

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-Q**

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended **September 30, 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: **001-41201**

**CinCor Pharma, Inc.**  
(Exact Name of Registrant as Specified in its Charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)  
230 Third Avenue, Waltham, MA 02451  
(Address of principal executive offices)

36-4931245  
(I.R.S. Employer  
Identification No.)  
02451  
(Zip Code)

Registrant's telephone number, including area code: (844) 531-1834

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, \$0.00001 par value per share	CINC	The Nasdaq Stock Market LLC

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of November 3, 2022, the registrant had 43,764,323 shares of common stock, \$0.00001 par value per share, outstanding.

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## SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q of CinCor Pharma, Inc., or CinCor or the Company, contains or incorporates statements that constitute forward-looking statements within the meaning of the federal securities laws. Any express or implied statements that do not relate to historical or current facts or matters are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “could,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “seeks,” “endeavor,” “potential,” “continue” or the negative of these terms or other comparable terminology.

Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These forward-looking statements include, without limitation, statements about the following:

- the timing, progress and results of our preclinical studies and clinical trials of baxdrostat (CIN-107) and any future product candidates, including statements regarding the timing of our planned IND submissions, initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the timing of any submission of filings for regulatory approval of, and our ability to obtain and maintain regulatory approvals for, baxdrostat and any future product candidates;
- our ability to identify patients with the diseases treated by our product candidate and to enroll these patients in our clinical trials;
- our expectations regarding the size of the patient populations, market acceptance and opportunity for and clinical utility of baxdrostat and any future product candidates, if approved for commercial use;
- business disruptions affecting the initiation, patient enrollment, development and operation of our clinical trials, including a public health emergency, such as the COVID-19 pandemic, or geopolitical events, including the ongoing military conflict between Russia and Ukraine, and related sanctions against Russia;
- macroeconomic events, including uncertain market conditions, higher inflation and supply chain disruptions;
- our expectations regarding the scope of any approved indication for baxdrostat or any future product candidate;
- our ability to successfully commercialize baxdrostat or any future product candidate, if approved;
- our expectations regarding the potential market size and the rate and degree of market acceptance for baxdrostat or any future product candidates that we develop;
- the effects of competition with respect to baxdrostat or any future product candidates, as well as innovations by current and future competitors in our industry;
- our ability to fund our working capital requirements;
- our intellectual property position, including the scope of protection we are able to establish, maintain and enforce for intellectual property rights covering baxdrostat;
- our financial performance and our ability to effectively manage our anticipated growth; and
- our ability to obtain additional funding for our operations.

You are urged to carefully review the disclosures we make concerning these risks and other factors that may affect our business and operating results under “Item 1A. Risk Factors” in the Annual Report on Form 10-K, as well as our other reports filed with the U.S. Securities and Exchange Commission (“SEC”). We may announce material business and financial

information to our investors using our investor relations website ([www.cincor.com/investor-relations](http://www.cincor.com/investor-relations)). We therefore encourage investors and others interested in CinCor to review the information that we make available from time to time on our website, in addition to following our filings with the SEC, webcasts, press releases and conference calls. Any public statements or disclosures by us following this Quarterly Report on Form 10-Q that modify or impact any of the forward-looking statements contained in this Quarterly Report on Form 10-Q will be deemed to modify or supersede such statements in this Quarterly Report on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this document. The Company does not intend, and undertakes no obligation, to update any forward-looking information to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events, unless required by law to do so.

#### **TRADEMARKS, TRADENAMES AND SERVICE MARKS**

This Quarterly Report on Form 10-Q includes trademarks, tradenames and service marks, certain of which belong to us and others that are the property of other organizations. Solely for convenience, trademarks, tradenames and service marks referred to in this Quarterly Report on Form 10-Q appear without the ®, ™ and SM symbols, but the absence of those symbols is not intended to indicate, in any way, that we will not assert our rights or that the applicable owner will not assert its rights to these trademarks, tradenames and service marks to the fullest extent under applicable law.

**PART I—FINANCIAL INFORMATION**  
**Item 1. Condensed Consolidated Financial Statements (Unaudited)**  
**CinCor Pharma, Inc.**  
**Condensed Consolidated Balance Sheets**

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	September 30, 2022 <i>(unaudited)</i>	December 31, 2021
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 292,556,851	\$ 136,605,613
Marketable securities	229,939,796	—
Prepaid research and development contracts	5,925,991	1,769,074
Prepaid expense and other current assets	596,728	2,731,953
<b>Total current assets</b>	<b>529,019,366</b>	<b>141,106,640</b>
<b>Long term assets:</b>		
Property and equipment, net	99,722	—
<b>Total long term assets</b>	<b>99,722</b>	<b>—</b>
<b>Total assets</b>	<b>\$ 529,119,088</b>	<b>\$ 141,106,640</b>
<b>Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 2,588,400	\$ 642,143
Related-party accounts payable	—	7,323
Warrant derivative liabilities	—	10,636,921
Accrued legal expense	430,131	2,104,766
Accrued research and development contracts	4,681,756	1,751,530
Accrued expenses and other liabilities	2,481,232	1,406,506
<b>Total current liabilities</b>	<b>10,181,519</b>	<b>16,549,189</b>
<b>Redeemable convertible preferred stock:</b>		
Series A redeemable convertible preferred stock, \$0.00001 par value, 0 and 35,714,282 shares authorized and outstanding at September 30, 2022 and December 31, 2021, respectively	—	47,173,259
Series B redeemable convertible preferred stock, \$0.00001 par value, 0 and 35,716,249 shares authorized and outstanding at September 30, 2022 and December 31, 2021, respectively	—	141,101,202
<b>Stockholders' equity (deficit):</b>		
Common stock, \$0.00001 par value per share; 95,000,000 and 13,731,721 shares authorized, and 43,764,323 and 2,557,341 outstanding at September 30, 2022 and December 31, 2021, respectively	438	26
Additional paid-in capital	656,273,482	13,986,033
Accumulated deficit	(136,452,934)	(77,703,069)
Accumulated other comprehensive loss	(883,417)	—
<b>Total stockholders' equity (deficit)</b>	<b>518,937,569</b>	<b>(63,717,010)</b>
<b>Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)</b>	<b>\$ 529,119,088</b>	<b>\$ 141,106,640</b>

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

**CinCor Pharma, Inc.**  
**Condensed Consolidated Statements of Operations (Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 17,725,092	\$ 4,647,620	\$ 44,576,704	\$ 12,135,441
General and administrative	4,519,288	3,042,278	12,724,801	5,141,861
Total operating expenses	<u>22,244,380</u>	<u>7,689,898</u>	<u>57,301,504</u>	<u>17,277,302</u>
<b>Loss from operations</b>	<b>(22,244,380)</b>	<b>(7,689,898)</b>	<b>(57,301,504)</b>	<b>(17,277,302)</b>
Other (income) expense:				
Interest income	(1,266,821)	(1,947)	(1,595,646)	(7,899)
Change in fair value of warrant derivative liabilities	—	1,335,852	3,044,006	3,755,509
Total other (income) expense, net	<u>(1,266,821)</u>	<u>1,333,905</u>	<u>1,448,360</u>	<u>3,747,610</u>
<b>Net loss</b>	<b>\$ (20,977,559)</b>	<b>\$ (9,023,803)</b>	<b>\$ (58,749,865)</b>	<b>\$ (21,024,912)</b>
			\$ -	
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.51)	\$ (5.19)	\$ (1.57)	\$ (14.59)
Weighted average number of common stock used in computing net loss per share attributable to common stockholders, basic and diluted	<u>40,806,123</u>	<u>1,739,516</u>	<u>37,343,549</u>	<u>1,440,916</u>

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

**CinCor Pharma, Inc.**  
**Condensed Consolidated Statements of Comprehensive Loss (Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss	\$ (20,977,559)	\$ (9,023,803)	\$ (58,749,865)	\$ (21,024,912)
Other comprehensive loss:				
Unrealized losses on available-for-sale securities	(171,651)	—	(883,417)	—
<b>Comprehensive loss</b>	<b>\$ (21,149,210)</b>	<b>\$ (9,023,803)</b>	<b>\$ (59,633,282)</b>	<b>\$ (21,024,912)</b>

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

**CinCor Pharma, Inc.**  
**Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) (unaudited)**

Redeemable Convertible Preferred Stock	Stockholders' Equity (Deficit)
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	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' (Deficit)
	Shares	Amount	Shares	Amount	Shares	Par Value				
Balance at January 1, 2022	35,714,282	\$ 47,173,259	35,716,249	\$ 141,101,202	2,557,341	\$ 26	\$ 13,986,033	\$ (77,703,069)	\$ —	\$ (63,717,010)
Issuance of common stock initial public offering, net of discounts and issuance costs of \$19,420,580	—	—	—	—	13,290,813	133	193,550,593	—	—	193,550,726
Conversion of redeemable convertible preferred stock into common stock upon initial public offering	(35,714,282)	(47,173,259)	(35,716,249)	(141,101,202)	21,008,970	210	188,274,133	—	—	188,274,343
Automatic conversion of the Roche warrants into common stock upon initial public offering	—	—	—	—	852,788	9	13,644,599	—	—	13,644,608
Stock-based compensation expense	—	—	—	—	—	—	1,224,208	—	—	1,224,208
Other comprehensive loss	—	—	—	—	—	—	—	—	(317,611)	(317,611)
Net loss	—	—	—	—	—	—	—	—	(16,696,903)	(16,696,903)
Balance at March 31, 2022	—	—	—	—	37,709,912	378	410,679,566	(94,399,972)	(317,611)	315,962,361
Stock-based compensation expense	—	—	—	—	—	—	1,241,157	—	—	1,241,157
Other comprehensive loss	—	—	—	—	—	—	—	—	(394,155)	(394,155)
Net loss	—	—	—	—	—	—	—	—	(21,075,404)	(21,075,404)
Balance at June 30, 2022	—	—	—	—	37,709,912	378	411,920,723	(115,475,376)	(711,766)	295,733,959
Issuance of common stock and sale of pre-funded warrants, net of discounts and issuance costs of \$574,818	—	—	—	—	6,054,411	60	242,650,096	—	—	242,650,156
Stock-based compensation expense	—	—	—	—	—	—	1,302,663	—	—	1,302,663
Proceeds from exercise of stock options	—	—	—	—	29,411	—	400,000	—	—	400,000
Other comprehensive loss	—	—	—	—	—	—	—	—	(171,651)	(171,651)
Net loss	—	—	—	—	—	—	—	—	(20,977,559)	(20,977,559)
Balance at September 30, 2022	—	—	—	—	43,793,734	438	656,273,482	(136,452,934)	(883,417)	518,937,569

Redeemable Convertible Preferred Stock				Stockholders' Deficit			
Series A Redeemable Convertible Preferred Stock	Series B Redeemable Convertible Preferred Stock	Common Stock	Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'	

	Shares	Amount	Shares	Amount	Shares	Par Value	Capital	Deficit	Loss	(Deficit)
Balance at January 1, 2021	35,714,282	\$ 47,173,259	—	\$ —	1,250,000	\$ 13	\$ 69,330	\$ (27,333,995)	\$ —	\$ (27,264,652)
Stock-based compensation expense	—	—	—	—	—	—	1,389,955	—	—	1,389,955
Net loss	—	—	—	—	—	—	—	(5,618,411)	—	(5,618,411)
Balance at March 31, 2021	35,714,282	47,173,259	—	—	1,250,000	13	1,459,285	(32,952,406)	—	(31,493,108)
Stock options exercised	—	—	—	—	142,636	1	1,232,799	—	—	1,232,800
Stock-based compensation expense	—	—	—	—	—	—	293,849	—	—	293,849
Net loss	—	—	—	—	—	—	—	(6,382,699)	—	(6,382,699)
Balance at June 30, 2021	35,714,282	47,173,259	—	—	1,392,636	14	2,985,933	(39,335,105)	—	(36,349,158)
Issuance of redeemable convertible preferred stock, net of issuance costs of \$897,567	—	—	33,702,500	134,219,013	—	—	—	—	—	—
Allocation of proceeds to warrant derivative liabilities	—	—	—	(866,255)	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	567,346	—	—	567,346
Net loss	—	—	—	—	—	—	—	(9,023,803)	—	(9,023,803)
Balance at September 30, 2021	35,714,282	47,173,259	33,702,500	133,352,758	1,392,636	14	3,553,279	(48,358,908)	—	(44,805,615)

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

**CinCor Pharma, Inc.**  
**Condensed Consolidated Statements of Cash Flows (Unaudited)**

	Nine Months Ended	
	2022	2021
<b>Operating activities:</b>		
Net loss	\$ (58,749,865)	\$ (21,024,912)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,768,028	2,251,150
Change in fair value of warrant derivative liabilities	3,044,006	3,755,509
Accretion of discount on available-for-sale securities	(432,227)	—
Depreciation	5,620	—
Changes in operating assets and liabilities:		
Prepaid research and development contracts	(4,156,917)	(2,664,497)
Prepaid expenses and other current assets	(471,058)	(1,303,409)
Accounts payable	1,659,978	226,547
Related-party accounts payable	(7,323)	350,650
Accrued expenses and other liabilities	2,958,983	(546,317)
<b>Net cash used in operating activities</b>	<b>(52,380,775)</b>	<b>(18,955,279)</b>
<b>Investing activities:</b>		
Purchases of marketable securities	(335,390,925)	—
Maturities of marketable securities	105,000,000	—
Purchase of property and equipment	(105,340)	—
<b>Net cash used in investing activities</b>	<b>(230,496,265)</b>	<b>—</b>
<b>Financing activities:</b>		
Proceeds from issuance of common stock and sale of pre-funded warrants, net of underwriting discounts	440,992,224	—
Issuance costs on common stock offerings and sale of pre-funded warrants	(2,563,946)	—
Proceeds from issuance of Series B redeemable convertible preferred stock inclusive of proceeds attributable to warrant derivative liabilities	—	134,250,326
Issuance cost of redeemable convertible preferred stock	—	(897,567)
Proceeds from stock option exercise	400,000	1,232,799
<b>Net cash provided by financing activities</b>	<b>438,828,278</b>	<b>134,585,558</b>
Net increase in cash and cash equivalents	155,951,238	115,630,279
Cash and cash equivalents at beginning of period	136,605,613	26,078,064
Cash and cash equivalents, at end of period <sup>(1)</sup>	<b>\$ 292,556,851</b>	<b>\$ 141,708,343</b>
<b>Supplemental disclosures for non-cash financing activities</b>		
Conversion of redeemable convertible preferred stock into common stock upon initial public offering	\$ 188,274,133	\$ —
Automatic conversion of the Roche warrants into common stock upon initial public offering	13,644,608	—

(1) Cash and cash equivalents excludes marketable securities of \$229.9 million. Cash, cash equivalents and marketable securities at September 30, 2022, was \$522.5 million.

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

**CinCor Pharma, Inc.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**1. Nature of Organization and Operations**

CinCor Pharma, Inc. and Subsidiary (the “Company”) is a clinical-stage biopharmaceutical company focused on developing its lead clinical candidate, baxdrostat, for the treatment of hypertension and other cardio-renal diseases. Baxdrostat is a highly selective, oral small molecule inhibitor of aldosterone synthase, the enzyme responsible for the synthesis of aldosterone in the adrenal gland. The Company is conducting multiple Phase 2 clinical trials using baxdrostat in differing populations of patients, all of whom are hypertensive.

The Company was incorporated in March 2018 and founded as a subsidiary of CinRx Pharma, LLC ("CinRx"), a biotechnology company focused on developing novel therapeutics. In May 2019, the Company entered into an agreement with F. Hoffmann-La Roche Ltd and Hoffmann La-Roche Inc. (collectively, "Roche") for an exclusive, worldwide, royalty-bearing license to certain Roche technology to research, develop, manufacture, and commercialize a novel aldosterone synthase inhibitor compound, baxdrostat, for any and all diseases and conditions. In connection with the in-licensing transaction with Roche, the Company was spun out as an independent company.

On August 17, 2022, the Company established a wholly-owned subsidiary, CinCor Pharma Bermuda Ltd ("CinCor Bermuda"). CinCor Bermuda is the Company's only subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, possible failure of preclinical studies or clinical trials, the need to obtain marketing approval for its product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, the need to successfully commercialize and gain market acceptance of any of the Company's products that are approved and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing, and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

### **Liquidity**

On January 11, 2022, the Company completed an initial public offering (the "IPO") of its common stock pursuant to which the Company issued and sold 13,290,813 shares of common stock at a price to the public of \$16.00 per share. The aggregate net proceeds from the IPO were approximately \$193.6 million after deducting underwriting discounts and commissions of \$14.9 million and offering expenses of approximately \$4.5 million. Upon completion of the IPO, all outstanding shares of Series A and Series B redeemable convertible preferred stock converted to 21,008,970 shares of common stock at a ratio of 3.4:1. In addition, the IPO also resulted in the automatic net exercise of the three outstanding warrants to purchase common stock issued to Roche for an aggregate of 852,788 shares of common stock (collectively, the "Roche Warrants").

On August 12, 2022, the Company closed an underwritten public offering of 6,025,000 shares of its common stock at a public offering price of \$30.00 per share and pre-funded warrants (the "Pre-Funded Warrants") to purchase 2,600,000 shares of common stock at a public offering price of \$29.99999 per share, which represented the per share public offering price for the common stock less the \$0.00001 per share exercise price for each such Pre-Funded Warrant. Proceeds, net of underwriting discounts and commissions, from the Pre-Funded Warrants were \$73.3 million and net proceeds raised by the Company from the public offering of common shares was \$169.6 million, after deducting underwriting discounts and commissions and other estimated offering expenses, bringing the total net proceeds to \$242.9 million.

The Company incurred significant losses from operations and had negative cash flows from operating activities for the three and nine months ended September 30, 2022 and 2021, and since inception. The Company's current operating plan indicates it will continue to incur losses from operations and generate negative cash flows from operating activities, given ongoing expenditures related to extensive research and development and the Company's lack of revenue-generating activities at this point in the Company's life cycle.

The Company expects that its existing cash and cash equivalents and marketable securities is sufficient to fund its operating expenses and capital expenditure requirements into 2026, including completing all of its ongoing Phase 2 trials, its currently planned Phase 3 clinical program in hypertension, CMC (chemistry manufacturing and control) development and GMP (good manufacturing practice) batch production, the additional activities needed to complete its planned new drug application submission and preparation for commercialization. The future viability of the Company beyond that point, including completing the development and commercialization, if approved, of baxdrostat for hypertension as well as any indication expansion opportunities, is dependent on its ability to raise additional capital to fund its operations.

If the Company is unable to obtain future funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations.

## **2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The unaudited condensed consolidated financial statements have been prepared in accordance with U.S. Securities and Exchange Commission (“SEC”) regulations and include all of the information and disclosures required by U.S. generally accepted accounting principles (“U.S. GAAP” or “GAAP”) for interim financial reporting, and, in the opinion of management include all adjustments necessary for a fair presentation of the condensed consolidated financial statements for each period presented. All adjustments are normal and recurring in nature. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”). These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2021 in the Company’s Annual Report on Form 10-K filed with the SEC on March 22, 2022. The results of operations for the interim periods are not necessarily indicative of results of operations for a full year. The Company’s condensed consolidated financial statements are stated in U.S. Dollars.

**Segment Information**

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment. All the assets and operations of the Company’s sole operating segment are located in the United States.

**Use of Estimates**

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls and in developing the estimates and assumptions that are used in the preparation of these condensed consolidated financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Estimates have been or are used in the following areas, among others: prepaid research and development contracts, fair value of the Company’s common stock prior to the IPO, fair value of the Pre-Funded Warrants, fair value of warrant derivative liabilities, stock compensation expense and income taxes.

Prior to its IPO, the Company utilized estimates and assumptions in determining the fair value of its common stock. The Company has granted stock options at exercise prices that represented the fair value of its common stock on grant date. The Company utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock prior to its IPO. Each valuation methodology includes estimates and assumptions that require the Company’s judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of redeemable convertible preferred stock, the superior rights and preferences of the redeemable convertible preferred stock senior to the Company’s common stock at the time, and a probability analysis of various liquidity events at that time, such as a public offering or sale of the Company, under differing scenarios. Changes to the key assumptions used in the valuations could have resulted in different fair values of common stock at each valuation date.

The Company’s results and business operations can also be affected or disrupted by economic, political, legislative, health concerns, such as the COVID-19 pandemic, regulatory, legal actions and geopolitical events, such as the ongoing military conflict between Ukraine and Russia and the related sanctions against Russia, particularly to the extent it escalates to involve additional countries, further economic sanctions or wider military conflict. Economic conditions, such as recessionary trends, inflation, interest, changes in regulatory laws and monetary exchange rates, and government fiscal policies, can also have a significant effect on operations. In addition, the conflict between Russia and Ukraine and related sanctions have had significant ramifications on global financial markets, including volatility and uncertainty in the U.S. and global financial markets, which has led and could continue to lead to disruptions to trade, commerce, pricing stability, credit availability, supply chain continuity and reduced access to liquidity on acceptable terms, in both Europe and globally, and has caused and may continue to cause volatility in the price of the Company’s common stock, which may adversely impact the Company’s ability to raise capital on favorable terms or at all. While the Company maintains reserves for anticipated liabilities, the Company could be affected by civil, criminal, regulatory, or administrative actions, claims, or proceedings. The extent to which the Company’s business can be impacted by future events is highly uncertain and cannot be predicted at this time.

**Concentration of Credit Risk and Other Risks and Uncertainties**

The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts, or other hedging arrangements. Financial instruments that potentially subject the Company to concentrations of credit risk

primarily consist of cash and cash equivalents, which consist of money market funds that invest primarily in short term U.S. government securities and short-term marketable securities that are primarily invested in fixed income securities.

The Company has not yet generated any revenue from the sale of its products and is subject to all of the risks and uncertainties that are typically faced by biopharmaceutical companies that devote substantially all of their efforts to research and development and clinical trials and do not yet have commercial products. The Company expects to continue incurring operating losses for the foreseeable future.

#### ***Cash and Cash Equivalents***

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include cash held in banks and amounts held primarily in interest-bearing money market accounts. Cash equivalents are carried at cost, which approximates their fair market value.

#### ***Marketable Securities***

The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation at each condensed consolidated balance sheet date. The Company classified all of its marketable securities at September 30, 2022 as “available-for-sale” pursuant to ASC Topic 320, *Investments – Debt and Equity Securities*. Investments not classified as cash equivalents are presented as either short-term or long-term investments based on both their maturities as well as the time period the Company intends to hold such securities. Available-for-sale securities are maintained by an investment manager and primarily consist of fixed income securities. Available-for-sale securities are carried at fair value with the unrealized gains and losses included in other comprehensive loss as a component of stockholders’ equity (deficit) until realized. Any premium or discount arising at purchase is amortized or accreted to interest income over the maturity of the fixed income security. Realized gains and losses are determined using the specific identification method and are included in other (income) expense, net. There were no material realized gains or losses on marketable securities recognized for the three and nine months ended September 30, 2022 or 2021.

#### ***Initial Public Offering Costs***

Costs directly attributable to the Company’s IPO which were incurred in 2021 were deferred and capitalized as prepaid expenses and other current assets at December 31, 2021. These costs primarily represented legal, underwriting and accounting costs related to the Company’s efforts to raise capital through a public sale of its common stock. Any additional costs incurred during the nine months ended September 30, 2022 were deferred until the completion of the IPO, which occurred on January 11, 2022, at which time they were reclassified to additional paid in capital as a reduction of the IPO gross proceeds. At December 31, 2021, the Company had capitalized \$2.6 million of deferred IPO costs, as prepaid expenses and other current assets. A total of \$4.5 million of IPO issuance costs were incurred through January 11, 2022, which were recorded as a reduction of the IPO gross proceeds and included the \$2.6 million previously capitalized at December 31, 2021.

#### ***Redeemable Convertible Preferred Stock***

In accordance with ASC Topic 480, *Distinguishing Liabilities from Equity* (“ASC 480”), preferred stock issued with redemption provisions that are outside of the control of the issuer or that contain certain redemption features in a Deemed Liquidation Event (as defined in our Amended and Restated Certificate of Incorporation) is required to be presented outside of stockholders’ equity (deficit) on the face of the condensed consolidated balance sheet and certain disclosures are required to be included in the notes to the condensed consolidated financial statements. If required, changes in fair value are recorded as additional paid in capital and/or accumulated deficit in the condensed consolidated balance sheets. Changes in fair value that would reduce the fair value of the redeemable convertible preferred stock below the original issue price are limited so that the value of the shares are not recorded below the original issue price.

#### ***Fair Value Measurements***

Financial assets and liabilities are recorded at fair value. The carrying amount of certain financial instruments, including accounts payable and other current liabilities approximate fair value due to their relatively short maturities. Assets and liabilities recorded at fair value on a recurring basis in the condensed consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

*Level 1*—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

*Level 2*—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

*Level 3*—Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

Where quoted prices are available in an active market, assets or liabilities are classified as Level 1.

To the extent that a valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest

for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. There were no transfers within the fair value hierarchy in 2022 and 2021.

#### ***Research and Development***

The Company charges all research and development costs, both internal and external, to expense when incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided to the Company by its clinical sites and vendors. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company. The Company's research and development expenses consist primarily of clinical trial expenses, consulting costs and stock-based compensation, and costs associated with required regulatory filings, licenses, and fees.

#### ***Stock-Based Compensation***

The Company accounts for its stock-based compensation awards in accordance with ASC Topic 718, *Compensation – Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based payments to employees, including grants of employee stock options and restricted stock units, to be recognized in the condensed consolidated statements of operations based on their fair values. The Company's stock-based awards are subject only to service-based vesting conditions. The Company estimates the fair value of its stock-based awards in the form of employee stock options, using the Black-Scholes option pricing model, which requires the input of assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends.

Prior to its IPO, the Company had based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. The Company believes the group selected has sufficient similar economic and industry characteristics and includes companies that are most representative of the Company.

The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term, as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term for options granted to employees and utilizes the contractual term for options granted to non-employees. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options.

Compensation expense related to awards to employees is calculated on a straight-line basis by recognizing the grant date fair value over the associated service period of the award, which is generally the vesting term.

#### ***Derivative Instruments, Including Warrant Derivative Liabilities***

The Company accounts for derivatives, specifically freestanding detachable stock purchase warrants, in accordance with ASC Topic 815, *Derivatives and Hedging* ("ASC 815"). This guidance establishes accounting and reporting principles for derivative instruments, including certain derivative instruments embedded in other contracts.

#### ***Pre-Funded Warrants***

The Company accounts for its Pre-Funded Warrants in accordance with ASC 480 and ASC 815. The Pre-Funded Warrants to purchase 2,600,000 shares of common stock were sold on August 15, 2022 pursuant to the Company's underwritten public offering price of \$29.99999 per share, which represented the per share public offering price for the common stock sold in the August public offering less the \$0.00001 per share exercise price for each such Pre-Funded Warrant. The Pre-Funded Warrants were classified as a component of permanent stockholders' equity within additional paid-in capital and were recorded at the date of sale. The Pre-Funded Warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holder to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria. In addition, such Pre-Funded Warrants do not provide any guarantee of value or return. The Company valued the Pre-Funded warrants at date of sale, concluding that their sales price approximated their fair value of \$73.3 million which was recorded as a component of additional paid-in capital.

#### ***Net Loss Per Share***

The Company's basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. The diluted net loss per share attributable to common stockholders is computed by giving effect to all potential common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, redeemable convertible preferred stock prior to the Company's IPO, stock options to purchase common stock, restricted stock units and the Pre-Funded Warrants are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share attributable to common stockholders as their effect is anti-dilutive.

### ***Income Taxes***

Income taxes are recorded in accordance with ASC Topic 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the condensed consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the condensed consolidated financial statement and tax bases of assets and liabilities and for loss and credit carryforwards using enacted tax rates anticipated to be in effect for the year in which the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that some or all the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of September 30, 2022, and December 31, 2021, the Company does not have any significant uncertain tax positions. If the Company were to incur interest and penalties on uncertain tax positions, it would classify them as income tax expense.

The Company files U.S. federal and state income tax returns.

The Company did not record a current or deferred income tax expense or benefit for the three and nine months ended September 30, 2022 and 2021, due to the Company's net and comprehensive losses and increases in its deferred tax asset valuation allowance.

### ***Comprehensive Loss***

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. For the three and nine months ended September 30, 2022, the Company's only element of other comprehensive loss was unrealized losses on available-for-sale securities. Comprehensive loss for the three and nine months ended September 30, 2021, equaled net loss for those periods.

### ***Litigation and Other Contingencies***

The Company may be subject to legal proceedings and claims arising from the ordinary course of its business, including contract and employment claims. U.S. GAAP requires that a liability for contingencies be recorded when it is probable that a liability has occurred, and the amount of the liability can be reasonably estimated. In the opinion of management, the aggregate liability, if any, with respect to such ordinary course of business actions will not have a material adverse effect on the financial position or results of operations of the Company.

### ***Reverse Stock Split***

On December 30, 2021, the Company's Board of Directors approved an amendment to the Company's amended and restated certificate of incorporation to effect a 3.4-for-1 reverse stock split of the Company's common stock, which was effected on December 30, 2021. Stockholders entitled to fractional shares as a result of the reverse stock split received a cash payment in lieu of receiving fractional shares. The par value of the common stock was not adjusted as a result of the reverse stock split. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the appropriate securities agreements. Shares of common stock reserved for issuance upon the conversion of our convertible preferred stock were proportionately reduced and the respective conversion prices were proportionately increased. All common share and per share data have been retrospectively revised including the three and nine months ended September 30, 2021, to reflect the reverse stock split.

### ***Recent Accounting Pronouncements***

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

### **3. Fair Value Measurements**

The following table represents the financial instruments measured at fair value on a recurring basis based on the fair value hierarchy at:

	<b>September 30, 2022</b>			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Cash and cash equivalents	\$ 292,556,851	\$ —	\$ —	\$ 292,556,851
<b>Marketable securities:</b>				
US Treasury bills	34,858,896	—	—	34,858,896
Certificate of deposit	62,592,523	—	—	62,592,523
US Government agency securities	—	132,488,377	—	132,488,377
<b>Total assets at fair value</b>	<b>\$ 390,008,270</b>	<b>\$ 132,488,377</b>	<b>\$ —</b>	<b>\$ 522,496,647</b>

	<b>December 31, 2021</b>			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Cash and cash equivalents	\$ 136,605,613	\$ —	\$ —	\$ 136,605,613
<b>Total assets at fair value</b>	<b>\$ 136,605,613</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 136,605,613</b>
<b>Liabilities:</b>				
Warrant derivative liabilities	\$ —	\$ —	\$ 10,636,921	\$ 10,636,921
<b>Total liabilities at fair value</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 10,636,921</b>	<b>\$ 10,636,921</b>

The amortized cost basis of marketable securities as of September 30, 2022 was \$255.8 million.

The fair value of money market funds, U.S. Treasury bills and certificates of deposits are based on unaudited quoted market prices, which are considered Level 1 inputs in the fair value hierarchy. Level 2 assets consists of U.S. Government agency securities and are based upon quoted market prices for similar securities in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third-party data providers, including but not limited to, benchmark yields, interest rate curves, reported trades, broker/dealer quotes and reference data.

The following table sets forth a summary of changes in the fair value of the warrant derivative liabilities, representing a recurring measurement that is classified within Level 3 of the fair value hierarchy:

January 1, 2022	\$	10,636,921
Change in fair value of warrant derivative liabilities		3,044,006
Automatic conversion of Roche warrants into common stock upon initial public offering		(13,680,927)
September 30, 2022	<u>\$</u>	<u>-</u>

The Company estimated the fair value of the warrant derivative liabilities using a Black-Scholes option pricing model. The valuation model used the following assumptions at December 31, 2021:

Fair value of common stock	\$	12.44
Volatility		64.00 %
Expected term (in years)		0.52
Risk-free interest rate		0.21 %
Dividend yield		—

The preceding methods described may produce a fair value calculation that may not be indicative of net realizable value or reflective of future fair values. Furthermore, although the Company believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value could result in a different fair value measurement at the reporting date.

#### 4. License Agreement

In May 2019, the Company entered into a license agreement (“Roche Agreement”) with Roche, pursuant to which the Company obtained an exclusive, worldwide, royalty-bearing license under certain patents and specified know-how owned or controlled by Roche and covering certain specified small molecule aldosterone synthase inhibitors (“Roche Technology”) to research, develop and commercialize products containing such aldosterone synthase inhibitors (“Licensed Products”) for any and all uses, including the treatment, prevention

or diagnosis of any and all diseases and medical conditions in humans and animals. Pursuant to the Roche Agreement, the Company paid Roche a one-time, upfront non-refundable license fee of \$2.0 million. Additionally, the Company is required to pay Roche certain regulatory event-based milestone payments, certain one time sales-based milestone payments, as well as tiered royalty payments based on the net sales of the Licensed products.

The Roche Agreement will expire, unless earlier terminated by either party, upon expiration of all royalty or other payment obligations under the Roche Agreement are or will become due.

## **5. Redeemable Convertible Preferred Stock**

### ***Series A Redeemable Convertible Preferred Stock***

In May 2019, the Company authorized the issuance of 35,714,282 shares to be issued in the form of Series A redeemable convertible preferred stock ("Series A preferred stock"). The Company issued 35,714,282 shares of Series A preferred stock at \$1.40 per share for total proceeds of \$50 million. The Company incurred \$2.1 million of Series A preferred stock issuance costs, which was recorded against the carrying amount of the Series A preferred stock as of December 31, 2021. The rights, preferences, and privileges of the Company's Series A preferred stock prior to IPO were as follows:

#### ***Voting***

Up until the IPO, the holders of Series A preferred stock were entitled to a number of votes equal to the number of whole shares of common stock into which the shares of Series A preferred stock were convertible. Except as provided by law or otherwise, the holders of the Series A preferred stock vote together with the holders of common stock as a single class.

Up until the IPO, the holders of Series A preferred stock, voting as a separate class, were entitled to elect three members of the Board of Directors. The holders of the common stock, voting as a separate class, were entitled to elect two members of the Board of Directors. The holders of Series A preferred stock and common stock, voting together as a single class on an as-converted basis, are entitled to elect any additional members of the Board of Directors.

#### ***Dividends***

Dividends were payable, if permitted by law, in accordance with the Series A preferred stock terms if and when declared by the Board of Directors. Holders of the Series A preferred stock were entitled to receive dividends out of any assets at the time legally available, at the applicable dividend rate specified for such shares of the Series A preferred stock. Dividends were not mandatory and were not cumulative. No dividends were declared or paid since inception of the Company.

#### ***Liquidation***

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, the holders of shares of the Series A preferred stock then outstanding were entitled to be paid out of the assets of the Company available for distribution to its stockholders or, in the case of a Deemed Liquidation Event, out of the consideration payable to stockholders in such an event, before any payment shall be made to the holders of common stock by reason of their ownership thereof, an amount per share equal to the Series A preferred stock original issue price, plus any dividends declared but unpaid. If upon any such liquidation, dissolution, or winding up of the Company or a Deemed Liquidation Event, the assets of the Company available for distribution to its stockholders are insufficient to pay the holders of shares of Series A preferred stock the full amount to which they were entitled, the holders of shares of the Series A preferred stock share ratably in any distribution of the assets available for distribution in proportion to the respective amounts that would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full. The remaining available proceeds would be distributed pro rata among the holders of the shares of the Series A preferred stock and common stock, based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to common stock pursuant to the applicable terms immediately prior to such liquidation, dissolution, or winding up of the Company.

#### ***Conversion***

Each share of the Series A preferred stock was convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of common stock as determined by dividing the Series A preferred stock original issue price by the Series A preferred stock conversion price in effect at the time of conversion. The applicable conversion price was subject to future adjustments upon the occurrence of certain events. However, holders of the Series A preferred stock did not have the right to convert any shares of the Series A preferred stock at the applicable conversion ratio in effect for preferred shares upon either (i) the closing of a qualified initial public offering of its common stock at a price per share of at least \$14.28 per share (subject to adjustment for any share split, combination or dividend or

distribution payable) resulting in at least \$50 million in gross proceeds to the Company net of the underwriting discount and commissions, or (ii) the election to convert the preferred shares by at least two of the following three holders of the Company's Series A preferred stock: (i) Sofinnova Venture Partners X, L.P., (ii) Sofinnova Capital IX and (iii) 5AM Ventures VI, L.P.

The Company evaluated the Series A preferred stock and determined that it was considered an equity host under ASC 815. In making this determination, the Company's analysis followed the whole instrument approach, which compares an individual feature against the entire Series A preferred stock instrument that includes that feature. The Company's analysis was based on a consideration of the economic characteristics and risks of the Series A preferred stock. More specifically, the Company evaluated all of the stated and implied substantive terms and features, including (i) whether the Series A preferred stock included redemption features, (ii) how and when any redemption features could be exercised, (iii) whether the holders of the Series A preferred stock were entitled to dividends, (iv) the voting rights of the Series A preferred stock, and (v) the existence and nature of any conversion rights. The Company concluded that, as the Series A preferred stock represents an equity host, the conversion feature included in the Series A preferred stock is clearly and closely related to the associated host instrument. Accordingly, the conversion feature is not considered an embedded derivative that requires bifurcation.

The Company accounts for potentially beneficial conversion features under ASC Topic 470-20, *Debt with Conversion and Other Options* ("ASC 470-20"). At the time of the issuances of the shares of Series A preferred stock, the Company's common stock into which the Company's Series A preferred stock was convertible had an estimated fair value less than the effective conversion prices of the shares of Series A preferred stock. Therefore, there was no beneficial conversion element on the issuance dates.

On January 11, 2022, the Company completed its IPO. Upon the closing of the IPO, the Series A preferred stock was converted into 10,504,199 shares of the Company's common stock.

### ***Redemption***

The holders of the Company's redeemable convertible preferred stock have no rights to cause the redemption of their shares outside of a Deemed Liquidation Event. A Deemed Liquidation Event would constitute a redemption event that may be outside of the Company's control.

Any redemption was deemed to be remote at December 31, 2021, and the fair value of Series A preferred stock was deemed to be the price paid by the Series A preferred stockholders.

Due to this redemption option, Series A preferred stock is recorded in mezzanine equity and is subject to subsequent measurement under the guidance provided under ASC 480. In accordance with that guidance, the Company has elected to recognize changes in redemption value immediately.

### ***Warrant Derivative Liabilities***

In connection with the Series A preferred stock financing, the Company issued two freestanding detachable stock purchase warrants to an unrelated third party to separately purchase 411,765 and 329,552 shares of common stock ("2019 Warrants"). The 2019 Warrants were exercisable in whole immediately prior to an initial public offering by the Company and, as such, remain issued, outstanding, and exercisable at December 31, 2021. The 2019 Warrants were issued with an initial exercise price of \$0.04 and an expiration date of May 13, 2029. The 2019 Warrants qualify as derivative liabilities, which must be accounted for separately from the Series A preferred stock and are measured at fair value on a recurring basis. At December 31, 2021, the 2019 Warrants were valued at \$9.2 million, with the change in fair value included in the condensed consolidated statements of operations in the period the change occurred.

On January 11, 2022, the Company completed its IPO. Upon the closing of the IPO, the 2019 Warrants were converted into 739,463 shares of the Company's common stock and are no longer outstanding.

### ***Series B Redeemable Convertible Preferred Stock***

In September 2021, the Company authorized the issuance of 35,716,249 shares to be issued in the form of Series B redeemable convertible preferred stock ("Series B preferred stock"). The Company issued 35,716,249 shares of Series B preferred stock at \$4.00 per share for total proceeds of \$142.9 million. The Company incurred \$0.9 million of Series B preferred stock issuance costs which were recorded against the carrying amount of the Series B preferred stock at December 31, 2021. The rights, preferences, and privileges of the Company's Series B preferred stock prior to the IPO were as follows:

### ***Voting***

Up until the IPO, the holders of Series B preferred stock were entitled to a number of votes equal to the number of whole shares of common stock into which the shares of Series B preferred stock were convertible. Except as provided by law or otherwise, the holders of the Series B preferred stock vote together with the holders of common stock as a single class.

Up until the IPO, holders of Series B preferred stock, voting as a separate class, were entitled to elect one member of the Board of Directors. The holders of preferred stock and common stock, voting together as a single class on an as-converted basis, were

entitled to elect any additional members of the Board of Directors other than directors elected by the holders of Series A preferred stock and directors elected by holders of the common stock.

#### ***Dividends***

Dividends at the rate per annum of \$0.32 per share accrued on shares of Series B preferred stock. Dividends on the shares of Series B preferred stock were not cumulative and were payable, if and when declared by the Board of Directors. The Company shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Company unless the holders of preferred stock then outstanding first or simultaneously receive a dividend on each outstanding share of redeemable convertible preferred stock in an amount at least equal to the sum of (i) the amount of the aggregate dividends accrued but unpaid on such shares of preferred stock and (ii) that dividend per share of preferred stock as would equal the product of (1) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into common stock and (2) the number of shares of common stock issuable upon conversion of a share of preferred stock. No dividends were declared or paid since inception of the Company.

#### ***Liquidation***

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, the holders of shares of the Series B preferred stock then outstanding were entitled to be paid out of the assets of the Company available for distribution to its stockholders or, in the case of a Deemed Liquidation Event, out of the consideration payable to stockholders in such an event, before any payment shall be made to the holders of Series A preferred stock or common stock by reason of their ownership thereof, an amount per share equal to the Series B preferred stock original issue price, plus any dividends declared but unpaid thereon. If upon any such liquidation, dissolution, or winding up of the Company or a Deemed Liquidation Event, the assets of the Company available for distribution to its stockholders are insufficient to pay the holders of shares of Series B preferred stock the full amount to which they were entitled, the holders of shares of the Series B preferred stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts that would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

In the event that the assets of the Company available for distribution exceeded the amount necessary to pay the holders of Series B preferred stock, the holders of shares of Series A preferred stock then outstanding were entitled to be paid out of the assets of the Company available for distribution to its stockholders or, in the case of a Deemed Liquidation Event, out of the consideration payable to stockholders in such an event, before any payment shall be made to the holders of common stock by reason of their ownership thereof, an amount per share equal to the Series A preferred stock original issue price, plus any dividends declared but unpaid thereon. If upon any such liquidation, dissolution, or winding up of the Company or a Deemed Liquidation Event, the assets of the Company available for distribution to its stockholders were insufficient to pay the holders of shares of Series A preferred stock the full amount to which they were entitled, the holders of shares of the Series A preferred stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts that would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

The remaining available proceeds would have been distributed pro rata among the holders of the shares of the Series B preferred stock, Series A preferred stock and common stock, based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to common stock pursuant to the applicable terms immediately prior to such liquidation, dissolution, or winding up of the Company.

#### ***Conversion***

Each share of the Series B preferred stock was convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of common stock as determined by dividing the Series B preferred stock original issue price by the Series B preferred stock conversion price in effect at the time of conversion. The Series B preferred stock conversion price shall initially be equal to the Series B original issue price. The applicable conversion price is subject to future adjustments upon the occurrence of certain events. Upon either (i) the closing of a qualified initial public offering of the Company's common stock resulting in at least \$100 million in proceeds net of the underwriting discount and commissions; (ii) the closing of a transaction or series of transactions in which the Company's outstanding shares of capital stock are exchanged for or converted into securities that are publicly listed on a securities exchange through a merger, acquisition, business combination or similar transaction with a "special purpose acquisition company" where the surviving or parent entity receives aggregate gross proceeds, excluding the cash resources of the Company, of at least \$100 million; or (iii) the date and time, or the occurrence of an event, specified by vote or written consent of the requisite holders and the Series B requisite holders, then all outstanding shares of preferred stock shall automatically be converted into shares of common stock at the effective conversion rate.

The Company evaluated the Series B preferred stock and determined that it was considered an equity host under ASC 815. In making this determination, the Company's analysis followed the whole instrument approach, which compares an individual feature against the entire Series B preferred stock instrument that includes that feature. The Company's analysis was based on a consideration of the economic characteristics and risks of the Series B preferred stock. More specifically, the Company evaluated all of the stated and implied substantive terms and features, including (i) whether the Series B preferred stock included redemption features, (ii) how and when any redemption features could be exercised, (iii) whether the holders of the Series B preferred stock were entitled to dividends, (iv) the voting rights of the Series B preferred stock, and (v) the existence and nature of any conversion rights. The Company concluded that, as the Series B preferred stock represents an equity host, the conversion feature included in the Series B preferred stock is clearly and closely related to the associated host instrument. Accordingly, the conversion feature is not considered an embedded derivative that requires bifurcation.

The Company accounts for potentially beneficial conversion features under ASC 470-20. At the time of the issuances of the shares of Series B preferred stock, the Company's common stock into which the Company's Series B preferred stock was convertible had an estimated fair value less than the effective conversion prices of the shares of Series B preferred stock. Therefore, there was no beneficial conversion element on the issuance dates.

On January 11, 2022, the Company completed its IPO. Upon the closing of the IPO, the Series B preferred stock was converted into 10,504,771 shares of the Company's common stock.

#### ***Redemption***

The holders of the Company's redeemable convertible preferred stock had no rights to cause the redemption of their shares outside of a Deemed Liquidation Event. A Deemed Liquidation Event would constitute a redemption event that may be outside of the Company's control.

Any redemption was deemed to be remote at December 31, 2021, and the fair value of Series B preferred stock was deemed to be the price paid by the Series B preferred stockholders.

Due to this redemption option, Series B preferred stock was recorded in mezzanine equity and is subject to subsequent measurement under the guidance provided under ASC 480. In accordance with that guidance, the Company elected to recognize changes in redemption value immediately.

#### ***Warrant Derivative Liabilities***

In connection with the Series B preferred stock, the Company issued freestanding detachable stock purchase warrants to an unrelated third party to separately purchase 113,610 shares of common stock ("2021 Warrants"). The 2021 Warrants were exercisable in whole immediately prior to an initial public offering by the Company and, as such, remained issued, outstanding, and exercisable at December 31, 2021. The 2021 Warrants were issued with an initial exercise price of \$0.01 and an expiration date of May 13, 2029. The 2021 Warrants qualified as derivative liabilities, which must be accounted for separately from the Series B preferred stock and are measured at fair value on a recurring basis. At December 31, 2021, the 2021 Warrants were valued at \$1.4 million with the change in fair value from the date of issuance included in the condensed consolidated statements of operations in the period the change occurred.

On January 11, 2022, the Company completed its IPO. Upon the closing of the IPO, the 2021 Warrants were converted into 113,325 shares of the Company's common stock.

## **6. Stockholders' Equity (Deficit) and Stock-Based Compensation**

#### ***Stock Options***

On December 30, 2021, the Board of Directors adopted, and the Company's stockholders approved, the 2022 Equity Incentive Plan ("2022 Plan"). The 2022 Plan provides for the grant of incentive stock options to employees of the Company, and for the grant of non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to employees, directors, and consultants, including employees and consultants of affiliates of the Company (collectively, "stock based awards"). The 2022 Plan is a successor to the 2019 Stock Option Plan ("2019 Plan"). Initially, the maximum number of shares of common stock that may be issued under the 2022 Plan after it became effective was 6,787,652 shares, which is the sum of (i) 3,905,911 new shares; plus (ii) the number of shares that was available for issuance under the 2019 Plan at the time the 2022 Plan became effective; and (iii) any shares subject to outstanding stock options or other stock awards that were granted under the 2019 Plan that are forfeited, terminated, expired or are otherwise not issued. In addition, the number of shares of common stock reserved for issuance under the 2022 Plan will automatically increase on January 1<sup>st</sup> of each calendar year, starting on January 1, 2023 and continuing through January 1, 2032, in an amount equal to 5% of the total number of shares of common stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Board of Directors. The

maximum number of shares of common stock that may be issued on the exercise of incentive stock options under the 2022 Plan is 20,362,956.

As of September 30, 2022 and December 31, 2021, a total of 3,984,910 and 3,368,572 awards, respectively, were available for issuance under the 2022 Plan and 2019 Plan, respectively.

The following is a summary of the Company's outstanding stock option activity:

	Stock Option Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2022	2,617,072	\$ 6.19	9.56	—
Granted	68,525	16.51	9.79	—
Exercised	—	—	—	—
Expired/cancelled	—	—	—	—
Outstanding, March 31, 2022	2,685,597	\$ 6.96	9.37	—
Granted	101,637	\$ 16.26	6.43	—
Exercised	—	—	—	—
Expired/cancelled	(4,400)	16.00	—	—
Outstanding, June 30, 2022	2,782,834	\$ 7.27	9.15	—
Granted	1,365	\$ 25.53	6.50	—
Exercised	(29,411)	13.60	—	—
Expired/cancelled	(11,596)	11.89	—	—
Outstanding, September 30, 2022	2,743,192	\$ 7.19	8.90	\$ 70,309,316
Expected to vest, September 30, 2022	2,743,192	\$ 7.19	8.90	\$ 70,309,316
Options exercisable, September 30, 2022	865,350	\$ 6.58	8.71	\$ 22,708,847

Unrecognized compensation cost related to stock option awards of \$12.3 million as of September 30, 2022, is expected to be recognized as expense over a weighted average period of 2.82 years. The total fair value of options vested was \$1.8 million and \$0.1 million for the three months period ended September 30, 2022 and 2021, respectively. The total fair value of options vested was \$3.4 million and \$1.6 million, for the nine months period ended September 30, 2022 and 2021, respectively.

Outstanding stock options, if not exercised, expire ten years from the date of grant. The Company issues new shares of common stock upon exercise of stock options. The weighted average grant date fair value per share for the outstanding options at September 30, 2022 and December 31, 2021 was \$10.30 and \$5.42, respectively.

The Company determined the grant-date fair value of stock options using the Black-Scholes option pricing model. The fair value of each stock option grant was determined using assumptions that are subjective and require significant judgment and estimation by management. The risk-free rate assumption was based on observed yields from governmental zero-coupon bonds with a term equivalent to the option. The expected volatility assumption was based on historical volatilities of a group of comparable industry companies whose share prices are publicly available. The peer group was developed based on companies in the therapeutics and pharmaceutical industries. The expected term of stock options represents the weighted average period that the stock options are expected to be outstanding. Because the Company does not have historical exercise behavior, it determined the expected life assumption using the simplified method, which is an average of the options ordinary vesting period and the contractual term. The expected dividend assumption was based on the Company's history and expectation of dividend payouts at the time of grant. The Company recognizes forfeitures on an actual basis and, as such, did not estimate forfeitures to calculate stock-based compensation.

The following table presents the weighted average assumptions used in the Black-Scholes option pricing model to determine the fair value of stock options granted during the following periods:

	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2022
Exercise price	\$7.19	\$7.19
Stock price on date of grant	\$7.19	\$7.19
Expected term (years)	6.5	3.9
Expected stock price volatility	76.37%	45.40%
Risk-free rate of interest	3.13%	1.67%
Expected dividend yield	0%	0%

There is a high degree of subjectivity involved when using option-pricing models to estimate stock-based compensation. There are currently no market-based mechanisms or other practical applications to verify the reliability and accuracy of the estimates stemming from these models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of the employee stock-based awards is determined using an option-pricing model, the value may not be indicative of the fair value that would be observed in a market transaction between a willing buyer and a willing seller. If factors change and the Company employs different assumptions when valuing its options, the compensation expense that the Company records in the future may differ significantly from what it has historically reported.

#### **Restricted Stock Units**

In 2022, certain employees were awarded restricted stock units with time-based vesting. During the three and nine months ended September 30, 2022, the Company granted to certain employees 30,148 time-based vesting restricted stock units, with a weighted average grant date fair value of \$16.00. As of September 30, 2022, none of the restricted stock units had vested. As of September 30, 2022, the Company had unrecognized stock-based compensation expense related to restricted stock units of approximately \$0.4 million with a weighted average vesting period of approximately 1.25 years. The expense is recognized over the vesting period of the award.

The Company recognized the following compensation cost related to employee stock-based compensation activity:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	\$ 278,961	\$ 40,673	\$ 764,087	\$ 572,603
General and administrative	1,023,702	485,711	3,003,941	1,678,547
Total	<u>\$ 1,302,663</u>	<u>\$ 526,384</u>	<u>\$ 3,768,028</u>	<u>\$ 2,251,150</u>

#### **7. Net Loss per Share Attributable to Common Stockholders**

Net loss per share is computed by dividing net loss by the weighted average number of common stock outstanding during the period. Since the Company had a net loss in each of the periods presented, basic and diluted net loss per common share are the same.

The following weighted average common stock equivalents were excluded from the calculation of diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect for the following periods:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Redeemed convertible preferred stock (if converted)	—	10,504,199	—	10,504,199
2019 Warrants	—	739,463	—	739,463
2021 Warrants	—	113,325	—	113,325
Pre-Funded Warrants	2,600,000	—	2,600,000	—
Outstanding equity awards exercisable	1,625,896	172,051	1,305,585	65,128

#### **8. Related-Party Transactions**

##### *CinRx Pharma LLC and Subsidiaries ("CinRx")*

Certain former executives and employees of the Company, including the Company's former chief executive officer and a former member of the Company's board of directors, are members of CinRx's board of managers and/or have equity investments in CinRx. The Company received business management services from CinRx from time to time as needed, under a management services agreement, which was terminated on February 2, 2022. There were no business management service fees from CinRx during the three and nine months ended September 30, 2022. During the three and nine months ended September 30, 2021, the Company recorded business management fees totaling \$0.3 million and \$1.1 million, respectively. For the three months ended September 30, 2021, \$0.2 million are included in research and development expenses, while \$0.01 million are in general and administrative expenses on the condensed consolidated statement of operations. For the nine months ending September 30, 2021, \$0.8 million of the fees are included in research

and development expenses, while \$0.3 million are in general and administrative expenses on the condensed consolidated statement of operations.

## 9. Commitments and Contingencies

### Lease

On February 24, 2022, the Company entered into a license agreement, commencing April 1, 2022, for 5,400 square feet of office space in Waltham, Massachusetts, which is the Company's new headquarters. The annual rent is \$0.3 million. As this license agreement has a term of less than 12 months, the Company has not recorded it on the condensed consolidated balance sheet, as allowed under ASC Topic 842, *Leases* ("ASC 842"). The Company also has an agreement to lease 221 square feet of office space at 7875 Montgomery Rd. Suite 42, Cincinnati, OH 45236 from COHatch Cincinnati for \$2,850 per month. As this lease has a term of less than 12 months, the Company has not recorded it on the condensed consolidated balance sheet, as allowed under ASC 842. The Company's total rent expense for the three and nine months ended September 30, 2022, were \$0.1 million and \$0.2 million, respectively, recorded in general and administrative expense on our condensed consolidated statements of operations. No rent expense was recognized for the three and nine months ended September 30, 2021.

## 10. Employee Benefit Plan

The Company maintains a defined contribution 401(k) plan available to full time employees. Employee contributions are voluntary and are determined on an individual basis, limited by the maximum amounts allowable under federal tax regulations. The Company provides a safe harbor contribution of 4% of the employee's salary. The Company's safe harbor contributions recorded for the three and nine months ending September 30, 2022, totaled approximately \$0.1 million and \$0.2 million, respectively, and are included in research and development expense and general and administrative expense on the condensed consolidated statements of operations. The 401(k) plan was not in place during the three and nine months ended September 30, 2021.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

*The following discussion of the financial condition and results of operations of CinCor Pharma, Inc. should be read in conjunction with the unaudited condensed consolidated financial statements and the notes to those statements included in this Quarterly Report on Form 10-Q, our audited financial statements and related notes thereto for the year ended December 31, 2021 included in our most recent Annual Report on Form 10-K filed with the SEC on March 22, 2022. Some of the information contained in this discussion and analysis including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risk, uncertainties and assumptions. You should read the "Risk Factors" sections of this Quarterly Report Form 10-Q, our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, and our other filings with the SEC, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Please also refer to the section under the heading "Note Regarding Forward-Looking Statements."*

### Overview

We are a clinical-stage biopharmaceutical company focused on developing our lead clinical candidate, baxdrostat (CIN-107), for the treatment of hypertension and other cardio-renal diseases. Baxdrostat is a highly selective, oral small molecule inhibitor of aldosterone synthase, the enzyme responsible for the synthesis of aldosterone in the adrenal gland. Baxdrostat has been designed to use differentiated mechanism of action, direct inhibition of aldosterone synthase production, with the goal of providing an improved treatment for patients suffering from hypertension, or high blood pressure. The baxdrostate development program currently includes four Phase 2 clinical trials designed to evaluate baxdrostat in differing populations of patients, all of whom are hypertensive.

We recently completed our Phase 2 BrigHtn trial, a randomized, double blind, placebo controlled dose ranging study, which was conducted in patients whose blood pressure is not controlled despite treatment with three or more antihypertensive agents at their maximally tolerated doses, one of which must be a diuretic; these patients are designated as having treatment resistant hypertension, or rHTN. On August 8, 2022, we announced topline results of our BrigHtn trial. The trial evaluated three active doses of baxdrostat (0.5 mg, 1.0 mg, and 2.0 mg) compared to placebo control in 275 patients randomized across all four dosing cohorts, with 248 patients completing. The primary endpoint of BrigHtn was the change in SBP from randomization to study end after 12 weeks of treatment.

Key clinical data from BrigHtn suggests impressive efficacy and meaningful dose dependency in the treatment of patients with resistant hypertension:

- BrigHtn successfully met its primary endpoint, demonstrating a statistically significant change from baseline in mean seated SBP versus placebo for the 2 mg and 1 mg doses:
- 20.3 mmHg SBP reduction at the 2 mg dose, or 11.0 mmHg placebo-adjusted decline ( $p < 0.0001$ )

- 17.5 mmHg SBP reduction at the 1 mg dose, or 8.1 mmHg placebo-adjusted decline ( $p = 0.0030$ )
- 12.1 mmHg SBP reduction at the 0.5 mg dose, or 2.7 mmHg placebo-adjusted decline ( $p = 0.3110$ )
- Secondary endpoint results included baxdrostat significantly lowering diastolic blood pressure (DBP) by 5.2 mmHg in the 2mg dose, and approximately 46% of patients in the 2 mg dose arm achieving blood pressure control (SBP less than 130mmHg)
- The BrigHtn trial completed enrollment with 275 patients after an Independent Data Review Committee determined that the trial had met pre-specified statistical criteria of overwhelming efficacy at the highest dose in this dose-ranging trial

Key clinical safety and tolerability findings of baxdrostat support a safe and well-tolerated profile

- No drug related serious adverse events (SAEs) observed or major safety concerns were reported across all three dose cohorts tested after 12 weeks of treatment
- Treatment-Emergent SAEs (TESAEs) were reported in 10 patients and deemed by investigators to be unrelated to baxdrostat. These TESAEs included hyponatremia, hyperkalemia, cellulitis, urinary tract infection, dehydration, hyperglycemia, arthralgia, dizziness, syncope, acute kidney injury, nephrolithiasis, acute respiratory failure, and respiratory failure, with one patient experiencing six of these SAEs
- One subject experienced an isolated instance of elevated potassium above 6mEq/L, which was deemed drug related, although upon retesting, the potassium level for this patient dropped sufficiently to allow resumption of baxdrostat, and the patient completed the trial with normal potassium levels. Overall, observed hyperkalemia rates in the trial were low, and resulted in no clinical safety concerns
- Low discontinuation rate of less than 1% (2 patients) due to treatment-related adverse events, which included hyperkalemia and hypotension

We are also conducting a separate randomized Phase 2 clinical trial, which we refer to as our HALO trial, to evaluate baxdrostat in patients whose blood pressure is not controlled despite treatment with up to two antihypertensive agents, which is referred to as uncontrolled hypertension, or uHTN. Enrollment for our HALO trial was completed in July 2022 with 249 patients randomized. Our last patient last visit occurred in October 2022. The precise effect of baxdrostat on systolic blood pressure and the safety profile of baxdrostat in the HALO trial will not be known until the trial results are unblinded, but the blinded, preliminary safety data that the clinical trial team has been permitted to review through July 2022 appears to reflect that the overall population of participants in the trial is experiencing a systolic blood pressure reduction consistent with the observations we previously reported on the blinded data in the BrigHtn trial. Due to the preliminary and blinded nature of the data, we currently do not know to what extent participants receiving baxdrostat in the HALO trial experienced any decrease in systolic blood pressure, or if any such decreases in systolic blood pressure differed from participants receiving placebo, nor do we know the extent of placebo effect in this trial prior to unblinding the data. In addition, the blinded results reflect all trial participants regardless of dose cohort, which means that they include blood pressure and safety data from the placebo and all dosing cohorts. The HALO trial is ongoing, and we will not know whether treatment with baxdrostat at any dose lowers systolic blood pressure in a clinically meaningful manner until all clinical trials we intend to complete prior to submitting a request for marketing authorization have been conducted and the U.S. Food and Drug Administration, or the FDA, makes its efficacy determination. We also will not know the safety profile of baxdrostat in the HALO trial population until the trial is completed and the unblinded data become available to us, which is expected before year-end 2022. Furthermore, this preliminary data is not subject to the same quality control measures as final data, which creates a risk that the final results could be materially different from the preliminary results observed in this blinded safety data. For example, the data that is available at the conclusion of a trial would be unblinded following a data cleansing review, source verification of data using documents from the local clinical trial sites, and other quality control measures to ensure a high level of accuracy and fidelity. In contrast, the blinded preliminary safety data discussed above did not undergo this process and is therefore highly preliminary and not yet validated.

Additionally, an open-label extension clinical trial, referred to as the OLE trial, for patients previously enrolled in our HALO trial has been initiated to evaluate the long-term safety and tolerability of baxdrostat over an extended treatment period of up to 52 weeks.

In June 2022 we enrolled our first patient into a randomized Phase 2 clinical trial, referred to as our the figHTN-CKD trial, designed to evaluate the efficacy and safety of baxdrostat in lowering the blood pressure of patients with chronic kidney disease, or CKD. The figHTN-CKD trial also includes secondary endpoints intended to explore the potential impact of baxdrostat on slowing the progression of renal disease by measuring biomarkers. Finally, we are also conducting an open label Phase 2 clinical trial, which we refer to as our spark-PA trial, evaluating baxdrostat in patients with primary aldosteronism, or PA, a condition characterized by overproduction of aldosterone due to non-malignant tumors or abnormal collections of aldosterone-producing cells in the adrenal glands, which often presents with an aggressive form of hypertension. The spark-PA trial was initiated in 2021 and amended in May 2022 to better facilitate patient recruitment. Our first patient was dosed during this period.

Since our inception in 2018, we have focused primarily on organizing and staffing our company, business planning, and acquiring and progressing our lead product candidate, baxdrostat, through clinical development after in-licensing the compound from F. Hoffmann-La Roche Ltd and Hoffmann La-Roche Inc., whom we collectively refer to as Roche, in 2019, and raising capital. We were initially founded as a subsidiary of CinRx Pharma, LLC, or CinRx, and spun out as an independent company in 2019.

On January 11, 2022, we completed an initial public offering, or the IPO, of our common stock pursuant to which we issued and sold 13,290,813 shares of our common stock at a price to the public of \$16.00 per share. The aggregate net proceeds from the IPO, were approximately \$193.6 million after deducting underwriting discounts and commissions of \$14.9 million and offering expenses of approximately \$4.5 million. Upon completion of the IPO, all outstanding shares of Series A and Series B redeemable convertible preferred stock converted to common stock at a 3.4-for-1 in line with the reverse stock split of the Company's common stock. In addition, the IPO also resulted in the automatic net exercise of the three outstanding warrants to purchase common stock issued to Roche, or the Roche Warrants, for an aggregate of 852,788 shares of common stock.

On August 15, 2022, we completed an underwritten public offering of 6,025,000 shares of our common stock at a public offering price of \$30.00 per share and pre-funded warrants, or the Pre-Funded Warrants to purchase 2,600,000 shares of common stock at a public offering price of \$29.99999 per share, which represented the per share public offering price for the common stock less the \$0.00001 per share exercise price for each such Pre-Funded Warrants. Net proceeds received to date from the offering were approximately \$242.9 million, after deducting underwriting discounts and commissions and other estimated offering expenses.

We do not have any product candidates approved for sale and have not generated any revenue from product sales or licensing agreements. From inception through September 30, 2022, we have funded our operations primarily through equity financings, and have raised an aggregate of approximately \$405.5 million of gross proceeds from the sale of shares of our preferred stock, common stock and Pre-Funded Warrants. As of September 30, 2022, we had cash and cash equivalents and marketable securities on hand of \$522.5 million.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for baxdrostat or any future product candidates, if ever. In addition, if we obtain regulatory approval for baxdrostat or any future product candidates and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as, and when, needed, could have a negative effect on our business, results of operations and financial condition. If we are unable to obtain funding, we will be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Although we continue to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

#### **Roche License Agreement**

In May 2019, we entered into a license agreement, or the Roche Agreement, with Roche, pursuant to which we obtained an exclusive, worldwide, royalty-bearing license under certain patents and specified know-how owned or controlled by Roche and Roche's interest in joint patents and covering certain specified small molecule aldosterone synthase inhibitors, or the Roche Technology, to research, develop, register, use, make, import, export, market, distribute, sell (as well as the right to have each of the foregoing done, as defined in the Roche Agreement) and otherwise exploit products containing such aldosterone synthase inhibitors, or the Licensed Products, for any and all uses, including the treatment, prevention or diagnosis of any and all diseases and medical conditions in humans and animals.

#### **Components of Results of Operations**

##### ***Revenue***

To date, we have not recognized any revenue from any sources, including from product sales or licensing agreements, and we do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for baxdrostat or any future product candidate is successful and results in regulatory approval, we may generate revenue in the future from product sales. However, there can be no assurance as to when we will generate such revenue, if at all.

##### ***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred for our research activities, including our research and discovery efforts and the development of baxdrostat and any future product candidates. We expense research and development costs as incurred, which include:

- external research and development expenses incurred under arrangements with third parties, such as Contract Research Organizations, or CROs, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- costs related to acquiring, developing, and manufacturing clinical study material for our preclinical studies and clinical trials, including fees paid to contract manufacturing organizations, or CMOs;
- personnel costs for employees and third party contractors/consultants involved in managing and supporting R&D activities
- laboratory supplies and research materials;
- upfront, milestone and maintenance fees incurred under license, acquisition and other third-party agreements; and
- costs related to compliance with clinical regulatory requirements.

Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided to us by our vendors and clinical sites and analyzing the progress of clinical trials or other services performed. Significant judgment and estimates are made in determining the accrued expense balances at the end of any reporting period.

We track external research and development costs on a program-by-program basis. External costs include fees paid to consultants, contractors and vendors, including CMOs and CROs, in connection with our clinical activities. We currently only have one product development program, baxdrostat.

Research and development activities will continue to be central to our business model. We anticipate that our research and development expenses will increase for the foreseeable future as we advance our product candidates through clinical trials, as well as acquire new product candidates. We also expect higher employee-related expenses, including higher stock-based compensation expenses, as well as higher consulting costs as we hire additional resources to support increasing development activity.

The successful development of baxdrostat or any future product candidate is highly uncertain. We cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete development of baxdrostat or any future product candidate due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of baxdrostat or any future product candidate, if they are approved.

The duration, costs and timing of the clinical development of our product candidates will depend on a variety of factors that include, but are not limited to, the following:

- the scope, rate of progress, and expenses of our ongoing research activities as well as any preclinical studies and clinical trials and other research and development activities;
- the number and scope of clinical programs we decide to pursue;
- the uncertainties in clinical trial design and patient enrollment rates, and any changes we make to our clinical trial protocols;
- establishing an appropriate safety and efficacy profile;
- successful enrollment in and completion of clinical trials;
- whether baxdrostat shows safety and efficacy in our clinical trials;
- the timing, receipt and terms of marketing approvals from applicable regulatory authorities;
- making arrangements with third-party CMOs for manufacturing;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for baxdrostat and any future product candidate;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

A change in the outcome of any of these variables with respect to the development of baxdrostat or any future product candidate would significantly change the costs and timing associated with the development of those product candidates. We may never succeed in achieving regulatory approval for any product candidate. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on other product candidates. For example, if the U.S. Food and Drug Administration, the European Medicines Agency, or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

#### **General and Administrative Expenses**

General and administrative expenses consist primarily of compensation and employee-related costs for our finance, human resources and other administrative personnel, including salaries, benefits and other related costs, as well as expenses for outside professional services, including legal, accounting and audit services and other consulting fees, rent expense, other general administrative expenses, and stock-based compensation.

We expect our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates, potential commercialization efforts, and increased costs associated with operating as a public company. These increases will likely include additional costs related to the hiring of new personnel, including higher stock-based compensation expenses, and fees to outside consultants, as well as other related expenses. We also anticipate that we will incur significantly increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company.

#### **Interest Income**

Interest income consists primarily of interest income received on our cash and cash equivalents and marketable securities.

#### **Change in Fair Value of Warrant Derivative Liabilities**

The change in fair value of warrant derivative liabilities consists of the change in fair value related to the three freestanding detachable stock purchase warrants issued to Roche in connection with the Roche Agreement, which we collectively refer to as the Roche Warrants. The Roche Warrants automatically net exercised in whole immediately prior to the IPO, which resulted in the issuance of 852,788 shares of our common stock.

The grant date fair value of the Roche Warrants were calculated using the Black Scholes valuation model. The valuation models used require the input of subjective assumptions, including assumptions about the expected life of the Roche Warrant, share price volatility and as a privately held company prior to the IPO, the estimated fair value of our common stock. These assumptions used represent our best estimates at the time of issuance and in subsequent reporting periods, but the estimates involve inherent uncertainties and the application of our judgment.

### **Results of Operations**

#### **Results of Operations for the Three Months Ended September 30, 2022 and 2021**

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021:

	2022	2021
Operating expenses:		
Research and development	\$ 17,725,092	\$ 4,647,620
General and administrative	4,519,288	3,042,278
Total operating expenses	<u>22,244,380</u>	<u>7,689,898</u>
<b>Loss from operations</b>	<b>(22,244,380)</b>	<b>(7,689,898)</b>
Other (income) expense:		
Interest income	(1,266,821)	(1,947)
Change in fair value of warrant derivative liabilities	—	1,335,852
Total other (income) expense, net	<u>(1,266,821)</u>	<u>1,333,905</u>
<b>Net loss</b>	<b>\$ (20,977,559)</b>	<b>\$ (9,023,803)</b>

#### *Research and Development Expenses*

Research and development expenses for the three months ended September 30, 2022, were \$17.7 million, compared to \$4.6 million for the three months ended September 30, 2021. The increase of \$13.1 million, or 281%, was primarily due to the progression of several Phase 2 clinical trials including the completion of our BrigHtn trial, the full enrollment in our HALO trial, the initiation of our figHTN-CKD trial, increased chemistry, manufacturing and controls spending and the addition of several important full-time research and development resources.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, as our programs advance into later stages of development, and we continue to conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. We will also incur increased expenses related to headcount to support our continued research activities and development of our product candidates.

#### *General and Administrative Expenses*

General and administrative expenses were \$4.5 million for the three months ended September 30, 2022, compared to \$3.0 million for the three months ended September 30, 2021. The increase of \$1.5 million, or 49%, is primarily related to the increased personnel costs, as we hired our first employee in March 2021 and continued to build out our team primarily based in Waltham, MA (19 employees as of September 30, 2022), as well as increased legal and professional fees and other costs associated with operating as a public company.

We anticipate that our general and administrative expenses will increase as we continue to build our infrastructure, support increasing operating expenses and prepare for commercialization.

#### *Interest Income*

Interest income was \$1.3 million for the three months ended September 30, 2022, compared to \$1.9 thousand for the three months ended September 30, 2021, reflecting interest earned on cash and cash equivalents and marketable securities. The difference was attributed primarily to our increased cash and cash equivalents and marketable securities, resulting from the IPO in January 2022 and our public offering of common stock and Pre-Funded Warrants in August 2022, as well as our investments in higher interest bearing securities during the three months ended September 30, 2022.

#### *Change in Fair Value of Warrant Derivative Liabilities*

There was no change in the fair value of the warrant derivative liabilities for the three months ended September 30, 2022, compared to \$1.3 million for the three months ended September 30, 2021. The \$1.3 million decrease is due to the conversion of warrants to common stock in connection with the IPO. The Roche Warrants were issued in connection with the Roche Agreement and in connection with our Series A redeemable convertible preferred stock financing in 2019, with an additional warrants issued in connection with our Series B redeemable convertible preferred stock financing in 2021. Prior to the IPO, we classified the Roche Warrants as a liability on our condensed consolidated balance sheets which we remeasured to fair value at each reporting date. We recognize changes in the fair value of the warrant derivative liabilities as a component of other (income) expense, net in our condensed consolidated statements of operations. The Roche Warrants were automatically net exercised for an aggregate of 852,788 shares of common stock upon the completion of the IPO in January 2022.

#### *Results of Operations for the Nine Months Ended September 30, 2022 and 2021*

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021:

	2022	2021
Operating expenses:		
Research and development	\$ 44,576,704	\$ 12,135,441
General and administrative	12,724,801	5,141,861
Total operating expenses	57,301,504	17,277,302
<b>Loss from operations</b>	<b>(57,301,504)</b>	<b>(17,277,302)</b>
Other (income) expense:		
Interest income	(1,595,646)	(7,899)
Change in fair value of warrant derivative liabilities	3,044,006	3,755,509
Total other expense, net	1,448,360	3,747,610
<b>Net loss</b>	<b>\$ (58,749,865)</b>	<b>\$ (21,024,912)</b>

#### *Research and Development Expenses*

Research and development expenses for the nine months ended September 30, 2022, were \$44.6 million, compared to \$12.1 million for the nine months ended September 30, 2021. The increase of \$32.4 million, or 267%, was primarily due to the progression of several

Phase 2 clinical trials including the completion of the BrighTn study, the full enrollment of HALO, the initiation of our CKD trial, increased chemistry, manufacturing and controls spending and the addition of several important full-time research and development resources.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, as our programs advance into later stages of development, and we continue to conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. We will also incur increased expenses related to headcount to support our continued research activities and development of our product candidates.

#### *General and Administrative Expenses*

General and administrative expenses were \$12.7 million for the nine months ended September 30, 2022, compared to \$5.1 million for the nine months ended September 30, 2021. The increase of \$7.6 million, or 147%, is primarily related to the increased personnel costs, as we hired our first employee in March 2021 and continued to build out our team primarily in Waltham, MA (19 employees as of September 30, 2022), as well as increased legal and professional fees and other costs associated with operating as a public company.

We anticipate that our general and administrative expenses will increase as we continue to build our infrastructure, support increasing operating activities and prepare for commercialization.

#### *Interest Income*

Interest income was \$1.6 million for the nine months ended September 30, 2022, compared to \$7.9 thousand for the nine months ended September 30, 2021, reflecting interest earned on cash and cash equivalents and marketable securities. The difference was attributed primarily to our increased cash and cash equivalents and marketable securities, resulting from the IPO in January 2022 and our public offering of common stock and Pre-Funded Warrants in August 2022, as well as our investment in higher interest bearing securities.

#### *Change in Fair Value of Warrant Derivative Liabilities*

The change in the fair value of the warrant derivative liabilities was \$3.0 million for the nine months ended September 30, 2022, compared to \$3.8 million for the nine months ended September 30, 2021. These amounts are related to the change in fair value of the Roche Warrants, which was recognized as a derivative liability. The Roche Warrants were issued in connection with the Roche Agreement and in connection with our Series A redeemable convertible preferred stock financing in 2019, with an additional warrants issued in connection with our Series B redeemable convertible preferred stock financing in 2021. Prior to the IPO, we classified the Roche Warrants as a liability on our condensed consolidated balance sheets which we remeasured to fair value at each reporting date. We recognize changes in the fair value of the warrant derivative liabilities as a component of other (income) expense, net in our condensed consolidated statements of operations. The Roche Warrants were automatically net exercised for an aggregate of 852,788 shares of common stock upon the completion of the IPO in January 2022.

### **Liquidity and Capital Resources**

#### *Sources of Liquidity*

Since our inception, we have not recognized any revenue and have incurred operating losses and negative cash flows from our operations. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. From inception through September 30, 2022, we have funded our operations through private equity financings, the IPO in January 2022 and a public offering of our common stock and Pre-Funded Warrants in August 2022, and have raised an aggregate of approximately \$670.2 million of gross proceeds from the sale of shares of our preferred stock, common stock and Pre-Funded Warrants. The net proceeds from these sales totaled \$625.2 million. As of September 30, 2022, we had cash and cash equivalents and marketable securities on hand of \$522.5 million. Until such time, if ever, as we can generate substantial revenue, we expect to finance our cash needs through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements.

## Cash Flows

### Comparison of Nine Months Ended September 30, 2022 and 2021

The following table summarizes our cash flows for the nine months ended September 30, 2022 and 2021:

	2022	2021
Net cash used in operating activities	\$ (52,380,775 )	\$ (18,955,279 )
Net cash used in investing activities	(230,496,265 )	—
Net cash provided by financing activities	438,828,278	134,585,558
Net increase in cash and cash equivalents	\$ 155,951,238	\$ 115,630,279
Net change in marketable securities	229,939,796	-
Net increase in cash and cash equivalents and marketable securities	<u>\$ 385,891,034</u>	<u>\$ 115,630,279</u>

#### Operating Activities

We have historically experienced negative operating cash outflows as we continue clinical development of baxdrostat. Our net cash used in operating activities primarily results from our net loss adjusted for non-cash expenses and changes in working capital components. Our primary uses of cash from operating activities are amounts due to CROs for the conduct of our clinical programs and employee-related expenditures for research and development, and general and administrative activities. Our cash flows from operating activities will continue to be affected by spending to advance and support our clinical development and other operating and general administrative activities.

For the nine months ended September 30, 2022, net cash used in operating activities was \$52.4 million and was primarily related to cash payments for clinical development activities, personnel costs, legal and professional fees and other costs associated with operating activities.

For the nine months ended September 30, 2021, net cash used in operating activities was \$19.0 million and was primarily related to cash payments for clinical development activities and personnel-related costs under our Management Services Agreement with CinRx, legal and professional fees, and other costs associated with operating activities.

#### Investing Activities

Cash used in investing activities for the nine months ended September 30, 2022 of \$230.5 million was attributable to \$227.2 million for the purchase of marketable securities, partially offset by the maturity of \$60.0 million of marketable securities. There was no cash used in investing activities for the nine months ended September 30, 2021.

#### Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2022 was \$438.4 million, consisting of net cash proceeds from the IPO in January 2022 and the underwritten public offering of common stock and Pre-Funded warrants in August 2022.

Net cash provided by financing activities for the nine months ended September 30, 2021 of \$134.6 million was attributable to proceeds received from the issuance of Series B Redeemable Convertible Stock.

#### Funding Requirements

As of September 30, 2022, our cash and cash equivalents and marketable securities on hand were \$522.5 million. Based on our current plans, we believe that our existing cash and cash equivalents and marketable securities is sufficient to fund our operating expenses and capital expenditure requirements into 2026, including completing all of our ongoing Phase 2 trials, our currently planned Phase 3 clinical program in hypertension, CMC (chemistry manufacturing and control) development and GMP (good manufacturing practice) batch production, and the additional activities needed to complete our planned new drug application submission but not to complete the development and commercialization, if approved, of baxdrostat for hypertension as well as any indication expansion opportunities. We have based this estimate on assumptions that may prove to be wrong, and we could expend our capital resources sooner than we expect. This estimate is based on our current business plan and does not include any additional expenditures related to potential future development of additional product candidates or indications or resulting from the potential in-licensing or acquisition of additional product candidates or technologies, or any associated development we may pursue. This period could be shortened if there are any significant increases beyond our expectations in spending on development programs or more rapid progress of development programs than anticipated.

We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through preclinical and clinical development, seek regulatory approval and pursue commercialization of any approved product candidates. We expect that our research and development and general and administrative costs will increase in connection with our planned clinical

development and pre-commercialization activities. In addition, we expect to incur increased costs associated with operating as a public company.

If we receive regulatory approval for baxdrostat, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. We may also require additional capital to pursue in-licenses or acquisitions of other product candidates.

Our future capital requirements will depend on a number of factors, including:

- the costs of conducting preclinical studies and clinical trials;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing, and clinical trials for product candidates we may develop, if any;
- the costs, timing, and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any license or collaboration agreements we might have at such time;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and research and development activities;
- the costs of building out internal accounting, legal, compliance and other operational and administrative functions;
- the timing and size of any milestone payments required under our existing or future arrangements, including the Roche Agreement; and
- the costs of operating as a public company.

Our existing cash, cash equivalents and available for sale securities will not be sufficient to commercialize baxdrostat or any other product candidate. Accordingly, we will be required to obtain further funding to achieve our business objectives.

Until such time, if ever, as we can generate substantial revenue, we expect to finance our cash needs through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. However, global economic conditions have been worsening, with disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide and rising inflation resulting from the effects of COVID-19, geopolitical events such as the conflict between Russia and Ukraine, including related sanctions, and otherwise. If these conditions persist and deepen, we could experience an inability to access additional capital, or our liquidity could otherwise be impacted. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs and/or future commercialization efforts. To the extent that we raise additional capital through the sale of equity or convertible debt securities, stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect our stockholders. Debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through potential collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

## **Contractual Obligations and Commitments**

### *License Agreement Obligations*

License agreement obligations relate to the Roche Agreement that we entered into with Roche in May 2019. Under the terms of the Roche Agreement, we obtained an exclusive, worldwide, royalty-bearing license to the Roche Technology to research, develop, register, use, make, import, export, market, distribute, sell (as well as the right to have each of the foregoing done) and otherwise exploit to a novel aldosterone synthase inhibitor compound, baxdrostat. Pursuant to the Roche Agreement, we paid Roche a one-time, upfront non-refundable license fee of \$2.0 million and one \$1.0 million milestone payment in connection with the completion of the multiple ascending dose Phase 1 clinical trial of baxdrostat. We are required to pay Roche certain tiered development event-based milestone payments, certain sales-based milestone payments, as well as a royalty from the future sales of Licensed Products. The royalty is tiered based on the combined net sales of each Licensed Product.

We are currently unable to estimate the timing or likelihood of achieving these clinical and commercial milestones or generating future product sales. See Note 4 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for a description of our license agreement with Roche.

#### *Purchase and Other Obligations*

In the normal course of business, we enter into contracts with CROs and other third parties for conducting research and development activities, preclinical studies and clinical trials, research and development supplies and other testing and manufacturing services. The scope of the services under these contracts can be modified and provide for termination on notice, and therefore are cancellable contracts.

#### **Emerging Growth Company Status and Smaller Reporting Company Status**

We are an “emerging growth company,” or EGC, under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Section 107 of the JOBS Act provides that an EGC can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we have irrevocably opted not to use the extended transition period for complying with any new or revised financial accounting standards, and as such, we are required to adopt new or revised standards at the same time as other public companies.

As an EGC, we may also take advantage of certain exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an EGC:

- we will avail ourselves of the exemption from providing an auditor’s attestation report on our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- we will avail ourselves of the exemption from complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis;
- we are providing reduced disclosure about our executive compensation arrangements; and
- we will not require nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments.

We will remain an EGC until the earliest of (i) December 31, 2027, (ii) the last day of the fiscal year in which we have total annual gross revenues of \$1.235 billion or more, (iii) the date on which we have issued more than \$1 billion in non-convertible debt during the previous rolling three-year period, or (iv) the date on which we are deemed to be a large accelerated filer under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million.

If we are a smaller reporting company at the time we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to EGCs, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

#### **Recently Issued and Adopted Accounting Pronouncements**

We do not expect that any recently issued accounting standards will have a material impact on our condensed consolidated financial statements or will otherwise apply to our operations.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

We are a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required by this Item.

**Item 4. Controls and Procedures.*****Management's Evaluation of our Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and our Chief Financial Officer, 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 designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In connection with the preparation of this Quarterly Report on Form 10-Q, an evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and the Company's Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of September 30, 2022. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded our disclosure controls and procedures are effective as of September 30, 2022, at the reasonable assurance level.

***Changes in Internal Control over Financial Reporting***

During the quarter ended September 30, 2022, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

***Inherent Limitations on Effectiveness of Controls***

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any control system, no matter how well designed and operated, is based upon certain judgments and assumptions and cannot provide absolute assurance that its objectives will be met. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

**PART II—OTHER INFORMATION****Item 1. Legal Proceedings.**

As of the date of this Quarterly Report on Form 10-Q, we are not involved in any material legal proceedings. However, from time to time, we could be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. In addition, we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property rights, as well as claims relating to employment matters and the safety or efficacy of our products. Regardless of the outcome, legal proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. Additionally, any such claims, whether or not successful, could damage our reputation and business.

**Item 1A. Risk Factors.**

Our business is subject to numerous risks, including the risks previously disclosed in Item 1A, subsection "Risk Factors" to Part I, Item 1A of the Annual Report. The occurrence of any of the events or developments described in the Annual Report could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

In addition to the risks described in our Annual Report, you should carefully consider the other information set forth in this Form 10-Q and the information in our other filings with the SEC, as they could materially affect our business, financial condition or future results of operations. There were no material changes during the period covered in this Form 10-Q to the risk factors previously disclosed in Part I, Item 1A of the Annual Report

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

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

through diversification of our investments and continuous monitoring of our portfolio's overall risk profile, the value of our investments may nevertheless decline.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

**(a) Recent Sales of Unregistered Equity Securities**

None.

**(b) Use of Proceeds from Initial Public Offering of Common Stock**

On January 11, 2022, we completed the IPO of our common stock pursuant to which we issued and sold 12,100,000 shares of our common stock at a price to the public of \$16.00 per share. On February 8, 2022, we issued and sold an additional 1,190,813 shares of our common stock at a price to the public of \$16.00 per share pursuant to a partial exercise of the underwriters' over-allotment option.

All of the shares issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No 333-261738), which was declared effective on January 6, 2022.

The aggregate net proceeds to us from the IPO, inclusive of proceeds from the over-allotment exercise, were approximately \$193.6 million after deducting underwriting discounts and commissions of \$14.9 million and offering expenses of approximately \$4.5 million.

Information related to use of proceeds through the later of disclosure of the application of all the offering proceeds, or disclosure of the termination of the offering, from the sale of registered securities is incorporated herein by reference to the "Use of Proceeds" sections of our final prospectus related to the IPO. There has been no material change in our planned use of the net proceeds from these offerings as described in the prospectus documents filed pursuant to Rule 424(b)(4) under the Securities Act with the U.S. Securities and Exchange Commission, or SEC, on January 7, 2022.

**(c) Issuer Purchases of Equity Securities**

None.

**Item 3. Defaults Upon Senior Securities.**

Not applicable.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

Exhibit Number	Description
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the Registrant (filed as Exhibit 3.1 to Registrant's Current Report on Form 8-K, filed with the SEC on January 11, 2022, and incorporated by reference herein).</a>
3.2	<a href="#">Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.2 to Registrant's Current Report on Form 8-K, filed with the SEC on January 11, 2022, and incorporated by reference herein).</a>
4.1	<a href="#">Form of Pre-Funded Warrant issued on August 15, 2022 (filed as Exhibit 4.1 to Registrant's Current Report on Form 8-K, filed with the SEC on August 11, 2022, and incorporated by reference herein).</a>
31.1*	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2*	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1+*	<a href="#">Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)









