	As of December 31, 2021			
	Adjusted Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable Securities:				
Debt securities:				
Corporate bonds	$ 1,153	$ —	$ (1)	$ 1,152
Municipal bonds	2,657	—	(1)	2,656
Total	$ 3,810	$ —	$ (2)	$ 3,808

All of the Company's investments in marketable debt securities are accounted for as available-for-sale securities and have contractual maturity dates of one year or less.

Fair Value Measurements

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase consistency and comparability in fair value measurements and related disclosures, ASC 820 establishes a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three broad levels.

As of December 31, 2021, all of the Company's marketable securities were classified as Level 2 assets.

(in thousands, except share and per share data)

The fair value of the embedded derivative liability identified in the 2021 Convertible Notes was a Level 3 fair value measurement. As of February 12, 2021, the embedded derivative was remeasured based upon the conversion price of $8.00 per share upon closing of the IPO. As such, an expense of $89 was recorded in the first quarter of 2021.

The following table presents the activity for the liability measured at estimated fair value using unobservable inputs for the year ended December 31, 2021:

Beginning balance, January 1, 2021	$ —
Additions during the year ended December 31, 2021	89
Transfer out of Level 3	89
Balance at December 31, 2021	$ —

5. LEASES

The Company has a financing lease in relation to equipment utilized in the commercial scale manufacturing of ADAIR. The Company evaluates renewal options at lease inception on an ongoing basis and includes renewal options that it is reasonably certain to exercise in its expected lease terms when classifying leases and measuring lease liabilities. Lease agreements generally do not require material variable lease payments, residual value guarantees or restrictive covenants.

Financing lease ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of minimum lease payments over the lease term. The Company utilized the interest rate implicit in the lease. The lease term is based on the non-cancellable period in the lease contract. Any termination fees are included in the calculation of the ROU asset and lease liability when it is assumed that the lease will be terminated.

The table below presents the finance lease assets and liabilities recognized on the Company's balance sheets:

		December 31,	
	Balance Sheet Line Item	**2021**	**2020**
Non-current finance lease assets	Other assets	$ 206	$ 279
Finance lease liabilities:			
Current finance lease liabilities	Other current liabilities	97	105
Non-current finance lease liabilities	Other liabilities	72	170
Total finance lease liabilities		$ 169	$ 275

The Company’s weighted average remaining lease term and weighted average discount rate for its financing lease as of December 31, 2021 are:

	December 31, 2021
Weighted-average remaining lease term - finance lease	1.75 years
Weighted-average discount rate - finance lease	13.50 %

Cash flows related to the measurement of financing lease assets and liabilities were as follows:

	Year Ended December 31,	
	2021	**2020**
Operating cash flows from finance lease amortization	$ 73	$ 74
Financing cash flows from finance lease payments	$ 106	$ 65

(in thousands, except share and per share data)

The maturities of the finance lease liability as of December 31, 2021 are as follows:

	December 31, 2021
2022	$ 114
2023	76
Total lease payments	190
Less: Imputed interest	21
Present value of lease liability	$ 169

6. ACCRUED EXPENSES

Accrued expenses consisted of:

	December 31,	
	2021	2020
Accrued expenses:		
Research and development	$ 894	$ 259
General and administrative	183	156
Payroll and related	291	342
Licensing related	62	81
Other	—	9
Total accrued expenses	$ 1,430	$ 847

7. PPP NOTE AND CONVERTIBLE NOTES

In May 2020, the Company issued a promissory note under the PPP (the PPP Note) totaling $61. The note had a stated interest rate of 1% and had a two-year maturity. Payments were required to be made over a 1.5 years period beginning in November 2020 unless forgiven. In January 2021, the Company was notified that the loan along with accumulated interest had been forgiven. As a result, the Company recorded income from the extinguishment of its obligation in the amount of $61 as other income on the accompanying statements of operations and comprehensive loss.

In January 2021, the Company entered into a Convertible Promissory Note Purchase Agreement with certain existing stockholders, including Salmon Pharma, an affiliate of Medice, and David Baker, the Company's Chief Executive Officer, pursuant to which the Company issued the 2021 Convertible Notes, for cash proceeds of $350. The 2021 Convertible Notes bore an interest rate of 7.0% per annum, non-compounding, and had a maturity date of September 30, 2021. The 2021 Convertible Notes converted into 54,906 shares of the Company's common stock upon completion of the IPO. The Company identified the mandatory conversion into shares of the Company's common stock as a redemption feature, which requires bifurcation from the 2021 Convertible Notes and treated it as a derivative liability under ASC 815 as the redemption feature was not clearly and closely related to the debt. The Company evaluated the fair value of the derivative liability. Upon the conversion of the 2021 Convertible Notes to common stock at the closing of the IPO, the embedded derivative liability was remeasured and removed from the balance sheet.

8. EMPLOYEE BENEFIT PLANS

The Company maintains a tax-qualified SIMPLE IRA retirement plan which covers all employees. Pursuant to the SIMPLE IRA program, employees are eligible to contribute to an individual SIMPLE IRA account on a tax-deferred basis. The Company makes matching contributions to the employee's SIMPLE IRA account in an amount up to 3% of the employee's base salary (subject to applicable IRS compensation limits). Expenses related to Company contributions were $24 and $17 for the years ended December 31, 2021 and 2020, respectively.

9. COMMITMENTS AND CONTINGENCIES

Employment agreements

The Company has entered into employment contracts with its officers that provide for severance and continuation of benefits in the event of termination of employment by the Company without cause or by the employee for good reason. In addition, in the event of termination of employment following a change in control, the vesting of certain equity awards may be accelerated.

(in thousands, except share and per share data)

Litigation

In November 2021, the Company was named as a defendant in a putative class action lawsuit filed in the California Superior Court, County of Los Angeles, styled *Rendon v. Vallon, Inc., et al*. The complaint brought one claim for violation of California's Unruh Civil Rights Act (Unruh Act), alleging that the Company's website is not compatible with software used by vision-impaired individuals. The Company settled the lawsuit for an immaterial amount.

COVID-19 Impact

The global COVID-19 pandemic continues to present uncertainty and unforeseeable new risks to the Company's operations and business plan. The Company has closely monitored recent COVID-19 developments, including states' lifting COVID-19 safety measures, drops in vaccination rates, and the spread of various coronavirus strains such as the Delta and Omicron variants. In light of these developments, the full impact of the COVID-19 pandemic on the Company's business, operations and clinical development plans remains uncertain and will vary depending on the pandemic's future impact on its clinical trial enrollment, clinical trial sites, clinical research organizations (CROs), third-party manufacturers, and other third parties with whom the Company does business, as well as any legal or regulatory consequences resulting therefrom. To the extent possible, the Company is conducting business as usual, with necessary or advisable modifications to employee travel and with most of its employees and consultants working remotely. The Company will continue to actively monitor the COVID-19 situation and may take further actions that alter its operations, including those that may be required by federal, state or local authorities, or that it determines is in the best interests of its employees and other third parties with whom the Company does business.

10. STOCKHOLDERS EQUITY (DEFICIT)

Common Stock

In February 2021, the Company completed its IPO of 2,250,000 shares of common stock at a public offering price of $8.00 per share. As a result of the IPO, the Company received approximately $15,500 in net proceeds, after deducting discounts and commissions of $1,600 and offering expenses of approximately $905.

Common Stock Warrants

In connection with the IPO, the Company granted the underwriters warrants (the Underwriters' Warrants) to purchase an aggregate of 112,500 shares of common stock at an exercise price of $10.00 per share. The Underwriters' Warrants have a five-year term and became exercisable after August 12, 2021.

The Black-Scholes option-pricing model was used to estimate the fair value of the warrants with the following weighted-average assumptions:

Volatility	85.0 %
Expected term in years	2.5
Dividend rate	0.0 %
Risk-free interest rate	0.155 %

As of December 31, 2021, all of the Underwriters' Warrants were outstanding.

11. STOCK-BASED COMPENSATION

The Company issues stock-based awards pursuant to its 2018 Equity Incentive Plan (the 2018 Plan). The 2018 Plan provides for the granting of stock options, restricted stock, or restricted stock units. The Company's employees, officers, directors and other persons are eligible to receive awards under the Plan. The number of shares of the Company's common stock authorized under the 2018 Plan will automatically increase on January 1st of each year until the expiration of the 2018 Plan, in an amount equal to four percent of the total number of shares of the Company's common stock outstanding on December 31st of the preceding calendar year, subject to the discretion of the Company's board of directors or compensation committee to determine a lesser number of shares shall be added for such year. The total number of shares authorized for issuance under the 2018 Plan was 621,022 as of December 31, 2021.

The amount, terms of grants, and exercisability provisions are determined and set by the Company's board of directors or compensation committee. The Company measures employee stock-based awards at grant-date fair value and records compensation

(in thousands, except share and per share data)

expense on a straight-line basis over the vesting period of the award. Stock-based awards issued to non-employees are revalued until the award vests.

The Company recorded stock-based compensation related to stock options issued under the 2018 Plan in the following expense categories of its accompanying statements of operations for the years ended December 31, 2021 and 2020 :

	For the Year Ended December 31,	
	2021	2020
Research and development	$ 83	$ 103
General and administrative	543	51
Total	$ 626	$ 154

The Company has granted stock options to purchase its common stock to employees and consultants under the 2018 Plan that generally have a contractual life of up to 10 years. The Company has also granted certain stock options outside of the 2018 Plan. As of December 31, 2021, all equity awards granted from the 2018 Plan were in the form of stock options.

The Company measures equity-based awards granted to employees, and non-employees based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period or performance-based period, which is generally the vesting period of the respective award. The measurement date for equity awards is the date of grant, and equity-based compensation costs are recognized as expense over the requisite service period, which is the vesting period or for certain performance-based awards. The Company records the expense for these awards if it concludes that it is probable that the performance condition will be achieved.

The table below represents the activity of stock options granted to employees and non-employees for the year ended December 31, 2021:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at December 31, 2020	266,250	$ 2.94	8.22
Granted	442,240	$ 4.00	
Exercised	—	—	
Forfeited	—	—	
Outstanding at December 31, 2021	708,490	$ 3.60	8.64
Exercisable at December 31, 2021	205,888	$ 2.94	7.80
Vested and expected to vest at December 31, 2021	708,490	$ 3.60	8.64

The Black-Scholes option-pricing model was used to estimate the grant date fair value of each stock option grant at the time of grant using the following weighted-average assumptions:

	For the Year Ended December 31,	
	2021	2020
Volatility	83.78 %	85.00 %
Expected term in years	5.85	5.80
Dividend rate	0.00 %	0.00 %
Risk-free interest rate	1.01 %	0.64 %
Fair value of common stock on grant date	$ 4.00	$ 4.72

The aggregate intrinsic value of stock options outstanding and stock options exercisable as of December 31, 2021 was $1,716 and $640, respectively. At December 31, 2021, the unrecognized compensation cost related to unvested stock options expected to vest was $885. This unrecognized compensation is expected to be recognized over a weighted-average amortization period of 2.49 years.

(in thousands, except share and per share data)

12. INCOME TAX

A reconciliation of income tax expense (benefit) at the US federal statutory income tax rate and the income tax provision in the financial statements is as follows:

	December 31,	
	2021	2020
Expected income tax benefit at the federal statutory rate	21.0%	21.0%
State and local taxes, net of federal benefit	10.6	12.8
Non-deductible items and other	(0.5)	—
Prior year provision to return adjustments	—	6.4
Change in valuation allowance	(31.1)	(40.2)
Total	—%	—%

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

The principal components of the Company's deferred tax assets and liabilities are as follows:

	December 31,	
	2021	2020
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 6,617	$ 3,939
Share based compensation	308	97
Lease liabilities	57	96
Accruals and other	98	108
Gross deferred tax assets	7,080	4,240
Less: deferred tax liabilities	(70)	(94)
Less: valuation allowance	(7,010)	(4,146)
Net deferred tax assets	$ —	$ —

Based on the Company's history of losses, the Company recorded a full valuation allowance against its deferred tax assets as of December 31, 2021 and 2020. The Company increased its valuation allowance by approximately $2,864 for the year ended December 31, 2021. The Company intends to maintain a valuation allowance until sufficient positive evidence exists to support a reversal of the allowance.

As of December 31, 2021, the Company had federal, state and local net operating loss carryforwards of $20,125, $20,362, and $15,866, respectively. The federal net operating loss carryforwards do not expire. The state and local losses begin to expire in the year ending December 31, 2038.

Under the provisions of Sections 382 and 383 of the Internal Revenue Code (IRC), certain substantial changes in the Company's ownership may have limited, or may limit in the future, the amount of net operating loss and credit carryforwards that can be used to reduce future income taxes if there has been a significant change in ownership of the Company, as defined by the IRC. Future owner or equity shifts could result in limitations on net operating loss and credit carryforwards.

The Company evaluates tax positions for recognition using a more-likely-than-not recognition threshold, and those tax positions eligible for recognition are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon the effective settlement with a taxing authority that has full knowledge of all relevant information. As of December 31, 2021 and 2020, the Company had no unrecognized income tax benefits that would affect the Company's effective tax rate if recognized. The Company would recognize both accrued interest and penalties related to unrecognized benefits in income tax expense. The Company's uncertain tax positions yet to be determined would be related to years that remain subject to examination by relevant tax authorities. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available.

13. RELATED PARTY TRANSACTIONS

On January 2020, the Company entered into a license agreement with Medice which grants Medice an exclusive license, with the right to grant sublicenses, to develop, use, manufacture, market and sell ADAIR throughout Europe. Medice is responsible for obtaining regulatory approval of ADAIR in the licensed territory. Under the license agreement, Medice paid Vallon a $100 upfront payment and is required to pay milestone payments upon first obtaining regulatory approval to market and sell ADAIR in any country, territory or region in the licensed territory and upon achieving certain annual net sales thresholds. Medice will also pay tiered royalties on annual net sales of ADAIR at rates in the low double-digits. The initial term of the license agreement will expire five years after the date on which Medice first obtains regulatory approval in any country, territory or region in the licensed territory.

In January 2021, the Company entered into a Convertible Promissory Note Purchase Agreement with certain existing stockholders, including Salmon Pharma, an affiliate of Medice, and David Baker, the Company's Chief Executive Officer, pursuant to which the Company issued the 2021 Convertible Notes for cash proceeds of $350. The 2021 Convertible Notes bore an interest rate of 7.0% per annum, non-compounding, and had a maturity date of September 30, 2021. The 2021 Convertible Notes converted into 54,906 shares of the Company's common stock upon completion of the IPO.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement of Vallon Pharmaceuticals, Inc. on Form S-8 (No. 333-255972) of our report dated February 14, 2022, on our audits of the financial statements as of December 31, 2021 and 2020 and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about February 14, 2022. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, New Jersey
February 14, 2022

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE AND FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Baker, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vallon Pharmaceuticals, 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: February 14, 2022

By: /s/ David Baker
David Baker
President and Chief Executive Officer
(Principal Executive, Financial and Accounting Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL EXECUTIVE AND FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Leanne Kelly, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vallon Pharmaceuticals, 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: February 14, 2022

By: /s/ Leanne Kelly
Leanne Kelly
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE AND FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, David Baker, President and Chief Executive Officer of Vallon Pharmaceuticals, Inc. (the Company), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Annual Report on Form 10-K of the Company for the year ended December 31, 2021 (the Annual 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 Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 14, 2022

By: /s/ David Baker
David Baker
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL EXECUTIVE AND FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Leanne Kelly, Chief Financial Officer of Vallon Pharmaceuticals, Inc. (the Company), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Annual Report on Form 10-K of the Company for the year ended December 31, 2021 (the Annual 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 Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 14, 2022

By: /s/ Leanne Kelly
Leanne Kelly
Chief Financial Officer
(Principal Financial and Accounting Officer)