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, 2022

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 **(Address of principal executive offices, including zip code)**	**(267) 607-8255 (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, 2022 (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 $5.2 million based on the last reported sale price of the registrant's common stock on The Nasdaq Capital Market on June 30, 2022.

As of February 15, 2023, 13,482,342 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 approval and closing of the Merger (as defined below), including the timing of the Merger;
- the Exchange Ratio (as defined below), and relative ownership levels as of the closing of the Merger;
- the cash balances of the potential combined company following the closing of the Merger, the Equity Financing (as defined below), and the Series T Warrant Exercises (as defined below);
- 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," "Vallon," "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. Our prospects currently depend largely the development of any potential future products, such as ADAIR or ADMIR.
- If serious adverse or unacceptable side effects are identified during the development of any potential future products, such as ADAIR or ADMIR, we may need to abandon or limit our development of some of such products.
- If we obtain approval to commercialize any future product, such as ADAIR or 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 any future products, such as ADAIR or 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 any future product, such as ADAIR or ADMIR, we may not be successful in commercializing any 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 any future product, such as ADAIR or ADMIR, or its or their approvals may be delayed, which would have a material adverse effect on our business and financial condition.

- Even if any proposed product that we develop, such as ADAIR or 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

Historically, we have been primarily focused on the development and commercialization of novel abuse-deterrent medications for CNS disorders. Our lead investigational product candidate, ADAIR, was a proprietary, abuse-deterrent oral formulation of immediate-release dextroamphetamine (the main active ingredient in Adderall®), which was being developed for the treatment of attention -deficit/hyperactivity disorder (ADHD) and narcolepsy. In March 2022, we announced that our Study to Evaluate the Abuse Liability, Pharmacokinetics, Safety and Tolerability of an Abuse-Deterrent d-Amphetamine Sulfate Immediate Release Formulation (SEAL) study for ADAIR did not reach its primary endpoint. In addition to ADAIR, our second product candidate, ADMIR, an abuse deterrent formulation of methylphenidate (Ritalin®), was also being developed for the treatment of ADHD.

While assessing the best path forward for the ADAIR and ADMIR development programs in relation to the results of the SEAL study, we engaged Ladenburg Thalmann &Co. Inc. (Ladenburg) to evaluate our strategic alternatives with the goal of maximizing stockholder value. Ladenburg was engaged to advise on the strategic review process, which could have included, without limitation, exploring the potential for a possible merger, business combination, investment into us, or a purchase, license or other acquisition of assets. In conjunction with the exploration of strategic alternatives, we streamlined operations to preserve our capital and cash resources.

After conducting a diligent and extensive process of evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction, which included the receipt of 15 formal merger proposals from interested parties and careful evaluation and consideration of those proposals, and following extensive negotiation with a number of possible candidates, on December 13, 2022, Vallon and GRI Bio, Inc. (GRI) entered into an Agreement and Plan of Merger (the Merger Agreement), pursuant to which a wholly-owned subsidiary of Vallon will merge with and into GRI, with GRI surviving as a wholly-owned subsidiary of Vallon (the Merger). The Merger will result in a clinical-stage biotechnology company focused on discovering, developing, and commercializing innovative therapies targeting serious diseases associated with dysregulated immune responses that lead to inflammatory, fibrotic, and autoimmune disorders.

At the effective time of the Merger (the Effective Time), each share of common stock of GRI, $0.01 par value per share (GRI Common Stock) outstanding immediately prior to the Effective Time, excluding any dissenting shares but including any shares of GRI Common Stock issued pursuant to the concurrent equity financing will be automatically converted into the right to receive a number of shares of common stock of Vallon, $0.0001 par value per share (Vallon Common Stock) equal to the exchange ratio formula described in the Merger Agreement (the Exchange Ratio), subject to adjustment for the proposed reverse stock split of Vallon Common Stock to be implemented prior to the consummation of the Merger as discussed in this proxy statement/prospectus/information statement (the Reverse Split). The exchange ratio may be adjusted based on Vallon's net cash at the consummation of the Merger (the Closing) and/or any reduction to Vallon's valuation required in order to meet the initial listing requirements of The Nasdaq Stock Market LLC (Nasdaq).

In connection with signing the Merger Agreement, on December 13, 2022, GRI, Vallon, and Altium Growth Fund, LP (the Investor) entered into a separate securities purchase agreement (the Equity SPA) pursuant to which, among other things, Vallon will issue to the Investor Series A-1 Warrants, Series A-2 Warrants, and Series T Warrants. We refer to the transactions contemplated by the Equity SPA as the "Equity Financing" in this Annual Report. The combined company may force the exercise of the Series T Warrants subject to the satisfaction of certain equity conditions, and we refer to the exercise of Series T Warrants and the resulting proceeds as the "Series T Warrant Exercises" in this Annual Report.

Although we have entered into the Merger Agreement and intend to consummate the transaction, there is no assurance that we will be able to successfully consummate the proposed Merger on a timely basis, or at all. If, for any reason, the Merger is not completed, we will reconsider our strategic alternatives and could pursue one or more of the following courses of action:

- Dissolve and liquidate our assets. If, for any reason, the Merger is not consummated and we are unable to identify and complete an alternative strategic transaction like a merger or potential collaborative, partnering or other strategic arrangements for our assets, or continue to operate our business due to the inability to raise additional funding, we may be required to dissolve and liquidate our assets. In such case, there can be no assurances as to the amount or timing of available cash left to distribute to our stockholders, if any, after paying our debts and other obligations and setting aside funds for reserves.
- Pursue potential collaborative, partnering or other strategic arrangements for our assets, including a sale or other divestiture.

- Continue to operate our business. Although presently not anticipated, we could elect to continue to operate our business and pursue licensing or partnering transactions. Based on our prior assessment, this would require a significant amount of time, financial resources, human capital and we would be subject to all the risk and uncertainties involved in the development of product candidates. In such instance, there is no assurance that we could raise sufficient capital to support these efforts, that our development efforts would be successful or that we could successfully obtain the regulatory approvals required to market any product candidate we pursued.
- Pursue another strategic transaction simialr to the proposed Merger.

Medice License Agreement

In January 2020, we entered into a license agreement with Medice (Medice License Agreement), which grants Medice an exclusive license to develop, use, manufacture, market and sell ADAIR throughout Europe. Under the Medice License Agreement, Medice paid 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.

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 three 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 two issued European patents and one issued Japanese patent which expire in 2038. Our international PCT application has entered national phase is under examination in several foreign countries and territories, including Australia, Canada and China. 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, 2023, we had two full-time employee and had engaged five 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.

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 $1.235 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 Related to the Proposed Merger

The Exchange Ratio is adjustable based on our net cash at closing and the Nasdaq Adjustment, so the consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed.

The relative proportion of the combined company that the Vallon stockholders will own when and if the Merger closes will be based on the valuations of Vallon and GRI and the Exchange Ratio as negotiated by the parties and as specified in the Merger Agreement. Under the Exchange Ratio formula described in the Merger Agreement, the equity holders of GRI immediately before the Closing (including the Investor in the Equity Financing) are expected to hold approximately between 83.0% to 96.7% of the aggregate number of outstanding shares of Vallon Common Stock immediately after the Closing and the equity holders of Vallon immediately prior to the Closing are expected to hold approximately between 17.0% to 3.3% of the aggregate number of outstanding shares of Vallon Common Stock immediately after the Closing, in each case as calculated on an adjusted fully diluted treasury stock method basis and after giving effect to the Equity Financing but before giving effect to the issuance of the Series A-1, A-2, and T Warrants. Assuming an Exchange Ratio of 1.7759 and without taking into account any beneficial ownership limitations, the outstanding equity of the combined company, as calculated on a fully diluted basis by including all shares underlying all options and warrants of the combined company after giving effect to the Merger, the Equity Financing (including the issuance of the Series A-1, A-2, and T Warrants), the Series T Warrant Exercises (including the Series A-1 Warrants and Series A-2 Warrants issuable upon exercise of the Series T Warrants) and assuming the Investor receives all escrowed shares, is expected to be held as follows: equity holders of GRI immediately prior to the Closing other than the Investor will hold approximately 12.5%; the Investor in the Equity Financing will hold approximately 84.7%; and the Vallon equity holders immediately prior to the Closing will hold approximately 2.7%. The Exchange Ratio formula is based upon a GRI valuation of $49.0 million and a Vallon valuation of $29.0 million, which is subject to adjustment based upon Vallon's net cash on the Closing Date and any reduction to Vallon's valuation required in order to meet the initial listing requirements of Nasdaq. The assumed Exchange Ratio of 1.7759 is calculated in accordance with the Exchange Ratio formula in the Merger Agreement after giving effect to the estimated Nasdaq Adjustment (as defined below) that would result if the price per share of Vallon Common Stock selected by Nasdaq for the purpose of determining whether the combined company will satisfy the Nasdaq initial listing standards is $0.30, and implies a GRI valuation of $62.3 million and a Vallon valuation of $12.7 million. Vallon anticipates that it will have approximately negative $3.5 million of net cash, as calculated pursuant to the Merger Agreement, at the Closing provided the Closing occurs during the second quarter of 2023.

The Nasdaq adjustment in the Merger Agreement (the Nasdaq Adjustment) provides that if, at the date of determination by Nasdaq of the market value of unrestricted publicly held shares of the combined company for the purpose of determining whether the combined company will satisfy the Nasdaq initial listing standards, the price per share of Vallon Common Stock as selected by Nasdaq for this purpose is insufficient to enable the combined company to satisfy the unrestricted publicly held shares requirement, then the GRI valuation shall be adjusted upward and the Vallon valuation will be adjusted downward (but not below $5.0 million) until the adjusted valuations enable the combined company to satisfy the Nasdaq's unrestricted publicly held shares requirement based on the price per share of the Vallon Common Stock selected by Nasdaq for that determination, and the Exchange Ratio will be recalculated based on the adjusted valuations. The price per share of Vallon Common Stock is volatile and uncertain and any Nasdaq Adjustment resulting from a low price per share of Vallon Common Stock could result in the stockholders of Vallon bearing substantial dilution. As of the date of this Annual Report, the parties expect there to be a Nasdaq Adjustment and have assumed an Exchange Ratio that assumes a price per share of Vallon Common Stock of $0.30.

There is no assurance that the proposed Merger between Vallon and GRI will be completed in a timely manner or at all. Failure to complete the Merger may result in Vallon or GRI paying a termination fee to the other party and could harm our common stock price and the future business and operations of each company.

The consummation of the Merger between Vallon and GRI is subject to a number of closing conditions, including approval by Vallon's and GRI's respective stockholders ofcertain stockholder proposals and other customary closing conditions. The closing conditions may not be waived without the consent of GRI, Vallon, Vallon Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Vallon (Merger Sub) and, pursuant to the Equity SPA, the Investor. The parties are targeting a closing of the transaction in the second quarter of 2023, however, there can be no assurance that the Merger will be consummated within this desired timeframe, or at all.

If the Merger between Vallon and GRI is not consummated, Vallon may be subject to a number of material risks, its business and stock price could be adversely affected, as follows:

- Vallon has incurred and expects to continue to incur significant expenses related to the Merger, such as legal and accounting fees, which must be paid even if the Merger is not consummated;
- Vallon could be obligated to pay GRI a $2.0 million termination fee and expense reimbursements up to $400,000 in connection with the termination of the Merger Agreement, depending on the reason for the termination;
- The market price of Vallon Common Stock may decline to the extent that the current market price reflects a market assumption that the Merger will be completed;
- Nasdaq could determine to delist Vallon's Common Stock, which could have an adverse effect on the Merger, the value of Vallon's Common Stock and any future ability to raise capital;
- Vallon may be forced to cease its operations, dissolve and liquidate its assets.

In addition, if the Merger Agreement is terminated and our board of directors determines to seek another business combination, there can be no assurance that Vallon will be able to find a partner willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the Merger or any partner at all.

We are substantially dependent on a limited number of employees to facilitate the consummation of the Merger.

As of February 15, 2023, we had only two full-time employees. Our ability to successfully complete the Merger depends in large part on our ability to retain certain of our remaining personnel. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of any of these employees could potentially harm our ability to consummate the Merger, to run our day-to-day business operations, and to fulfill our reporting obligations as a public company.

Competition among biotechnology companies for qualified employees is intense, and our ability to retain our key employees is critical to our ability to effectively manage our resources and consummate the Merger. If we develop new product candidates, such development would require expertise from a number of different disciplines, some of which are not widely available. The results of the SEAL study of ADAIR will likely make it more challenging for us to retain qualified personnel and more difficult to recruit personnel in the future, if necessary. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects and ability to consummate the Merger would be harmed.

If the conditions to the closing of the Merger are not met, the Merger may not occur.

Even if the Merger and other stockholder matters are approved by our stockholders, specified conditions must be satisfied or waived to complete the Merger. These conditions are set forth in the Merger Agreement, such as the Equity Financing and Vallon's net cash not exceeding negative $4.0 million. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or will be delayed, and we may lose some or all of the intended benefits of the Merger.

The pendency of the Merger could have an adverse effect on the trading price of our common stock and our business, financial condition, and prospects.

While there have been no significant adverse effects to date, the pendency of the Merger could disrupt our business in many ways, including:

- the attention of our remaining management and employees may be directed toward the completion of the Merger and related matters and may be diverted from our day-to-day business operations; and

- third parties may seek to terminate or renegotiate their relationships with us as a result of the Merger, whether pursuant to the terms of their existing agreements with us or otherwise.

Should they occur, any of these matters could adversely affect the trading price of our common stock or harm our business, financial condition, and prospects.

The Merger may be completed even though material adverse changes may result from the announcement of the Merger, industry-wide changes, and/or other causes.

In general, either Vallon or GRI can refuse to complete the Merger if there is a material adverse change affecting the other party between the date of the Merger Agreement, and the closing of the Merger. However, certain types of changes do not permit either party to refuse to complete the Merger, even if such change could be said to have a material adverse effect on Vallon or GRI, including:

- general business or economic conditions generally affecting the industry in which GRI or Vallon operate;
- the taking of any action, or the failure to take any action, by the either party that is required to comply with the terms of Merger Agreement;
- any natural disaster or epidemics, pandemics (including COVID-19 or other outbreaks of diseases or quarantine restrictions), or other force majeure events, or any act or threat of terrorism or war, any armed hostilities or terrorist activities; or
- any change in, or any compliance with or action taken for the purpose of complying with, any law or generally accepted accounting principles (GAAP) (or interpretations of any law or GAAP).

If adverse changes occur and Vallon and GRI still complete the Merger, the stock price of the combined company following the closing of the Merger may suffer. This in turn may reduce the value of the Merger to the stockholders of Vallon, GRI, or both.

Some of our executive officers and directors have interests in the Merger that are different from the respective stockholders of Vallon and GRI and that may influence them to support or approve the Merger without regard to the interests of the respective stockholders of Vallon and GRI.

Some of our officers and directors are parties to arrangements that provide them with interests in the Merger that are different from the respective stockholders of Vallon and GRI, including, among others, service as an officer or director of the combined company following the closing of the Merger, severance benefits, the acceleration of equity award vesting, and continued indemnification.

Based on the terms of their respective agreements, certain of our current executive officers may be entitled to receive vesting acceleration and cash bonuses in connection with the consummation of the Merger and any associated termination of employment from Vallon.

The market price of our common stock following the Merger may decline as a result of the Merger.

The market price of our common stock may decline as a result of the Merger for a number of reasons, including if:

- investors react negatively to the prospects of the combined company's business and prospects following the closing of the Merger;
- the effect of the Merger on the combined company's business and prospects following the closing of the Merger is not consistent with the expectations of financial or industry analysts; or
- the combined company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by stockholders or financial or industry analysts.

Our securityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the closing of the Merger as compared to their current ownership and voting interest in the respective companies.

After the completion of the Merger, our current securityholders will own a smaller percentage of the combined company than their ownership in their respective companies prior to the Merger. Under the Exchange Ratio formula described in the Merger Agreement, the equity holders of GRI immediately before the Closing (including the Investor in the Equity Financing) are expected to hold approximately between 83.0% to 96.7% of the aggregate number of outstanding shares of Vallon Common Stock immediately after the Closing and the equity holders of Vallon immediately prior to the Closing are expected to hold

approximately between 17.0% to 3.3% of the aggregate number of outstanding shares of Vallon Common Stock immediately after the Closing, in each case as calculated on an adjusted fully diluted treasury stock method basis and after giving effect to the Equity Financing but before giving effect to the issuance of the Series A-1, A-2, and T Warrants. Assuming an Exchange Ratio of 1.7759 and without taking into account any beneficial ownership limitations, the outstanding equity of the combined company, as calculated on a fully diluted basis by including all shares underlying all options and warrants of the combined company after giving effect to the Merger, the Equity Financing (including the issuance of the Series A-1, A-2, and T Warrants), the Series T Warrant Exercises (including the Series A-1 Warrants and Series A-2 Warrants issuable upon exercise of the Series T Warrants) and assuming the Investor receives all escrowed shares, is expected to be held as follows: equity holders of GRI immediately prior to the Closing other than the Investor will hold approximately 12.5%; the Investor in the Equity Financing will hold approximately 84.7%; and the Vallon equity holders immediately prior to the Closing will hold approximately 2.7%. The Exchange Ratio formula is based upon a GRI valuation of $49.0 million and a Vallon valuation of $29.0 million, which is subject to adjustment based upon Vallon's net cash on the Closing Date and any reduction to Vallon's valuation required in order to meet the initial listing requirements of Nasdaq. The assumed Exchange Ratio of 1.7759 is calculated in accordance with the Exchange Ratio formula in the Merger Agreement after giving effect to the estimated Nasdaq Adjustment that would result if the price per share of Vallon Common Stock selected by Nasdaq for the purpose of determining whether the combined company will satisfy the Nasdaq initial listing standards is $0.30, and implies a GRI valuation of $62.3 million and a Vallon valuation of $12.7 million. We anticipate that we will have approximately negative $3.5 million of net cash, as calculated pursuant to the Merger Agreement, at the Closing provided the Closing during the second quarter of 2023. As of January 30, 2023, the parties expect there to be a Nasdaq Adjustment and have assumed an Exchange Ratio that assumes a price per share of Vallon Common Stock of $0.30.

During the pendency of the Merger, we may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses.

Covenants in the Merger Agreement impede our ability to make acquisitions, subject to specified exceptions relating to fiduciary duties, or complete other mergers, sales of assets, or other business combinations that are not in the ordinary course of business pending completion of the Merger. As a result, if the Merger is not completed, we may be at a disadvantage to our competitors during that period. In addition, while the Merger Agreement is in effect, we are generally prohibited from soliciting, initiating, encouraging, or entering into specified extraordinary transactions, such as a merger, sale of assets, or other business combination, with any third party, subject to specified exceptions, even if any such transaction could be favorable to our stockholders.

Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit us from soliciting competing proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when our board of directors determines in good faith, after consultation with its independent financial advisor, if any, and outside counsel, that an unsolicited competing proposal constitutes, or would reasonably be expected to result in, a superior competing proposal and that failure to take such action would result in a breach of the fiduciary duties of the board of directors. In addition, if we or GRI terminate the Merger Agreement under specified circumstances, including terminating because of a decision of a board of directors to recommend a superior competing proposal, GRI may be required to pay us a termination fee of $2.0 million and/or up to $0.4 million in expense reimbursements or we may be required to pay GRI a termination fee of $2.0 million, and/or up to $0.4 million in expense reimbursements. This termination fee may discourage third parties from submitting competing proposals to us or our stockholders and may cause our board of directors to be less inclined to recommend a competing proposal.

Because the lack of a public market for GRI's capital stock makes it difficult to evaluate the fairness of the Merger,we may pay more than the fair market value of GRI's capital stock.

The outstanding capital stock of GRI is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of GRI's capital stock. Because the percentage of our equity to be issued to GRI stockholders was determined based on negotiations between the parties, it is possible that we may pay more than the aggregate fair market value for GRI's capital stock.

The combined company will incur significant transaction costs as a result of the Merger, including investment banking, legal, and accounting fees. In addition, the combined company will incur significant operating expenses which cannot be accurately estimated at this time. Actual transaction costs may substantially exceed the parties' estimates and may have an adverse effect on the combined company's financial condition and operating results.

Because the Merger will result in an ownership change under Section 382 of the Code for us, our pre-merger net operating loss ("NOL") carryforwards and certain other tax attributes will be subject to limitation. In addition, the NOL carryforwards and other tax attributes of GRI and of the combined company may also be subject to limitation as a result of ownership changes.

As of December 31, 2022, we had U.S. federal, state and local NOL carryforwards of $25.6 million, $25.9 million and $18.6 million, respectively. As of Decembr 31, 2022, GRI had U.S. federal NOL carryforwards of $11.7 million and state NOL carryforwards of $12.0 million. Under Sections 382 and 383 of the Code and corresponding provisions of state law, if a corporation undergoes an "ownership change" (within the meaning of Section 382 of the Code ("Section 382")), the corporation's NOL carryforwards and certain other tax attributes (such as research tax credits) arising before the ownership change are subject to limitation on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points (by value) over a rolling three-year period. Similar rules may apply under state tax laws. The Merger will result in an ownership change for us and, accordingly, our NOL carryforwards and certain other tax attributes will be subject to limitations (or disallowance) on their use after the Merger. Our NOL carryforwards may also be subject to limitation as a result of prior shifts in equity ownership and/or the Merger. Additional ownership changes in the future could result in additional limitations on our, GRI's, and the combined company's NOL carryforwards. Consequently, even if the combined company achieves profitability, it may not be able to utilize a material portion of our, GRI's or the combined company's NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, the combined company's existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Certain stockholders could attempt to influence changes within the combined company which could adversely affect the combined company's operations, financial condition, and the value of the combined company's common stock.

The combined company's stockholders may from time-to-time seek to acquire a controlling stake in the combined company, engage in proxy solicitations, advance stockholder proposals, or otherwise attempt to effect changes. Campaigns by stockholders to effect changes at publicly-traded companies are sometimes led by investors seeking to increase short-term stockholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases, or sales of assets or the entire company. Responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, and could disrupt the combined company's operations and divert the attention of the combined company's board of directors and senior management from the pursuit of the Merger. These actions could adversely affect the combined company's operations, financial condition, ability to consummate the Merger, and the value of the combined company's common stock.

Litigation relating to the Merger could require us to incur significant costs and suffer management distraction, and could delay or enjoin the Merger.

Vallon could be subject to demands or litigation related to the Merger, whether or not the Merger is consummated. Such demands or litigation may create uncertainty relating to the Merger, or delay or enjoin the Merger, and responding to such demands could divert management time and resources. In addition, such demands or litigation could lead to a dissolution or bankruptcy of either Vallon or GRI or both parties if the costs associated with such demands or litigation are significant enough.

If Nasdaq does not approve our listing application for the combined company and the parties, including the Investor, waive the Nasdaq closing condition and continue with the Merger, we may be subject to delisting.

We have filed an initial listing application with Nasdaq pursuant to Nasdaq's "reverse merger" rules. In the event the application is not accepted by Nasdaq and the parties, including the Investor, waive the Nasdaq closing condition and proceed with the merger, the combined company will be subject to delisting proceedings and could be delisted. If our shares lose their status on The Nasdaq Capital Market, we believe that our shares would likely be eligible to be quoted on the inter-dealer electronic quotation and trading system operated by OTC Markets Group Inc., such as the OTC Pink marketplace and now known as the OTCQB market. These markets are generally considered not to be as efficient as, and not as broad as, The Nasdaq Capital Market. If our common stock is delisted, this would, among other things, substantially impair its ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us. Additionally, investors would find it more difficult to buy and sell shares of our common stock.

If our common stock were delisted from Nasdaq, we would be subject to the risks relating to penny stocks.
If our common stock were to be delisted from trading on The Nasdaq Capital Market and the trading price of our common stock were below $5.00 per share on the date its common stock is delisted, trading in our common stock would also be subject to the requirements of certain rules promulgated under the Exchange Act. These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a "penny stock" and impose various sales practice requirements on

broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

On June 27, 2022, we received notice from the Listing Qualifications Department of Nasdaq indicating that, because the closing bid price for our common stock had fallen below $1.00 per share over the previous 30 consecutive business days, we no longer complied with the minimum bid price requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) (the Bid Price Rule). Nasdaq's notice had no immediate effect on the listing of our common stock on The Nasdaq Capital Market. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), Nasdaq provided us with an initial compliance period of 180 calendar days, or until December 27, 2022, to regain compliance with the Bid Price Rule.

On December 28, 2022, having not regained compliance with the Bid Price Rule, we received a letter from the Staff notifying us that, unless we timely request a hearing, our common stock would be scheduled for delisting from The Nasdaq Capital Market and would be suspended at the opening of business on January 6, 2023. According to the letter from Nasdaq, we had not regained compliance with the Bid Price Rule and were not eligible for a second 180 day extension period because we did not comply with the minimum $5.0 million stockholders' equity initial listing requirement for The Nasdaq Capital Market.

Accordingly, we filed an appeal and requested a hearing before the Nasdaq Hearings Panel (the Panel). The hearing request resulted in a stay of any suspension or delisting action pending the hearing and the expiration of any extension period granted by the Panel following the hearing. In that regard, the Panel had the right to grant us an extension to regain compliance with the Bid Price Rule. The hearing before the Panel was held on February 16, 2023. The Panel reached a decision on February 21, 2023, and informed the Company that it was granting the Company's request for a stay of delisting procedures on The Nasdaq Stock Market until April 28, 2023, subject to the Company meeting certain conditions, including the Company having completed the Merger and having satisfied all initial listing requirements of The Nasdaq Stock Market on or before April 28, 2023. The Panel stated that it based its decision on the efforts made by the Company thus far to complete the Merger and the associated proposed reverse stock split and the relatively short duration of the requested exception period. There can be no assurance that we will be able to regain compliance with all applicable requirements for continued listing or the conditions required by the Panel. If the trading of our common stock is suspended, it will cease to be quoted on The Nasdaq Capital Market and, as a result, the Merger and the Equity Financing will not be consummated unless the related closing conditions under the Merger Agreement and the Equity SPA are waived by GRI, Vallon, Merger Sub and, pursuant to the Equity SPA, the Investor.

We have incurred and will continue to incur significant transaction costs in connection with the Merger.

We have incurred and will continue to incur significant transaction costs in connection with the Merger. We estimate total aggregate direct transaction costs associated with the Merger to be approximately $4.7 million and approximately $0.2 million for our portion of shared transaction expenses, as well as additional costs associated with the commencement of the combined organization's operation as a public company, which cannot be estimated accurately at this time.

Risks Relating to Our Business and Industry

We have incurred net losses in every year since our inception and anticipates that we will continue to incur net losses in the future.

We are a biopharmaceutical company with a limited operating history. Investment in product development in the healthcare industry, including of biopharmaceutical products, is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date. As a result, we are not profitable and have incurred losses in each period since our inception. For the year ended December 31, 2022, we reported a net loss of $7.0 million. As of December 31, 2022, we had an accumulated deficit of $28.9 million.

To become and remain profitable, we or any potential future collaborator must develop and eventually commercialize products with significant market potential at an adequate profit margin after cost of goods sold and other expenses. This will require us to be successful in a range of challenging activities, including completing clinical trials, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable would decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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 Annual 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.

Additional capital will be required to fund our operations, ADAIR product development activities or the development of any new product. If we fail to obtain necessary financing, we will not be able to complete the development and commercialization of product candidates.

Our operations have consumed substantial amounts of cash since inception. While we have significantly decreased our research and development expenses as we assesses the best path forward for ADAIR, we expect to continue to spend a considerable amount of resources on pursuing strategic opportunities. Furthermore, to move forward with the development of ADAIR or any other product candidates, we would be required to spend substantial amounts to conduct clinical trials of such programs, to validate the manufacturing process and specifications for any such product candidate, to seek regulatory approvals for such product candidate and to launch and commercialize any products for which we receives regulatory approval, including potentially building ours own commercial organization. As of December 31, 2022, we had approximately $3.8 million of cash and cash equivalents on hand. Our future capital requirements and the period for which our existing resources will support its operations may vary significantly from what we currently expect and may change if our business plan changes from our current expected operating plan. Our monthly spending levels will vary based on development and corporate activities. Because of the uncertainty regarding our future development pathway, we are unable to estimate the actual funds we will require for development of any potential product candidate and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the timing and structure of any strategic options that we pursue, including the proposed Merger;
- the terms of any collaboration agreements we may choose to initiate or conclude;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, and other comparable foreign regulatory authorities;
- delay or failure in obtaining the necessary approvals from regulators or institutional review boards (IRBs) in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;
- failure of third-party contractors, such as contract research organizations (CROs), or investigators to comply with regulatory requirements, including Good Clinical Practices (GCPs);
- governmental or regulatory delays and changes in regulation or policy relating to the development and commercialization of a product candidate by the FDA or other comparable foreign regulatory authorities;
- undertaking and completing additional pre-clinical studies to generate data required to support the clinical development of a product candidate;
- inability to enroll sufficient patients to complete clinical trials;
- difficulty in having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- problems with biopharmaceutical product candidate storage, stability and distribution;

- our inability to add new or additional clinical trial sites;
- varying interpretations of the data generated from our preclinical or clinical trials;
- inability to manufacture, or obtain from third parties, adequate supply of biopharmaceutical product candidate sufficient to complete our preclinical studies and clinical trials;
- the costs of establishing, maintaining, and overseeing a quality system compliant with current good manufacturing practice requirements (cGMPs) and a supply chain for the development and manufacture of our product candidate;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the effect of competing technological and market developments;
- the cost and timing of establishing, expanding and scaling manufacturing capabilities;
- the cost of establishing sales, marketing and distribution capabilities for any product candidate for which we may receive regulatory approval in regions where we choose to commercialize its products on its own; and
- potential unforeseen business disruptions or market fluctuations that delay our product development or clinical trials and increase our costs or expenses, such as business or operational disruptions, delays, or system failures due to malware, unauthorized access, terrorism, war, natural disasters, strikes, geopolitical conflicts, restrictions on trade, import or export restrictions, or public health crises, such as the current COVID-19 outbreak.

We do not have any committed external source of funds or other support for our development efforts, and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient product or royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible into or exchangeable for common stock, each existing investors' ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring or licensing intellectual property rights. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to its product candidate, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize itself. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Management transition creates uncertainties and could harm our business.

We will experience significant changes in executive leadership, including the changes in executive leadership as a result of the Merger. Changes to company strategy, which can often times occur with the appointment of new executives, can create uncertainty, may negatively impact our ability to execute quickly and effectively, and may ultimately be unsuccessful. In addition, executive leadership transition periods are often difficult as the new executives gain detailed knowledge of our operations, and friction can result from changes in strategy and management style. Management transition inherently causes some loss of institutional knowledge, which can negatively affect strategy and execution. Until we integrate new personnel, and unless they are able to succeed in their positions, we may be unable to successfully manage and grow our business, and our results of operations and financial condition could suffer as a result. In any event, changes in our organization as a result of executive management transition may have a disruptive impact on our ability to implement our strategy and could have a material adverse effect on our business, financial condition, and results of operations.

Our auditors have expressed substantial doubt about our ability to continue as a going concern, and we may not be able to continue as a going concern if we do not obtain additional financing.

We have incurred losses since inception and have not demonstrated an ability to generate revenues from the sales of our proposed products. The report of our independent registered public accounting firm on our financial statements as of and for the

year ended December 31, 2022 includes an explanatory paragraph indicating that there is substantial doubt about its 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. Our ability to continue as a going concern is dependent on raising capital from the sale of our common stock and/or obtaining debt financing. Our cash and cash equivalents balance at December 31, 2022 was approximately $3.8 million. Based on our current expected level of operating expenditures, we expect to be able to fund our operations for more than four months from this filing after paying all current obligations. Our ability to remain a going concern is wholly dependent upon our ability to continue to obtain sufficient capital to fund our operations.

Despite our ability to secure capital in the past, there can be no assurance that additional equity or debt financing will be available to us when needed or that it may be able to secure funding from any other sources. In the event that we are not able to secure funding, we may be forced to curtail operations, delay or stop ongoing clinical trials, cease operations altogether, or file for bankruptcy.

We are a clinical-stage company with no approved products and a lack of operating history, which makes it difficult to evaluate our technology and product development capabilities and predict our future performance.

We have no products approved for commercial sale and have not generated any revenue from product sales. Our ability to generate product revenue or profits was dependent on the successful development and eventual commercialization of ADAIR. Given that the results of our SEAL study of ADAIR for the treatment of ADHD failed to meet statistical significance for the primary endpoint of E_{max} Drug Liking and we are assessing the best path forward for the ADAIR program, we may never be able to develop or commercialize a marketable product.

Our current and future programs and product candidates will require additional discovery research, preclinical development, clinical development, regulatory approval to commercialize the product, manufacturing validation, obtaining manufacturing supply, capacity and expertise, building of a commercial and distribution organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. In addition, any drug product candidate must be approved for marketing by the FDA or certain other health regulatory agencies before we may commercialize any product in the respective jurisdictions.

Our limited operating history may make it difficult to evaluate our, or any new, technology and industry and predict its future performance. Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in evolving fields. If we do not address these risks successfully, our business will suffer. Similarly, we expect that our financial condition and operating results will fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. As a result, our stockholders should not rely upon the results of any quarterly or annual period as an indicator 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 any 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.

Our prospects were highly dependent on a single product candidate, ADAIR, and while we are assessing the best path forward for ADAIR, we may not complete the development or commercialization of ADAIR.

Our long-term prospects were highly dependent on future acceptance and revenues from our lead product candidate, ADAIR. In March 2022, we announced that topline data from our SEAL study of ADAIR for the treatment of ADHD failed to meet statistical significance for the primary endpoint of E_{max} Drug Liking and that, given that result, we are currently assessing the best path forward for ADAIR. Any further development of ADAIR would require substantial capital and time to complete, and there is no guarantee that any future clinical trial, if pursued, would be timely or successful, or that ADAIR would be approved or, if approved, that commercialization would be successful. Concurrently, we have been evaluating strategic alternatives to maximize stockholder value, which could involve, without limitation, exploring the potential for a possible merger, business combination, investment into the Company, or a purchase, license or other acquisition of assets. However, there is no assurance that we will be successful in our pursuit of a strategic alternative, failure of which may have a material adverse impact on our business, financial condition, and results of operations.

We may try to out license the rights to develop and commercialize ADAIR or ADMIR in the United States or other markets but be unsuccessful.

Given the results of the SEAL study and the required additional development activity necessary to gain regulatory approval of ADAIR, we may never be able to out license or sell ADAIR to another pharmaceutical or biotechnology company even if we decide to pursue such efforts. ADMIR is based on similar technology to ADAIR and is not yet a clinical stage drug, therefore, it may be of no more interest to a potential acquiror than ADAIR. We have a small number of employees and consultants who could be dedicated to an asset sale or out license effort.

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

If any other future product, such as ADAIR or 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 any other future product, such as ADAIR or 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.

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 historical business strategy was to develop a pipeline of product candidates and products by acquiring or in-licensing products, businesses or technologies that we believed were 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. 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 be subject to litigation that will be costly to defend or pursue and uncertain in its outcome.

Our business may bring it into conflict with licensees, licensors, or others with whom we have contractual or other business relationships or with our competitors or others whose interests differ from ours. If we are unable to resolve these conflicts on terms that are satisfactory to all parties, we may become involved in litigation brought by or against such parties. Any litigation is likely to be expensive and may require a significant amount of management's time and attention, at the expense of other aspects of our business. The outcome of litigation is always uncertain, and in some cases, could include judgments against us which could have a materially adverse effect on our business.

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 and Ms. Leanne Kelly, our Chief Financial Officer. We also have 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, and Leanne Kelly, our Chief Financial Officer. Our key consultants include Dr. Timothy Whitaker, our Chief Medical Officer, as well as consultants for bookkeeping, pre-clinical and formulation development 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.

We entered into employment contracts with members of our senior management team that contain significant anti-termination provisions which could make future changes in management difficult or expensive.

We have entered into employment agreements with members of our senior management team. These agreements may require the payment of severance in the event one of these employees ceases to be employed. These provisions make the replacement of these employees very costly and could cause difficulty in effecting any required changes in management or a change in control.

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

The use of any 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 any future product in development, such as ADAIR or 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 any future product, including ADAIR or ADMIR, could be delayed.

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.

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

As the COVID-19 pandemic continues around the globe, the pandemic 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 (CMOs) due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays in receiving approval from local regulatory authorities to initiate Vallon's 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.

Risks Relating to Finances and Capital Requirements

If the Merger is not completed, we may be unsuccessful in completing an alternative strategic transaction on terms that are as favorable as the terms of the proposed transaction with GRI, or at all, and we may be unable to reestablish a viable operating business.

We have not generated revenue from any product sales and 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. In March 2022, we announced that topline data from our SEAL study of ADAIR for the treatment of ADHD did not meet statistical significance for the primary endpoint of E_{max} Drug

Liking. We are continuing to assess the best path forward for the ADAIR and ADMIR programs and commenced a process of evaluating strategic alternatives to maximize stockholder value. Our assets currently consist primarily of cash, cash equivalents, our intellectual property portfolio, and our listing on The Nasdaq Capital Market. While we have entered into the Merger Agreement with GRI, the consummation of the Merger may be delayed or may not occur at all. If the Merger is not completed, the board of directors may elect to pursue an alternative strategic transaction similar to the proposed Merger. Attempting to complete an alternative transaction will be costly and time consuming. If the Merger is not completed and our board of directors determines to pursue an alternative transaction, the terms of any such alternative transaction may not be as favorable to us and our stockholders as the terms of the Merger with GRI. We can make no assurances that such an alternative transaction would occur at all. Further, if the Merger is not completed, given the level of investment and time that would be required to continue development of its existing developmental products or acquire new developmental products, it is unlikely that we would be able to obtain the funding required to recommence its product development activities on terms favorable to our stockholders, or at all.

If the Merger is not completed, our board of directors may decide to pursue a dissolution and liquidation of Vallon. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the Merger will be completed. If the Merger is not completed, our board of directors may decide to pursue a dissolution and liquidation of Vallon. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution will continue to decrease as we fund our operations while we evaluate our strategic alternatives. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of Vallon, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provisions for contingent and unknown obligations, prior to making any distributions in liquidation to its stockholders. Our commitments and contingent liabilities may include (i) regulatory and clinical obligations; (ii) obligations under employment and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control; and (iii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of Vallon. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. In the event of a dissolution or liquidation, there may be no cash to distribute in a wind down and we may owe more than we have at that time. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution, or winding up of Vallon.

If we were to continue to advance our research and development activities and pursue development of any of our pipeline products, we would require substantial additional funding. Raising additional capital would cause dilution to our existing stockholders, and may restrict our operations or require us to relinquish rights to our technologies or to a product candidate.

We currently do not have any committed external source of funds and do not expect to generate any commercial revenue in the foreseeable future. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expects if our operating plans change. If the Merger is not completed and we decide to pursue further research and development activities, we will require substantial additional funding to operate. Additional funds may not be available when we need them on terms that are acceptable to us, or may not be available at all.

To the extent that we raise additional capital through the sale of equity or convertible debt, the ownership interests of our stockholders will be diluted. In addition, the terms of any equity or convertible debt we agree to issue may include liquidation or other preferences that adversely affect the rights of our stockholders. Convertible debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, and declaring dividends, and may impose limitations on our ability to acquire, sell, or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

Furthermore, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the pandemic has resulted in a significant disruption of global financial markets, and the ongoing impact of the COVID-19 pandemic on the global financial markets may reduce our access to capital, when and if needed. If adequate funds are not available to us on a timely basis, we may be required to curtail or cease our operations.

If the Merger is not completed, raising additional funding through debt or equity financing could be difficult or not successful at all, and may cause the market price of our common stock to decline.

If the Merger is not completed, raising additional funding through debt or equity financing could be difficult or unavailable altogether given the turbulent financial markets. The issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline and existing stockholders may not agree with the financing plans or the terms of such financings.

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, 2022, we had an accumulated deficit of $28.9 million and our net loss was $7.0 million for the year ended December 31, 2022. 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 any future product, such as ADAIR or ADMIR, that we may in-license and develop;
- our ability to successfully commercialize any future product, such as ADAIR or ADMIR;
- the amount of sales and other revenues from any future product, such as ADAIR or 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 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 Annual 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 $1.235billion 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, 2022, we had NOL carryforwards available to reduce future taxable income, if any, for federal and state income tax purposes of $25.6 million and $25.9 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.

Risks Relating to Intellectual Property

We have filed multiple patent applications and have three issued patents by the U.S. PTO and two issued patents 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 three patents granted and one additional patent application directed to ADAIR for ADHD and narcolepsy filed in the United States, have had two patents granted in Europe, has one patent granted in Japan, and we are seeking patent protection for ADAIR internationally in several foreign countries and territories, including Australia, Canada, and China. The U.S. patents will expire in 2037 and the European and Japanese patents will expire in 2038. It is impossible to predict whether or how our PCT applications will result in any issued patent. Even if the pending applications issue, they 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 any future product, such as ADAIR or ADMIR. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize any 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 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.

See also the risk factor captioned "If our common stock were delisted from Nasdaq, we would be subject to the risks relating to penny stocks." in this Annual Report.

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 any future product, including ADAIR or 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 any future product, such as ADAIR or 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 February 15, 2023, 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 54.3% 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.

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, 2023, there were 7 holders of record of our common stock. As of such date, there were 13,482,342 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

None.

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.

On May 17, 2022, the Company sold 3,700,000 shares of common stock pursuant to a securities purchase agreement at a purchase price of $1.0632 per share in a registered direct offering (the Offering). The gross proceeds from the Offering were approximately $3.9 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company of approximately $0.6 million.

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, 2022.

Dividend Policy

We have not declared or paid any cash or other dividends on our common stock, and we do not expect to declare or pay any cash or other dividends in the foreseeable future.

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

Historically, we have been primarily focused on the development and commercialization of novel abuse-deterrent medications for CNS disorders. Our lead investigational product candidate, ADAIR, was a proprietary, abuse-deterrent oral formulation of immediate-release dextroamphetamine (the main active ingredient in Adderall®), which was being developed for the treatment of attention-deficit/hyperactivity disorder (ADHD) and narcolepsy. In March 2022, we announced that our Study to Evaluate the Abuse Liability, Pharmacokinetics, Safety and Tolerability of an Abuse-Deterrent d-Amphetamine Sulfate Immediate Release Formulation (SEAL) study for ADAIR did not reach its primary endpoint. In addition to ADAIR, our second product candidate, ADMIR, an abuse deterrent formulation of methylphenidate (Ritalin®), was also being developed for the treatment of ADHD.

While assessing the best path forward for the ADAIR and ADMIR development programs in relation to the results of the SEAL study, we engaged Ladenburg Thalmann & Co. Inc. (Ladenburg) to evaluate our strategic alternatives with the goal of maximizing stockholder value. Ladenburg was engaged to advise on the strategic review process, which could have included, without limitation, exploring the potential for a possible merger, business combination, investment into us, or a purchase, license or other acquisition of assets. In conjunction with the exploration of strategic alternatives, we streamlined operations to preserve our capital and cash resources.

After conducting a diligent and extensive process of evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction, which included the receipt of 15 formal merger proposals from interested parties and careful evaluation and consideration of those proposals, and following extensive negotiation with a number of possible candidates, on December 13, 2022, Vallon and GRI Bio, Inc. (GRI) entered into an Agreement and Plan of Merger (the Merger Agreement), pursuant to which a wholly-owned subsidiary of Vallon will merge with and into GRI, with GRI surviving as a wholly-owned subsidiary of Vallon (the Merger). The Merger will result in a clinical-stage biotechnology company focused on discovering, developing, and commercializing innovative therapies targeting serious diseases associated with dysregulated immune responses that lead to inflammatory, fibrotic, and autoimmune disorders.

At the effective time of the Merger (the Effective Time), each share of common stock of GRI, $0.01 par value per share (GRI Common Stock) outstanding immediately prior to the Effective Time, excluding any dissenting shares but including any shares of GRI Common Stock issued pursuant to the concurrent equity financing will be automatically converted into the right to receive a number of shares of common stock of Vallon, $0.0001 par value per share (Vallon Common Stock) equal to the exchange ratio, subject to adjustment for the proposed reverse stock split of Vallon Common Stock to be implemented prior to the consummation of the Merger as discussed in this Annual Report (the Reverse Split). The exchange ratio may be adjusted based on Vallon's net cash at Closing and/or any reduction to Vallon's valuation required in order to meet the initial listing requirements of The Nasdaq Stock Market LLC (Nasdaq).

Medice License Agreement

In January 2020, we entered into a license agreement with Medice ("Medice License Agreement"), which grants Medice an exclusive license to develop, use, manufacture, market and sell ADAIR throughout Europe. Under the Medice License Agreement, Medice paid 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.

COVID-19

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 the lifting of COVID-19 safety measures, the drop in vaccination rates, the implementation of, and reaction to, vaccine mandates, the spread of new strains or variants of the coronavirus (such as the Delta and Omicron variants), and supply chain and labor shortages. In light of these developments, the full impact of the COVID-19 pandemic on our business and operations remains uncertain and will vary depending on the pandemic's future impact on the 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 its employees and consultants working remotely. We will continue to actively monitor the COVID-19 pandemic 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 are in the best interests of its 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

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.

Our research and development expenses have significantly decreased and will continue to decrease as we considers our future plans regarding the ADAIR and ADMIR programs and as a result of the proposed Merger.

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 incur 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, legal and accounting costs and investor relations costs. Our general and administrative expenses have increased are expected to continue to increase due to increases in professional and advisory fees as a result of the proposed Merger.

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.

Warrant Liability, Change in Fair Value and Warrant Conversion

We evaluated the warrants issued in connection with the May 2022 registered direct financing in accordance with ASC 815-40, *Derivatives and Hedging — Contracts in Entity's Own Equity (ASC 815-40)*, and concluded that a provision in the warrants related to the reduction of the exercise price in certain circumstances precludes the warrants from being accounted for as components of equity. As the warrants meet the definition of a derivative as contemplated in ASC 815, the warrants are recorded as derivative liabilities on the Balance Sheets and measured at fair value at inception and at each reporting date in accordance with ASC 820, Fair Value Measurement, with changes in fair value recognized in the accompanying Statements of Operations and Comprehensive Loss in the period of change. The derivative liabilities will ultimately be converted into our common stock when the warrants are exercised, or will be extinguished upon expiry of the warrant term. Upon exercise, the intrinsic value of the shares issued will be transferred to stockholders' equity. The difference between the intrinsic value of the stock issued and the fair value of the warrant is recorded as gain or loss on the exchange in the accompanying Statements of Operations and Comprehensive Loss in the period of exercise.

Interest Income (Expense), net

Interest income (expense), net, consists of interest earned on our cash, cash equivalents and marketable securities held with institutional banks, the amortization of discounts and accretion of 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, 2022, we adopted ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*. ASU 2020-06 address issues identified as a result of the complexity associated with applying generally accepted accounting principles (GAAP) for certain financial instruments with characteristics of liabilities and equity.The amendments focused on amending the guidance on convertible instruments and the guidance on the derivatives scope exception for contracts in an entity's own equity. The adoption of this standard did not have a material impact on our 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.

Emerging Growth Company Status

Vallon is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and may remain an emerging growth company for up to five years. For so long as Vallon remains an emerging growth company, Vallon is permitted and intends to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- reduced disclosure about its executive compensation arrangements;
- no non-binding stockholder advisory votes on executive compensation or golden parachute arrangements; and

- exemption from the auditor attestation requirement in the assessment of its internal control over financial reporting.

Vallon has taken advantage of reduced reporting requirements in this Annual Report and may continue to do so until such time that we are no longer an emerging growth company. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Therefore, Vallon may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. Vallon will remain an emerging growth company until the earliest of (a) the last day of the fiscal year in which it has total annual gross revenues of $1.235 billion or more, (b) December 31, 2026, the last day of the fiscal year following the fifth anniversary of the completion of the IPO, (c) the date on which it has issued more than $1.0 billion in nonconvertible debt during the previous three years or (d) the date on which Vallon is deemed to be a large accelerated filer under the rules of the SEC. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table sets forth our results of operations for the year ended December 31, 2022 compared to the year ended December 31, 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 1,170	$ 5,187
General and administrative	5,758	4,072
Total operating expenses	6,928	9,259
Loss from operations	(6,928)	(9,259)
Other income	—	61
Change in fair value of derivative liability	—	(89)
Change in warrant liability	384	—
Loss on warrant conversion	(506)	—
Interest expense, net	26	(16)
Net loss	$ (7,024)	$ (9,303)

Research and Development Expenses

Research and development expenses were $1.2 million and $5.2 million for the years ended December 31, 2022 and 2021, respectively. The $4.0 million decrease in research and development expenses was primarily due to decreases of $3.3 million in expenses related to the registration development program of ADAIR, $0.4 million in personnel expense, including non-cash stock compensation, of $0.3 million, $0.2 million in consulting fees, and a decrease of $0.1 million in expenses related to the formulation work for ADMIR.

General and Administrative Expenses

General and administrative expenses were $5.8 million and $4.1 million for the years ended December 31, 2022 and 2021, respectively. The $1.7 million increase was primarily related to increased costs as a result of our evaluation of strategic alternatives.

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 as a result of 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, resulting in an $89,000 decrease in the fair value of the derivative liability associated with the 2021 Convertible Notes.

Change in Fair Value of Warrant Liability and Loss on Warrant Conversion

In May 2022, we issued 3,700,000 shares of common stock pursuant to a securities purchase agreement at a purchase price of $1.0632 per share in a registered direct offering. In connection with the registered direct offering, we issued warrants to purchase an aggregate of 3,700,000 shares of common stock at an exercise price of $0.9382 per share (May 2022 Warrant Agreement). The warrants were classified as a liability in accordance with ASC 815-40 and the fair value of $1.3 million was recorded as a liability at inception.

The May 2022 Warrant Agreement entitled the holders to receive one share of common stock for each warrant in lieu of the aggregate number of shares of common stock that would have been received using the cashless exercise formula set forth in the May 2022 Warrant Agreement (Alternate Cashless Exercise). In July 2022, we amended the terms of the May 2022 Warrant Agreement to obligate each warrant holder who signed the warrant amendment (Applicable Holder) to effect an Alternate Cashless Exercise, in whole, by August 10, 2022 (the Expiration Date). If the warrants held by the Applicable Holders were not exercised by the Expiration Date, they were automatically exercised pursuant to the Alternate Cashless Exercise. A total of 2,220,000 warrants were exercised pursuant to the May 2022 Warrant Agreement amendment. In December 2022, an additional 740,000 warrants were exercised pursuant to the Alternate Cashless Exercise under the original terms of the May 2022 Warrant Agreement. As a result of the warrant conversions, we recognized a $0.8 million reversal of the warrant liability and a loss of $0.5 million.

The change in fair value of $0.4 million represents a decrease in the fair value of the warrants outstanding during the year ended December 31, 2022.

Interest Income (Expense), net

Interest income, net, was $26,000 for the year ended December 31, 2022. Interest expense, net, was $16,000 for the year ended December 31, 2021.

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 $7.0 million and $9.3 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $28.9 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, 2022, we had $3.8 million in cash and cash equivalents.

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

	Year Ended December 31,	
	2022	2021
Net cash provided by (used in):		
Operating activities	$ (7,135)	$ (8,312)
Investing activities	3,782	(3,842)
Financing activities	3,432	15,747
Net increase in cash and cash equivalents	$ 79	$ 3,593

Cash Flows from Operating Activities

For the years ended December 31, 2022 and 2021, $7.1 million and $8.3 million were used in operating activities, respectively. The $1.2 million decrease was primarily due to a $2.3 million decrease in our net loss and a decrease of $0.5 million in cash used for prepaid and other expenses and accounts payable, offset by a $0.4 million decrease in non-cash adjustments, including stock based compensation expense, the change in fair value of the warrant liability, and the loss on warrant conversion, and a $1.3 million increase in cash used for the payment of accrued expenses.

Cash Flows from Investing Activities

Net cash provided by investing activities was $3.8 million for the year ended December 31, 2022, which was primarily related to the maturities of marketable securities. 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.

Cash Flows from Financing Activities

Net cash provided by financing activities was $3.4 million during the year ended December 31, 2022, which was related to which was related to the net proceeds from the registered direct financing in May 2022. Net cash provided by financing activities was $15.7 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

To date, we have not generated any revenue from the sale of any products. Substantially all of our revenue to date has been generated by the Medice license agreement from which we received a $0.1 million license fee in January 2020. We do not know when, or if, we will generate any revenue. In March 2022, we announced that the SEAL study of ADAIR for the treatment of ADHD did not meet statistical significance for its primary endpoint and that we are evaluating our strategic alternatives with the goal of maximizing stockholder value. While assessing the best path forward for the ADAIR and ADMIR development programs in relation to the results of the SEAL study, we engaged Ladenburg to evaluate our strategic alternatives with the goal of maximizing stockholder value. On December 13, 2022, Vallon and GRI Bio, Inc. (GRI) entered into an Agreement and Plan of Merger, pursuant to which a wholly-owned subsidiary of Vallon will merge with and into GRI, with GRI surviving as a wholly-owned subsidiary of Vallon. The Merger will result in a clinical-stage biotechnology company focused on discovering, developing, and commercializing innovative therapies targeting serious diseases associated with dysregulated immune responses that lead to inflammatory, fibrotic, and autoimmune disorders.

Although we have entered into the Merger Agreement and intend to consummate the transaction, there is no assurance that we will be able to successfully consummate the proposed merger on a timely basis, or at all. If, for any reason, the merger is not completed, we will reconsider our strategic alternatives and could pursue one or more of the following courses of action:

- Dissolve and liquidate our assets. If, for any reason, the merger is not consummated and we are unable to identify and complete an alternative strategic transaction like a merger or potential collaborative, partnering or other strategic arrangements for our assets, or continue to operate our business due to the inability to raise additional funding, we may be required to dissolve and liquidate our assets. In such case, there can be no assurances as to the amount or timing of available cash left to distribute to our stockholders, if any, after paying our debts and other obligations and setting aside funds for reserves.
- Pursue potential collaborative, partnering or other strategic arrangements for our assets, including a sale or other divestiture.
- Continue to operate our business. Although presently not anticipated, we could elect to continue to operate our business and pursue licensing or partnering transactions. Based on our prior assessment, this would require a significant amount of time, financial resources, human capital and we would be subject to all the risk and uncertainties involved in the development of product candidates. In such instance, there is no assurance that we could raise sufficient capital to support these efforts, that our development efforts would be successful or that we could successfully obtain the regulatory approvals required to market any product candidate we pursued.
- Pursue another strategic transaction like the proposed merger.

Our ability to continue as a going concern is dependent on raising capital from the sale of our common stock and/or obtaining debt financing. Our future capital requirements are difficult to forecast and will depend on many factors, including but not limited to the closing of the Merger or the terms and timing of any other strategic alternatives including a merger or business combination, asset acquisitions or sales, collaborations or licensing arrangements. Our ability to remain a going concern is wholly dependent upon our ability to continue to obtain sufficient capital to fund our operations.

Despite our ability to secure capital in the past, there can be no assurance that additional equity or debt financing will be available to us when needed or that we may be able to secure funding from any other sources. In the event that we are not able to secure funding, we may be forced to curtail operations, delay or stop ongoing clinical trials, cease operations altogether, or file for bankruptcy.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any equity or debt financing may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to other parties' rights to develop or commercialize our drug candidates that we would prefer to retain. Therefore, there is substantial doubt about our ability to continue as a going concern. We expect to continue to incur expenses and operating losses at least for the foreseeable future as we evaluate future plans for the ADAIR and ADMIR programs as well as our strategic alternatives.

See the "Risk Factors" section of this Annual Report for additional risks associated with our substantial capital requirements.

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 did not have during the periods presented, and do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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 Annual 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, 2022.

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, 2022. 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, 2022, our internal control over financial reporting was effective.

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

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

As previously disclosed, on June 27, 2022, the Company received notice from the Listing Qualifications Department of Nasdaq indicating that, because the closing bid price for the Company's common stock had fallen below $1.00 per share over the previous 30 consecutive business days, the Company no longer complied with the minimum bid price requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) (the Bid Price Rule). Nasdaq's notice had no immediate effect on the listing of the Company's common stock on The Nasdaq Capital Market. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), Nasdaq provided the Company with an initial compliance period of 180 calendar days, or until December 27, 2022, to regain compliance with the Bid Price Rule.

On December 28, 2022, having not regained compliance with the Bid Price Rule, the Company received a letter from the Staff notifying the Company that, unless the Company timely requests a hearing, the Company's common stock would be scheduled for delisting from The Nasdaq Capital Market and would be suspended at the opening of business on January 6, 2023. According to the letter from Nasdaq, the Company had not regained compliance with the Bid Price Rule and was not eligible for a second 180 day extension period because the Company did not comply with the minimum $5.0 million stockholders' equity initial listing requirement for The Nasdaq Capital Market.

Accordingly, the Company filed an appeal and requested a hearing before the Nasdaq Hearings Panel (the Panel). The hearing request resulted in a stay of any suspension or delisting action pending the hearing and the expiration of any extension period granted by the Panel following the hearing. In that regard, the Panel had the right to grant the Company an extension to regain compliance with the Bid Price Rule. The hearing before the Panel was held on February 16, 2023. The Panel reached a decision on February 21, 2023, and informed the Company that it was granting the Company's request for a stay of delisting procedures on The Nasdaq Stock Market until April 28, 2023, subject to the Company meeting certain conditions, including the Company having completed the Merger and having satisfied all initial listing requirements of The Nasdaq Stock Market on or before April 28, 2023. The Panel stated that it based its decision on the efforts made by the Company thus far to complete the Merger and the associated proposed reverse stock split and the relatively short duration of the requested exception period. There can be no assurance that the Company will be able to regain compliance with all applicable requirements for continued listing or the conditions required by the Panel.

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	59	President, Chief Executive Officer and Director *(Principal Executive Officer)*
Leanne Kelly	46	Chief Financial Officer *(Principal Financial and Accounting Officer)*
Non-Employee Directors and Director Nominee		
Marella Thorell[(1)]	55	Director, Chair of the Board
Joseph Payne[(1)(2)(3)]	51	Director
Richard Ammer	52	Director
Meenu Karson[(1)(3)]	55	Director
Key Consultant		
Timothy Whitaker, M.D.	64	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 $74 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.

Non-Executive Directors

Marella Thorell joined our board of directors on February 12, 2021 and has served as the chairperson of the board of directors since July 1, 2022. 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 Financial Officer of Evelo Biosciences, Inc. (Nasdaq: EVLO). Prior to joining Evelo Biosciences, Inc., Ms. Thorell was 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.

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.

Meenu Karson has served as a director since February 2022 and is the chairperson of our audit committee and nominating and corporate governance committee. Ms. Karson brings over two decades of experience in various leadership roles in the life sciences and biotechnology industries. Most recently, she served as President and Chief Executive Officer of Proteostasis Therapeutics, Inc. a clinical stage biopharmaceutical company focused on the discovery and development of novel therapeutics

to treat cystic fibrosis (CF) from May 2014 until December 2020. She let Proteostasis Therapeutics, Inc. through a successful IPO and raised over $300 million to advance the CF pipeline from discovery to successful completion of Phase 2 studies with three novel CFTR modulators delivered as a proprietary combination enabling the first ever personalized medicine registrational study for CF. She also led the strategic merger of Proreostasis Therapeutics, Inc. with Yumanity Therapeutics, Inc. in December 2020. From 2007 to 2014, Ms. Karson was President and Chief Executive Officer at Allozyne, Inc. Prior to her time at Allozyne, Inc., she served as the Chief Business Officer at BioXell SpA, a spin-off from Roche Pharmaceuticals where she led corporate development and financing activities. Ms. has also held roles of increasing responsibility at Novartis, Fresenius Kabi AG, Warner-Lambert Company, LLC, and Bristol-Myers Squibb Company. Currently, she serves on the board of Vasomune Therapeutics, Inc., a clinical stage biopharmaceutical company focused on the treatment of acute respiratory distress syndrome and is on the Board of Directors for the Biotechnology Innovation Organization (BIO) on its Emerging Companies Section Board. She obtained her M.B.A. from York University and her B.Sc. from the University of Toronto.

We believe Ms. Karson's extensive experience in the biopharmaceuticals industry and as the chief executive officer of a biopharmaceutical company 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 director is David Baker, and his term expires at the annual meeting of stockholders to be held in 2024;
- the Class II directors are Richard Ammer and Marella Thorell, and their term expires at the annual meeting of stockholders to be held in 2025; and

- the Class III directors are Joseph Payne and Meenu Karson, and their term expires at the annual meeting of stockholders to be held in 2023.

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 Marella Thorell, Joseph Payne and Meenu Karson, 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 Meenu Karson, 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 ($)	Stock Awards ($)[1]	Option Awards ($)[2]	Non-Equity Incentive Compensation ($)[3]	All Other Compensation ($)	Total ($)
David Baker	2022	417,266	20,820	251,494	210,000	24,183 [4]	923,764
President and Chief Executive Officer	2021	391,553	—	259,136	150,000	26,191 [4]	826,880
Leanne M. Kelly	2022	283,893	20,820	210,428	150,000	8,400 [5]	673,541
Chief Financial Officer	2021	177,604	—	259,136	55,772	6,347 [5]	498,859
Penny S. Toren	2022	82,437	—	84,171	—	131,729 [5][7]	298,337
Senior Vice President, Regulatory Affairs & Program Management	2021	256,871	—	64,784	30,174	7,544 [5]	359,373

(1) The amounts in this column represent the aggregate grant date fair value of the restricted stock units (RSUs) 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 Vallon's audited financial statements (Note 3. *Summary of Significant Accounting Policies -Stock-based compensation* and Note 11. *Stock-based Compensation*) included in this Annual Report on Form 10-K for the year-ended December 31, 2022. In accordance with SEC rules, the grant date fair value of any award subject to a performance condition is based upon the probable outcome of the performance conditions. RSU awards with performance conditions that have been deemed not probable of achievement as of the grant date have not been included in this column as no compensation expense has been recognized under ASC Topic 718 during the year ended December 31, 2022. In December 2022, the RSU awards granted to Mr. Baker and Ms. Kelly were cancelled. Compensation expense equal to the grant date fair value of the cancelled awards expected to vest at the date of cancellation was recognized under ASC Topic 718. No RSUs were granted to Ms. Toren.

(2) 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 Vallon's audited financial statements (Note 3. *Summary of Significant Accounting Policies -Stock-based compensation* and Note 11. *Stock-based Compensation*) included in this Annual Report on Form 10-K for the year-ended December 31, 2022..

(3) 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 "Executive Compensation of Vallon -Elements of Compensation -Non-Equity Incentive Plan Compensation" below.

(4) The amounts reflect matching contributions to the named executive officer's account under Vallon's SIMPLE IRA plan, an auto allowance and amounts paid with respect to short and long-term disability and life insurance for the benefit of the named executive officer. The amounts reflect SIMPLE IRA matching contribution of $10,200 and $12,000 for 2022 and 2021, respectively; an auto allowance of $6,000 in both 2022 and 2021, and insurance benefits of $7,983 in both 2022 and 2021.

(5) The amounts reflect matching contributions to the named executive officers' accounts under our SIMPLE IRA plan.

(6) On April 19, 2022, Penny S. Toren's position as Senior Vice President, Regulatory Affairs & Project Management of Vallon was eliminated, effective immediately.

(7) Amounts include severance payments of $129,500 as a result of the elimination of the named executive officer's position on April 19, 2022.

Elements of Compensation

2022 Base Salaries

Effective as of March 1, 2022, Mr. Baker's annual salary was increased to $420,000, Ms. Kelly's salary was increased to $285,500 and Ms. Toren's annual salary was increased to $259,000.

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 2022, the target bonus opportunities for Mr. Baker and Ms. Kelly, expressed as a percentage of base salary, were 50%,and 35% , 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 2022, the corporate objectives, consisted primarily of: (i) fundraising; (ii) exploration of strategic alternatives; (iii) opening and IND for ADMIR; (iv) execution of key non-clinical studies; and (v) manufacture of ADAIR. Based on the results of the SEAL Study, reported in March 2022, these corporate objectives were revised to focus on cash preservation and strategic alternatives. .In the first quarter of 2023, 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 100% of the target bonus opportunity, subject to adjustments for personal performance. Actual bonus amounts earned with respect to 2022 are reflected in the "Non-Equity Incentive Compensation" column of the Summary Compensation Table above. As a result of the elimination of her position, Ms.Toren did not earn a bonus in 2022.

In addition to annual performance bonuses, in December 2022, each of Mr. Baker and Ms. Kelly were granted a bonus of $75,000 to be paid upon the closing of the Merger subject to the executive's continued employment at the date of closing.

Option Awards and Restricted Stock Units Granted During 2022

On February 15, 2022, each of Mr. Baker, Ms. Kelly and Ms. Toren was granted a non-qualified stock option to purchase 61,000, 50,000 and 20,000 shares of our common stock, respectively, with an exercise price of $5.63 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 February 15, 2023, with the remainder vesting in equal quarterly installments thereafter through February 15, 2026. As a result of the elimination of her position, Ms.Toren's 2022 option grant was forfeited.

On May 16, 2022, Mr. Baker and Ms. Kelly were each granted 75,000 restricted stock units of our common stock. Vesting of the restricted stock units was subject to the achievement of certain milestones. In December 2022, the restricted stock units granted to Mr. Baker and Ms. Kelly were cancelled.

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 2022, 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 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 either 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 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 continued base salary for six months. Ms. Toren's employment was terminated without cause on April 19, 2022, and she therefore was entitled to receive this severance payment on the terms, and subject to the conditions, of her employment.

Outstanding Equity Awards at Fiscal Year-End

Stock and Stock Option Awards

The following table sets forth information concerning the outstanding equity awards for each of our named executive officers as of December 31, 2022. All equity awards granted to our named executive officers were made pursuant to our 2018 Equity Incentive Plan.

	Option Awards[6]					Stock Awards[6]	
Name	Number of Securities Underlying Unexercised, Options (#) Exercisable	Number of Securities Underlying Unexercised, Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units, or Other Rights That Have Not Vested ($)
David Baker	46,875	—	—	1.84	10/1/2028		
	61,250	—	—	2.20	2/5/2029		
	—	—	37,500 [1]	4.72	5/22/2030		
	37,500	62,500 [2]	—	3.66	5/14/2031		
	—	61,000 [3]	—	5.63	2/15/2032	— [5]	—
Leanne Kelly	26,250	43,750 [4]	30,000 [4]	3.66	5/14/2031		
	—	50,000 [3]	—	5.63	2/15/2032	— [5]	—

(1) The stock option award will vest upon satisfaction of certain performance milestones.
(2) 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 Vallon.
(3) The stock options award will vest 25% on the first anniversary of the vesting start date (February 15, 2022) and 6.25% (1/16th of such shares) for each subsequent full quarter that the executive remains employed with Vallon.
(4) 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.
(5) On May 16, 2022, Mr. Baker and Ms. Kelly were each granted 75,000 restricted stock units of our common stock. Vesting of the restricted stock units was subject to the achievement of certain milestones. In December 2022, the restricted stock units granted to Mr. Baker and Ms. Kelly were cancelled.
(6) Penny S. Toren's position was eliminated on April 19,2022 and all outstanding stock option awards were forfeited. Ms. Toren had no outstanding option or stock awards as of December 31, 2022.

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.

In January 2022, and effective as of July 1, 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 corporate governance committee of $5,000. In addition, the director serving as chairperson of the board as of July 1 of any calendar year will be automatically granted a restricted stock unit award with a value of $20,000. The number of restricted stock units granted will be based on the average closing per-share price of the Company's common stock for the 30 trading days immediately preceding the date of grant and shall vest in equal quarterly installments over one year. 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. A non-employee director who (i) is serving on the Board as of the date of any annual meeting of our stockholders after July 2, 2022 and has been serving as a non-employee director for at least six months as of the date of such meeting, and (ii) will continue to serve as a non-employee director immediately following such meeting, shall be automatically granted an option grant to purchase 7,500 shares on the date of such annual meeting, which generally will vest in quarterly installments over one year. Non-employee directors generally may elect to receive the $30,000 annual retainer in an award of a stock option in lieu of cash.

The following table provides information on compensation paid to our non-employee directors in 2022:

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)[1]	Option Awards ($)[2][7]	Total ($)
Richard Ammer	15,123	—	3,005 [3]	18,129
Meenu Karson	25,205	—	83,687 [4]	108,893
Ofir Levi[5]	—	—	—	—
Joseph Payne	20,164	—	3,005 [3]	23,169
Marella Thorell	32,479	23,574 [6]	3,005 [3]	35,484

(1) The amounts in this column represent the aggregate grant date fair value of the RSUs 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 Vallon's audited financial statements (Note 3. *Summary of Significant Accounting Policies -Stock-based compensation* and Note 11. *Stock-based Compensation*) included in our Annual Report on Form 10-K for the year-ended December 31, 2022, as filed with the SEC.

(2) 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 3. Summary of Significant Accounting Policies - Stock-based compensation and Note 11. Stock-based Compensation) included in this Annual Report on Form 10-K for the year-ended December 31, 2022.

(3) Options to purchase 7,500 shares of common stock were granted on June 9, 2022 and vest quarterly over a 12-month period.

(4) Options to purchase 15,000 shares of common stock were granted on February 23, 2022 which vest monthly over a 24-month period..

(5) Dr. Levi resigned from the Company's Board of Directors on March 28, 2022.

(6) Includes 38,023 RSUs granted on July 1, 2022 which vest quarterly over a 12-month period. In December 2022, 28,517 unvested RSUs were cancelled.

(7) The following table shows the aggregate number of outstanding shares of common stock underlying outstanding option and stock awards held by our non-employee directors as of December 31, 2022:

Name	Outstanding Option Awards	Outstanding Stock Awards
Richard Ammer	32,704	—
Meenu Karson	15,000	—
Joseph Payne	36,786	—
Marella Thorell	22,500	—

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, 2022, 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, 2022. 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 13,482,342 shares of common stock deemed to be outstanding as of December 31, 2022.

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	11.3%
FGP Protective Opportunity Master Fund LP[2]	1,480,000	11.0%
Lincoln Park Capital Fund, LLC[3]	1,480,000	11.0%
Armistice Capital Master Fund Ltd.[4]	1,480,000	10.4%
Arcturus Therapeutics, Inc. (fka successor to Arcturus Therapeutics Ltd.)[5]	843,750	6.3%
Lind Global Fund II LP[6]	740,000	5.5%
Lind Global Macro Fund LP[7]	740,000	5.5%
Bigger Capital Fund LP[8]	738,498	5.5%
Directors and Named Executive Officers[9]		
David Baker[10]	175,968	1.3%
Leanne Kelly[11]	49,375	*
Richard Ammer[12]	1,550,876	11.5%
Joseph Payne[13]	892,411	6.6%
Marella Thorell[14]	28,256	*
Meenu Karson[15]	7,500	*
All directors and named executive officers as a group (6 persons)	2,704,386	19.6%

* Represents beneficial ownership of less than one percent of our outstanding common stock.

(1) The address of the principal business office of SALMON Pharma GmbH is Sankt-Jakobs-Strasse 90, CH-9002 Basel, Switzerland.

(2) Consists of 740,000 shares of common stock purchased by FGP Protective Opportunity Master Fund LP directly from Vallon in a registered direct offering of common stock on May 17, 2022 and a warrant to purchase 740,000 shares of common stock common stock purchased by FGP Protective Opportunity Master Fund LP directly from Vallon in a concurrent private placement. The address of the principal business office of FGP Protective Opportunity Master Fund LP is 94 Solaris Avenue, 2nd Floor, Camana Bay, PO box 30745, Grand Cayman.

(3) Based on the Schedule 13G filed by Lincoln Park Capital Fund, LLC ("LPC Fund") on May 18, 2022. Consists of 740,000 shares of Common Stock purchased by LPC Fund directly from Vallon in a registered direct offering of Common Stock on May 17, 2022 (the "Registered Direct Offering") and a

warrant to purchase 740,000 shares of common stock (the "Warrant") purchased by LPC Fund directly from the Issuer in a concurrent private placement (the "Private Placement"). The Warrant, however, contains a 9.99% contractual cap on the amount of outstanding shares of the Issuer's common stock that LPC Fund may own upon exercise of such Warrant. Therefore, the number of shares of the Issuer's common stock beneficially owned by LPC Fund under the Warrant as of the date of the filing was 310,232 shares, which, when combined with the 740,000 shares of Common Stock owned as of May 18, 2022, is 9.99% of the 10,512,836 shares that were outstanding on that date (as reported in the Vallon's prospectus supplement filed on May 13, 2022). The shares outstanding includes the 740,000 shares of Common Stock of the Issuer owned directly by LPC Fund, but does not include any shares issuable upon exercise of the Warrant issued to LPC Fund or any other investor in the Private Placement. The address of the principal business office of Lincoln Park Capital Fund, LLC is 440 North Wells, Suite 410, Chicago, Illinois 60654.

(4) Consists of 740,000 shares of common stock purchased by Armistice Capital Master Fund Ltd directly from Vallon in a registered direct offering of common stock on May 17, 2022 and a warrant to purchase 740,000 shares of common stock common stock purchased by Armistice Capital Master Fund Ltd directly from Vallon in a concurrent private placement. The address of the principal business office of Armistice Capital Master Fund Ltd. is 510 Madison Avenue, 7th Floor, New York, New York, 10022.

(5) The address of the principal business office of Arcturus Therapeutics Ltd is 10628 Science Center Drive, Suite 250, San Diego, California 92121.

(6) Based on the 13G filed by Lind Global Fund II LP on May 23, 2022. Consists of 370,000 shares of common stock purchased by Lind Global Fund II LP directly from Vallon in a registered direct offering of common stock on May 17, 2022 and a warrant to purchase 370,000 shares of common stock purchased by Lind Global Fund II LP directly from Vallon in a concurrent private placement. The address of the principal business office of Lind Global Fund II LP is 444 Madison Avenue, Floor 41, New York, New York 10022.

(7) Based on the 13G filed by Lind Global Macro Fund LP on May 23, 2022. Consists of 370,000 shares of common stock purchased by Lind Global Macro Fund LP directly from Vallon in a registered direct offering of common stock on May 17, 2022 and a warrant to purchase 370,000 shares of common stock purchased by Lind Global Macro Fund LP directly from Vallon in a concurrent private placement. The address of the principal business office of Lind Global Macro Fund LP is 444 Madison Avenue, Floor 41, New York, New York 10022.

(8) Based on the Schedule 13G filed by Bigger Capital Fund, LP ("Bigger Capital") on May 23, 2022. Consists of 368,498 shares of common stock and 370,000 shares of common stock issuable upon exercise of warrants. Both Bigger Capital Fund GP, LLC ('Bigger GP"), the general partner of Bigger Capital and Michael Bigger, the managing member of Bigger GP, may be deemed to beneficially own the he 368,498 shares of common stock and 370,000 shares of common stock issuable upon exercise of warrants beneficially owned by Bigger Capital. Each of Bigger GP and Mr. Bigger disclaims beneficial ownership of the shares of common stock beneficially owned by Bigger Capital. The address of the principal business office of Bigger Capital is 2250 Red Springs Drive, Las Vegas, Nevada 89135.

(9) 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.

(10) Consists of (i) 8,843 shares of common stock and (ii) 167,125 shares of common stock issuable pursuant to stock options exercisable within 60 days of December 31, 2022.

(11) Consists of (i) 6,250 shares of common stock and (ii) 43,125 shares of common stock issuable pursuant to stock options exercisable within 60 days of December 31, 2022.

(12) 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) 27,079 shares of common stock issuable pursuant to stock options exercisable within 60 days of December 31, 2022.

(13) 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) 31,161 shares of common stock issuable pursuant to stock options exercisable within 60 days of December 31, 2022.

(14) Consists of (i) 9,506 shares of common stock and (ii) 18,750 shares of common stock issuable pursuant to stock options exercisable within 60 days of December 31, 2022.

(15) Includes 7,500 shares of common stock issuable pursuant to stock options exercisable within 60 days of December 31, 2022.

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, 2022 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]	694,240	$ 3.94	189,789
Equity compensation plans not approved by security holders	—	$ —	—
Total	694,240	$ 3.94	189,789

(1) Includes shares of our common stock under our 2018 Equity Incentive Plan. For a description of this plan, refer to Note 11 to the financial statements included in this Annual Report on Form 10-K.

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, 2021, 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, 2022 and 2021; 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.

Medice

Medice, through its affiliated entity, Salmon Pharma, owns approximately 11.3% of our issued and outstanding shares of common stock, and accordingly controls approximately 11.3% 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. On May 17, 2022, the 2020 Voting Agreement terminated when Messrs. Malnik and Fiengold's collective beneficial ownership of Vallon common stock fell below 9.99%.

Equity Financings

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]		
SALMON Pharma GmbH[2]	$ 300,000	54,906

(1) Additional details regarding these stockholders and their equity holdings are provided in this Annual 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 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, 2022 and 2021 by us.

	December 31,	
	2022	2021
Audit Fees [1]	$ 224,962	$ 180,760
Audit Related Fees [2]	—	—
Tax Fees [3]	—	—
All Other Fees [4]	—	—
Total	$ 224,962	$ 180,760

(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
2.1	Agreement and Plan of Merger, dated as of December 13, 2022, by and among Vallon Pharmaceuticals, Inc., GRI Bio, Inc., and Vallon Merger Sub, Inc.	8-K	12/13/22	2.1
2.2	Amendment to Agreement and Plan of Merger, dated as of February 17, 2023, by and among Vallon Pharmaceuticals, Inc., GRI Bio, Inc., and Vallon Merger Sub, Inc.			
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
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Vallon Pharmaceuticals, Inc.	8-K	2/16/21	3.2
3.4	Amendment No. 1 to the Amended and Restated Bylaws of Vallon Pharmaceuticals, Inc.	8-K	5/18/22	3.1
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
4.6	Form of Bridge Warrant	8-K	12/13/22	4.1
4.7	Form of Equity Warrant	8-K	12/13/22	4.2
4.8	Form of Exchange Warrant	8-K	12/13/22	4.3
4.9	Registration Rights Agreement, by and between Vallon Pharmaceuticals, Inc. and the investor party thereto, dated December 13, 2022.	8-K	12/13/22	4.4
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
10.21	Placement Agency Agreement, dated May 13, 2022, between Vallon Pharmaceuticals, Inc. and Ladenburg Thalmann & Co., Inc.	8-K	5/13/22	10.1
10.22	Non-Employee Director Compensation Program of Vallon Pharmaceuticals, Inc., effective on June 9, 2022.	10-Q	7/28/22	10.2
10.23	Amendment No. 1 to Securities Purchase Agreement, dated July 25, 2022, by and among Vallon Pharmaceuticals, Inc. and each purchaser identified on the signature pages thereto	8-K	7/26/22	10.1
10.24	Form of Amendment No.1 to Common Stock Purchase Warrant	8-K	7/26/22	10.2
10.25	Form of Vallon Support Agreement, dated as of December 13, 2022, by and between GRI Bio, Inc. and each of the parties named in each agreement therein	8-K	12/13/22	10.1
10.26	Form of GRI Support Agreement, dated as of December 13, 2022, by and between Vallon Pharmaceuticals, Inc. and each of the parties named in each agreement therein.	8-K	12/13/22	10.2
10.27	Form of Lock-Up Agreement	8-K	12/13/22	10.3
10.28	Securities Purchase Agreement, dated December 13, 2022, by and between GRI Bio, Inc. and the investor party thereto	8-K	12/13/22	10.4
10.29	Securities Purchase Agreement, dated December 13, 2022, by and among Vallon Pharmaceuticals, Inc., GRI Bio, Inc. and the investor party thereto	8-K	12/13/22	10.5
10.30	Omnibus Amendment to Securities Purchase Agreements, dated February 17, 2023, by and among Vallon Pharmaceuticals, Inc., GRI Bio, Inc. and the investor party thereto			
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 23, 2023

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 23, 2023
/s/ Leanne Kelly Leanne Kelly	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 23, 2023
/s/ Marella Thorell Marella Thorell	Director, Chair of the Board	February 23, 2023
/s/ Joseph Payne Joseph Payne	Director	February 23, 2023
/s/ Richard Ammer Richard Ammer	Director	February 23, 2023
/s/ Meenu Karson Meenu Karson	Director	February 23, 2023

INDEX TO FINANCIAL STATEMENTS

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, 2022 and 2021, 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, 2022 and 2021, 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 23, 2023

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

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 3,781	$ 3,702
Marketable securities, available-for-sale	—	3,808
Prepaid expenses and other current assets	371	619
Total current assets	4,152	8,129
Other assets	—	206
Total assets	$ 4,152	$ 8,335
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 977	$ 918
Accrued expenses	711	1,430
Warrant liability	122	—
Other current liabilities	—	97
Total current liabilities	1,810	2,445
Other liabilities	—	72
Total liabilities	1,810	2,517
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.0001 par value; 250,000,000 shares authorized; 13,482,342 and 6,812,836 shares issued and outstanding as of December 31, 2022 and 2021, respectively	1	—
Additional paid-in-capital	31,267	27,722
Accumulated other comprehensive loss	—	(2)
Accumulated deficit	(28,926)	(21,902)
Total stockholders' equity	2,342	5,818
Total liabilities and stockholders' equity	$ 4,152	$ 8,335

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,	
	2022	2021
Operating expenses:		
Research and development	$ 1,170	$ 5,187
General and administrative	5,758	4,072
Total operating expenses	6,928	9,259
Loss from operations	(6,928)	(9,259)
Other income	—	61
Revaluation of derivative liability	—	(89)
Change in fair value of warrant liability	384	—
Loss on warrant conversion	(506)	—
Interest income (expense), net	26	(16)
Net loss	$ (7,024)	$ (9,303)
Other comprehensive loss:		
Unrealized gain (loss) on marketable securities, available-for-sale	2	(2)
Total comprehensive loss	$ (7,022)	$ (9,305)
Net loss per share of common stock, basic and diluted	$ (0.69)	$ (1.42)
Weighted-average common shares outstanding, basic and diluted	10,143,205	6,541,097

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 Gain (Loss)	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount				
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
Stock-based compensation expense	—	—	99	—	—	99
Issuance of common stock, net of offering expenses	3,700,000	1	2,160	—	—	2,161
Issuance of common stock upon warrant exercise	2,960,000	—	1,286	—	—	1,286
Vesting of restricted stock	9,506	—	—	—	—	—
Unrealized gain on marketable securities, available-for sale	—	—	—	2	—	2
Net loss	—	—	—	—	(7,024)	(7,024)
Balance, December 31, 2022	13,482,342	$ 1	$ 31,267	$ —	$ (28,926)	$ 2,342

See accompanying notes to financial statements.

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

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (7,024)	$ (9,303)
Adjustments to reconcile net loss to cash used in operating activities:		
Amortization of finance lease right-of-use asset	206	73
Amortization of marketable securities premiums	28	32
Stock-based compensation expense	99	626
Revaluation of derivative liability	—	89
Change in fair value of warrant liability	(384)	—
Loss on warrant conversion	506	—
Forgiveness of PPP note	—	(61)
Non-cash interest, depreciation and other expense	—	12
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	248	(55)
Accounts payable	(95)	(308)
Accrued expenses	(719)	583
Cash used in operating activities	(7,135)	(8,312)
Investing activities:		
Purchase of marketable securities	(640)	(3,842)
Maturities of marketable securities	4,422	—
Cash provided by (used in) investing activities	3,782	(3,842)
Financing activities:		
Proceeds from common stock issuance, net of offering expenses	3,447	15,104
Proceeds from issuance of warrants	—	399
Proceeds from convertible notes	—	350
Payment of finance lease liability	(15)	(106)
Cash provided by financing activities	3,432	15,747
Net increase in cash and cash equivalents	79	3,593
Cash and cash equivalents at beginning of period	3,702	109
Cash and cash equivalents at end of period	$ 3,781	$ 3,702
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 21	$ 29
Supplemental disclosure or noncash activities:		
Conversion of convertible notes to common stock	$ —	$ 350
Non-cash exercise of warrants	$ 782	$ —
Finance lease liability within accounts payable	$ 154	$ —

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 which has historically 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, was a proprietary, abuse-deterrent oral formulation of immediate-release dextroamphetamine (the main active ingredient in Adderall®), which was being developed for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) and narcolepsy. In March 2022, the Company announced that its Study to Evaluate the Abuse Liability, Pharmacokinetics, Safety and Tolerability of an Abuse-Deterrent d-Amphetamine Sulfate Immediate Release Formulation (SEAL) study for ADAIR did not reach its primary endpoint. In addition to ADAIR, the Company's second product candidate, ADMIR, an abuse deterrent formulation of methylphenidate (Ritalin®), was also being developed for the treatment of ADHD.

While assessing the best path forward for the ADAIR and ADMIR development programs in relation to the results of the SEAL study, the Company engaged Ladenburg Thalmann & Co. Inc. (Ladenburg) to evaluate its strategic alternatives with the goal of maximizing stockholder value. Ladenburg was engaged to advise on the strategic review process, which could have included, without limitation, exploring the potential for a possible merger, business combination, investment into the Company, or a purchase, license or other acquisition of assets. In conjunction with the exploration of strategic alternatives, the Company streamlined operations to preserve its capital and cash resources.

After conducting a diligent and extensive process of evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction, which included the receipt of 15 formal merger proposals from interested parties and careful evaluation and consideration of those proposals, and following extensive negotiation with a number of possible candidates, on December 13, 2022, Vallon and GRI Bio, Inc. (GRI) entered into an Agreement and Plan of Merger (the Merger Agreement), pursuant to which a wholly-owned subsidiary of Vallon will merge with and into GRI, with GRI surviving as a wholly-owned subsidiary of Vallon (the Merger). The Merger will result in a clinical-stage biotechnology company focused on discovering, developing, and commercializing innovative therapies targeting serious diseases associated with dysregulated immune responses that lead to inflammatory, fibrotic, and autoimmune disorders.

At the effective time of the Merger (the Effective Time), each share of common stock of GRI, $0.01 par value per share (GRI Common Stock) outstanding immediately prior to the Effective Time, excluding any dissenting shares but including any shares of GRI Common Stock issued pursuant to the concurrent equity financing will be automatically converted into the right to receive a number of shares of common stock of Vallon, $0.0001 par value per share (Vallon Common Stock) equal to the exchange ratio, subject to adjustment for the proposed reverse stock split of Vallon Common Stock to be implemented prior to the consummation of the Merger as discussed in this Annual Report (the Reverse Split). The exchange ratio may be adjusted based on Vallon's net cash at Closing and/or any reduction to Vallon's valuation required in order to meet the initial listing requirements of The Nasdaq Stock Market LLC (Nasdaq).

2. 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 $28,926 in accumulated deficit through December 31, 2022. 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.

On May 17, 2022, the Company entered into a Securities Purchase Agreement with certain investors (the Securities Purchase Agreement) for the sale of up to 3,700,000 shares of the Company's common stock, par value $0.0001 per share (the Shares), at a purchase price of $1.0632 per Share in a registered direct offering (the Offering). In a concurrent private placement also pursuant to the Securities Purchase Agreement (the Private Placement), for each Share of common stock purchased by an investor, such investor

was entitled receive from the Company an unregistered warrant (the Warrant and, together with the Shares, the Securities) to purchase one Share of common stock. The gross proceeds from the Offering and Private Placement were approximately $3,900, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company of approximately $572, of which $85 related to the warrants was expensed.

As of December 31, 2022, the Company had cash and cash equivalents of approximately $3,781.

Although the Company has entered into the Merger Agreement and intends to consummate the transaction, there is no assurance that the Company will be able to successfully consummate the proposed merger on a timely basis, or at all. If, for any reason, the Merger is not completed, the Company will reconsider its strategic alternatives and could pursue one or more of the following courses of action:

- Dissolve and liquidate its assets. If, for any reason, the merger is not consummated and the Company is unable to identify and complete an alternative strategic transaction like a merger or potential collaborative, partnering or other strategic arrangements for its assets, or continue to operate its business due to the inability to raise additional funding, the Company may be required to dissolve and liquidate our assets. In such case, there can be no assurances as to the amount or timing of available cash left to distribute to its stockholders, if any, after paying its debts and other obligations and setting aside funds for reserves.
- Pursue potential collaborative, partnering or other strategic arrangements for its assets, including a sale or other divestiture.
- Continue to operate its business. Although presently not anticipated, the Company could elect to continue to operate its business and pursue licensing or partnering transactions. Based on its prior assessment, this would require a significant amount of time, financial resources, human capital and is would be subject to all the risk and uncertainties involved in the development of product candidates. In such instance, there is no assurance that the Company could raise sufficient capital to support these efforts, that its development efforts would be successful or that the Company could successfully obtain the regulatory approvals required to market any product candidate we pursued.
- Pursue another strategic transaction like the proposed merger.

The Company's ability to continue as a going concern is dependent on raising capital from the sale of our common stock and/or obtaining debt financing. The Company's future capital requirements are difficult to forecast and will depend on many factors, including but not limited to the closing of the Merger or the terms and timing of any other strategic alternatives including a merger or business combination, asset acquisitions or sales, collaborations or licensing arrangements. The Company's ability to remain a going concern is wholly dependent upon its ability to continue to obtain sufficient capital to fund its operations.

If the Company raises additional funds by issuing equity securities, its stockholders may experience dilution. Any future debt financing may impose upon it covenants that restrict our operations, including limitations on its ability to incur liens or additional debt, pay dividends, repurchase its common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any equity or debt financing may contain terms that are not favorable to the Company or its stockholders. If the Company is unable to raise additional funds when needed, it may be required to delay, reduce or terminate some or all of its development programs and clinical trials. The Company may also be required to sell or license to other parties' rights to develop or commercialize its drug candidates that it would prefer to retain. Therefore, there is substantial doubt about the Company's ability to continue as a going concern. The Company expects to continue to incur expenses and operating losses at least for the foreseeable future.

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).

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 and subsequent revaluations, 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, 2022 and 2021 included investment in money market funds.

Marketable securities

Marketable securities consist of debt securities that are designated as available-for-sale. 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.

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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.

Warrant Liabilities, Change in Fair Value and Warrant Conversion

The Company evaluated the warrants issued in connection with the May 2022 registered direct financing (Note 10) in accordance with ASC 815-40, *Derivatives and Hedging — Contracts in Entity's Own Equity* (ASC 815-40), and concluded that a provision in the warrants related to the reduction of the exercise price in certain circumstances precludes the warrants from being accounted for as components of equity. As the warrants meet the definition of a derivative as contemplated in ASC 815, the warrants are recorded as derivative liabilities on the accompanying Balance Sheets and measured at fair value at inception and at each reporting date in accordance with ASC 820, *Fair Value Measurement*, with changes in fair value recognized in the accompanying Statements of Operations and Comprehensive Loss in the period of change. The derivative liabilities will ultimately be converted into the Company's common stock when the warrants are exercised, or will be extinguished upon expiry of the warrant term. Upon exercise, the intrinsic value of the shares issued is transferred to stockholders' equity. The difference between the intrinsic value of the stock issued and the fair value of the warrant is recorded as gain or loss on the exchange in the accompanying Statements of Operations and Comprehensive Loss in the period of exercise.

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.

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, 2022 and 2021, 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, 2022, the Company adopted ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*. ASU 2020-06 address issues identified as a result of the complexity associated with applying generally accepted accounting principles (GAAP) for certain financial instruments with characteristics of liabilities and equity.The amendments focused on amending the guidance on convertible instruments and the guidance on the derivatives scope exception for contracts in an entity's own equity. The adoption of this standard did not have a material impact on the Company's 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.

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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

The Company had no available-for-sale securities as of December 31, 2022.

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, *Fair Value Measurement*, 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: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liabilities.

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

As of December 31, 2022, the Company's financial instruments included cash and cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses, and the warrant liability. The carrying amounts reported in the balance sheets for cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair value based on the short-term maturity of these 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.

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The following table presents, for each of the fair value hierarchy levels required under ASC 820, the Company's liabilities that are measured at fair value on a recurring basis as of the dates indicated:

	As of December 31, 2022		
	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Liabilities:			
Warrant liability	$ —	$ —	$ 122

	As of December 31, 2021		
	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:			
Marketable securities, available-for-sale	$ —	$ 3,808	$ —

On May 17, 2022, the Company issued 3,700,000 shares of common stock pursuant to a securities purchase agreement at a purchase price of $1.0632 per share in a registered direct offering (Note 10). In connection with the registered direct offering, the Company issued warrants to purchase an aggregate of 3,700,000 shares of common stock at an exercise price of $0.9382 per share (May 2022 Warrant Agreement). The warrants were classified as a liability in accordance with ASC 815-40 and the fair value of $122 is reflected in warrant liability on the accompanying Balance Sheets. The warrant liability was measured at fair value at inception and is revalued at each financial statement date, with changes in fair value presented within change in fair value of warrant liability in the accompanying Statements of Operations and Comprehensive Loss.

The May 2022 Warrant Agreement entitled the holders to receive one share of common stock for each warrant in lieu of the aggregate number of shares of common stock that would have been received using the cashless exercise formula set forth in the May 2022 Warrant Agreement (Alternate Cashless Exercise) at a specified future date. In July 2022, the Company amended the terms of the May 2022 Warrant Agreement to obligate each warrant holder who signed the warrant amendment (Applicable Holder) to effect an Alternate Cashless Exercise, in whole, by August 10, 2022 (the Expiration Date). If the warrants held by the Applicable Holders were not exercised by the Expiration Date, they were automatically exercised pursuant to the Alternate Cashless Exercise. A total of 2,220,000 warrants were exercised pursuant to the May 2022 Warrant Agreement amendment. In December 2022, an additional 740,000 warrants were exercised pursuant to the Alternate Cashless Exercise under the original terms of the May 2022 Warrant Agreement. As a result of the warrant conversions, the Company recognized a $782 reversal of the warrant liability.

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The following table presents the changes is the fair value of the Level 3 liability:

	Warrant Liability
Fair value as of December 31, 2021	$ —
Initial measurement on May 17, 2022	1,288
Warrant conversion	(782)
Change in valuation	(384)
Balance as of December 31, 2022	$ 122

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

	(Initial Measurement) May 17, 2022	December 31, 2022
Volatility	130.8 %	133.3 %
Expected term in years	2.5	2.5
Dividend rate	0.0 %	0.0 %
Risk-free interest rate	2.665 %	4.240 %

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.

5. LEASES

The Company had 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 was based on the non-cancellable period in the lease contract. 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	2022	2021
Non-current finance lease assets	Other assets	$ —	$ 206
Finance lease liabilities:			
Current finance lease liabilities	Other current liabilities	—	97
Non-current finance lease liabilities	Other liabilities	—	72
Total finance lease liabilities		$ —	$ 169

During the year ended December 31, 2022, the remaining payments due under the Company's financing lease were accelerated and included in accounts payable. As a result, as of December 31, 2022, the Company had no finance lease assets or liabilities.

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

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	Year Ended December 31,	
	2022	2021
Operating cash flows from finance lease amortization	$ 206	$ 73
Financing cash flows from finance lease payments	$ 15	$ 106

6. ACCRUED EXPENSES

Accrued expenses consisted of:

	December 31,	
	2022	2021
Accrued expenses:		
Research and development	$ 42	$ 894
General and administrative	268	183
Payroll and related	401	291
Licensing related	—	62
Total accrued expenses	$ 711	$ 1,430

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 $21 and $24 for the years ended December 31, 2022 and 2021, 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.

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

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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.

On May 17, 2022, the Company sold 3,700,000 shares of common stock pursuant to a securities purchase agreement at a purchase price of $1.0632 per share in a registered direct offering (the Offering). The gross proceeds from the Offering were approximately $3,900, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company of approximately $572 of which $85 related to the warrants was expensed.

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 warrants were classified as equity and the fair value of $399 is reflected as additional paid-in capital. 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 %

In connection with the Offering, the Company issued warrants to purchase an aggregate of 3,700,000 shares of common stock at an exercise price of $0.9382 per share (May 2022 Warrant Agreement). The warrants have a five-year term. The warrants were classified as a liability and are revalued at each balance sheet date.

The May 2022 Warrant Agreement entitled the holders to receive one share of common stock for each warrant in lieu of the aggregate number of shares of common stock that would have been received using the cashless exercise formula set forth in the May 2022 Warrant Agreement (Alternate Cashless Exercise). In July 2022, the Company amended the terms of the May 2022 Warrant Agreement to obligate each warrant holder who signed the warrant amendment (Applicable Holder) to effect an Alternate Cashless Exercise, in whole, by August 10, 2022 (the Expiration Date). If the warrants held by the Applicable Holders were not exercised by the Expiration Date, they were automatically exercised pursuant to the Alternate Cashless Exercise. A total of 2,220,000 warrants were exercised pursuant to the May 2022 Warrant Agreement amendment. In December 2022, an additional 740,000 warrants were exercised pursuant to the Alternate Cashless Exercise under the original terms of the May 2022 Warrant Agreement. As a result of the warrant conversions, the Company recognized a $782 reversal of the warrant liability and a loss of $506. The fair value of $122 as of December 31, 2022 is reflected in warrant liability on the accompanying Balance Sheets (Note 4).

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As of December 31, 2022, the Company had the following warrants outstanding to purchase common stock.

Number of Shares	Exercise Price per Share	Expiration Date
112,500	$10.00	February 12, 2026
740,000	$0.9382	May 17, 2027

11. STOCK-BASED COMPENSATION

The Company recorded stock-based compensation related to stock options and restricted stock units (RSUs) issued under the Company's 2018 Equity Incentive Plan (2018 Plan) in the following expense categories of its accompanying statements of operations for the years ended December 31, 2022 and 2021:

	For the Year Ended December 31,	
	2022	2021
Research and development	$ (202)	$ 83
General and administrative	301	543
Total	$ 99	$ 626

Stock Options

The Company has granted stock options to purchase its common stock to employees and consultants under the 2018 Plan, under which the Company may issue stock options, restricted stock and other equity-based awards. The Company has also granted certain stock options outside of the 2018 Plan. Stock options granted by the Company generally have a contractual life of up to 10 years.

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 service-based 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 for certain performance-based awards. The Company records expense for performance-based awards if it concludes that it is probable that the performance condition will be achieved. During the year ended December 31, 2022, the Company reversed stock based compensation related to performance awards with performance conditions deemed not probable of achievement.

The table below represents the activity of stock options granted to employees and non-employees for the year ended December 31, 2022:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at December 31, 2021	708,490	$ 3.60	8.64
Granted	204,500	$ 5.22	
Exercised	—	—	
Forfeited	(218,750)	4.06	
Outstanding at December 31, 2022	694,240	$ 3.94	8.05
Exercisable at December 31, 2022	338,490	$ 3.38	7.60
Vested and expected to vest at December 31, 2022	605,178	$ 3.91	8.12

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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,	
	2022	2021
Volatility	90.39 %	83.78 %
Expected term in years	5.98	5.85
Dividend rate	0.00 %	0.00 %
Risk-free interest rate	2.00 %	1.01 %
Fair value of common stock on grant date	$ 3.86	$ 4.00

As of December 31, 2022, all of the outstanding and exercisable stock options were out of the money and therefore had no intrinsic value. At December 31, 2022, the unrecognized compensation cost related to unvested stock options expected to vest was $753. This unrecognized compensation is expected to be recognized over a weighted-average amortization period of 2.64 years.

Restricted Stock Units

The Company has issued performance-based and time-based RSUs. Vesting of the performance-based RSUs is subject to the achievement of certain milestones.

The following table summarizes the activity related to RSUs granted to employees for the year ended December 31, 2022:

	Shares
Outstanding at December 31, 2021	—
Granted	188,023
Vested and settled	(9,406)
Expired/forfeited/canceled	(178,517)
Outstanding at December 31, 2022	—

During the year ended December 31, 2022, the Company granted 188,023 RSUs at a weighted average grant date fair value of $0.5683, of which 150,000 were performance-based RSUs and 38,023 were time-based RSUs. In December 2022, all unvested RSUs were canceled. Upon cancellation, fifty percent of the milestones associated with the performance-based RSUs were deemed probable of achievement and the Company recognized $42 of stock-based compensation expense during the year ended December 31, 2022. Upon cancellation, compensation expense related to time-based RSUs was accelerated and $24 of expense was recognized for the year ended December 31, 2022. No RSUs were outstanding as of December 31, 2022.

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,	
	2022	2021
Expected income tax benefit at the federal statutory rate	21.0 %	21.0 %
State and local taxes, net of federal benefit	10.8	10.6
Non-deductible items and other	(0.8)	(0.5)
Change in valuation allowance	(31.0)	(31.1)
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.

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

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

	December 31,	
	2022	2021
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 8,346	$ 6,617
Share based compensation	342	308
Lease liabilities	55	57
Research and development costs	315	—
Accruals and other	136	98
Gross deferred tax assets	9,194	7,080
Less: deferred tax liabilities	—	(70)
Less: valuation allowance	(9,194)	(7,010)
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, 2022 and 2021. The Company increased its valuation allowance by approximately $2,184 for the year ended December 31, 2022. The Company intends to maintain a valuation allowance until sufficient positive evidence exists to support a reversal of the allowance.

As of December 31, 2022, the Company had federal, state and local net operating loss carryforwards of $25,635, $25,925, and $18,560, 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, 2022 and 2021, 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

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 2.2

AMENDMENT TO AGREEMENT AND PLAN OF MERGER

This Amendment to Agreement and Plan of Merger, dated as of February 17, 2023 (this "**Amendment**"), is entered into by and among Vallon Pharmaceuticals, Inc., a Delaware corporation, Vallon Merger Sub, Inc., a Delaware corporation, and GRI Bio, Inc., a Delaware corporation (each a "**Party**" and collectively, the "**Parties**").

WHEREAS, reference is made to that certain Agreement and Plan of Merger, dated as of December 13, 2022 (the "**Effective Date**"), by and among the Parties; and

WHEREAS, the Parties desire to amend the Agreement as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Definitions. Capitalized terms used and not defined in this Amendment have the respective meanings assigned to them in the Agreement.

2. Amendment to the Agreement. The Agreement is hereby amended, effective as of the Effective Date, as follows:

   a. Section 3.20 of the Agreement is hereby amended and restated in its entirety as follows:

      "No Financial Advisors. Other than Ecoban Securities, LLC, no broker, finder or investment banker is entitled to any brokerage fee, finder's fee, opinion fee, success fee, transaction fee or other fee or commission in connection with the Contemplated Transactions based upon arrangements made by or on behalf of the Company."

3. Effect of the Amendment. Except as expressly provided in this Amendment, all of the terms and provisions of the Agreement are and will remain in full force and effect in accordance with the terms and provisions of the Agreement as modified by this Amendment, taken together as a single agreement reflecting the terms modified hereby, and are hereby ratified and confirmed by the Parties.

4. Miscellaneous. Article 11 of the Agreement shall apply to this Amendment *mutatis mutandis* and to the Agreement as modified by this Amendment, taken together as a single agreement reflecting the terms as modified hereby.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the date first written above.

VALLON PHARMACEUTICALS, INC.

By: /s/ David Baker
Name: David Baker
Title: Chief Executive Officer

VALLON MERGER SUB, INC.

By: /s/ David Baker
Name: David Baker
Title: Chief Executive Officer

GRI BIO, INC.

By: /s/ Marc Hertz
Name: Marc Hertz
Title: Chief Executive Officer

Exhibit 10.30

OMNIBUS AMENDMENT TO SECURITIES PURCHASE AGREEMENTS

This Omnibus Amendment to Securities Purchase Agreements, dated as of February 17, 2023 (this "**Amendment**"), is entered into by and among GRI Bio, Inc., a Delaware corporation (the "**PrivateCo**"), Vallon Pharmaceuticals, Inc., a Delaware corporation ("**PubCo**"), and Altium Growth Funds, LP, a New York limited partnership (the "**Buyer**") (each a "**Party**" and collectively, the "**Parties**").

WHEREAS, reference is made to (i) that certain Securities Purchase Agreement, dated as of December 13, 2022 (the "**Effective Date**"), by and between the PrivateCo and the Buyer (the "**Bridge SPA**"), (ii) that certain Securities Purchase Agreement, dated as of the Effective Date, by and among the PrivateCo, the Buyer, and PubCo (the "**Primary Financing SPA**" and together with the Bridge SPA, the "**SPAs**") and (iii) that certain Agreement and Plan of Merger, dated December 13, 2022, by and among Vallon Merger Sub, Inc. ("**Merger Sub**"), PrivateCo and PubCo (the "**Merger Agreement**"); and

WHEREAS, the Parties desire to amend the SPAs as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Amendments to the SPAs. Each of the SPAs is hereby amended and modified, effective as of the Effective Date, to replace the words "Evolution Venture Partners, LLC", in each instance in which such words appear each of the SPAs, with the words "Ecoban Securities, LLC".

2. Consent to Merger Agreement Amendment. Buyer hereby consents to PrivateCo, PubliCo and Merger Sub amending the Merger Agreement as set forth in the form of amendment to the Merger Agreement attached hereto as Exhibit A.

3. Effect of the Amendment. Except as expressly provided in this Amendment, all of the terms and provisions of the Agreement are and will remain in full force and effect and are hereby ratified and confirmed by the Parties.

4. Miscellaneous. Article 9 of the Bridge SPA and Article 10 of the Primary Financing SPA shall apply to this Amendment *mutatis mutandis* and to each of the SPAs as modified by this Amendment, each taken together with this Amendment as a single agreement reflecting the terms as modified hereby.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the date first written above.

GRI BIO, INC.

By: /s/ Marc Hertz
Name: Marc Hertz
Title: Chief Executive Officer

VALLON PHARMACEUTICALS, INC.

By: /s/ David Baker
Name: David Baker
Title: Chief Executive Officer

ALTIUM GROWTH FUND, LP

By: Altium Capital Management, LP

By: /s/ Mark Gottlieb
Name: Mark Gottlieb
Title: Authorized Signatory

EXHIBIT A

Amendment to
Agreement and Plan of Merger

[See Attached]

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Vallon Pharmaceuticals, Inc. on Form S-8 (No. 333-255972), Form S-3 (No. 333-264488), Form S-1 (No. 333-265302) and Form S-4 (No. 333-268977) of our report dated February 23, 2023, on our audits of the financial statements as of December 31, 2022 and 2021 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 23, 2023. 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 23, 2023

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 23, 2023

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 23, 2023

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, 2022 (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 23, 2023

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, 2022 (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 23, 2023

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