

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 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, 2020

**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: 001-38583

**Crinetics Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation or organization)

10222 Barnes Canyon Road, Bldg. #2,  
San Diego, California  
(Address of principal executive offices)

26-3744114  
(I.R.S. Employer  
Identification No.)

92121  
(Zip code)

Registrant's telephone number, including area code: (858) 450-6464

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	CRNX	Nasdaq Global Select Market

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 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 checked="" type="checkbox"/>
Non-accelerated filer	<input 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 October 31, 2020, the registrant had 32,922,328 shares of common stock (\$0.001 per share par value) outstanding.

**QUARTERLY REPORT ON FORM 10-Q**  
**For the Quarter Ended September 30, 2020**

**TABLE OF CONTENTS**

	<u>Page</u>
<b><u>PART I – FINANCIAL INFORMATION</u></b>	
Item 1.	3
	3
	4
	5
	6
	7
Item 2.	17
Item 3.	25
Item 4.	25
<b><u>PART II — OTHER INFORMATION</u></b>	
Item 1.	26
Item 1A.	26
Item 2.	26
Item 3.	27
Item 4.	27
Item 5.	27
Item 6.	28

## Item 1. Condensed Financial Statements

**Crinetics Pharmaceuticals, Inc.**  
**Condensed Consolidated Balance Sheets**  
(In thousands)

	September 30, 2020 (Unaudited)	December 31, 2019
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 117,820	\$ 40,326
Investment securities	69,004	78,066
Prepaid expenses and other current assets	7,298	4,947
Total current assets	194,122	123,339
Property and equipment, net	3,389	3,946
Operating lease right-of-use asset	2,306	2,510
Restricted cash	500	500
Other assets	—	82
Total assets	<u>\$ 200,317</u>	<u>\$ 130,377</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 4,690	\$ 5,498
Accrued compensation and related expenses	3,333	2,118
Other current liabilities	810	724
Total current liabilities	8,833	8,340
Operating lease liability, non-current	4,234	4,849
Unvested stock liability	28	49
Total liabilities	13,095	13,238
<b>Commitments and contingencies (Note 7)</b>		
<b>Stockholders' equity:</b>		
Preferred stock, \$0.001 par value; 10,000 shares authorized; no shares issued or outstanding at September 30, 2020 or at December 31, 2019	—	—
Common stock and paid-in capital, \$0.001 par value; 200,000 shares authorized; 32,941 shares issued and 32,921 shares outstanding at September 30, 2020; 24,296 shares issued and 24,263 shares outstanding at December 31, 2019	333,151	210,793
Accumulated other comprehensive income	44	148
Accumulated deficit	(145,973)	(93,802)
Total stockholders' equity	187,222	117,139
Total liabilities and stockholders' equity	<u>\$ 200,317</u>	<u>\$ 130,377</u>

*See the accompanying notes to these unaudited condensed consolidated financial statements.*

**Crinetics Pharmaceuticals, Inc.**

**Condensed Consolidated Statements of Operations and Comprehensive Loss**

(In thousands, except per share data)  
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Grant revenues	\$ —	\$ 505	\$ 71	\$ 872
<b>Operating expenses:</b>				
Research and development	13,699	11,823	40,168	29,363
General and administrative	4,752	3,911	13,065	10,127
Total operating expenses	<u>18,451</u>	<u>15,734</u>	<u>53,233</u>	<u>39,490</u>
Loss from operations	<u>(18,451)</u>	<u>(15,229)</u>	<u>(53,162)</u>	<u>(38,618)</u>
<b>Other income (expense):</b>				
Interest income	122	835	938	2,805
Other income (expense), net	9	(36)	53	(60)
Total other income (expense), net	<u>131</u>	<u>799</u>	<u>991</u>	<u>2,745</u>
Net loss	<u>(18,320)</u>	<u>(14,430)</u>	<u>(52,171)</u>	<u>(35,873)</u>
<b>Other comprehensive income (loss):</b>				
Unrealized gain (loss) on investment securities	(83)	(36)	(104)	137
<b>Comprehensive loss</b>	<u>\$ (18,403)</u>	<u>\$ (14,466)</u>	<u>\$ (52,275)</u>	<u>\$ (35,736)</u>
<b>Net loss per share:</b>				
Net loss per share – basic and diluted	<u>\$ (0.56)</u>	<u>\$ (0.60)</u>	<u>\$ (1.76)</u>	<u>\$ (1.49)</u>
Weighted average shares outstanding – basic and diluted	<u>32,890</u>	<u>24,208</u>	<u>29,608</u>	<u>24,155</u>

*See the accompanying notes to these unaudited condensed consolidated financial statements.*

**Crinetics Pharmaceuticals, Inc.**  
**Condensed Consolidated Statements of Stockholders' Equity**

(In thousands, except per share data)  
(Unaudited)

	Common Stock Shares	Common stock and Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance at July 1, 2020	32,882	\$ 330,300	\$ 127	\$ (127,653)	\$ 202,774
Vesting of stock subject to repurchase	4	5	—	—	5
Exercise of stock options	35	64	—	—	64
Stock-based compensation	—	2,782	—	—	2,782
Comprehensive loss	—	—	(83)	—	(83)
Net loss	—	—	—	(18,320)	(18,320)
Balance at September 30, 2020	<u>32,921</u>	<u>\$ 333,151</u>	<u>\$ 44</u>	<u>\$ (145,973)</u>	<u>\$ 187,222</u>
Balance at January 1, 2020	24,263	\$ 210,793	\$ 148	\$ (93,802)	\$ 117,139
Issuance of stock in public offering, net of issuance costs of \$7,259	8,223	107,856	—	—	107,856
Stock issued in at-the-market offering, net of costs of \$199	276	6,427	—	—	6,427
Vesting of stock subject to repurchase	13	21	—	—	21
Exercise of stock options	119	191	—	—	191
Issuance of stock under Stock Purchase Plan	27	407	—	—	407
Stock-based compensation	—	7,456	—	—	7,456
Comprehensive loss	—	—	(104)	—	(104)
Net loss	—	—	—	(52,171)	(52,171)
Balance at September 30, 2020	<u>32,921</u>	<u>\$ 333,151</u>	<u>\$ 44</u>	<u>\$ (145,973)</u>	<u>\$ 187,222</u>
Balance at July 1, 2019	24,195	\$ 206,690	\$ 234	\$ (64,823)	\$ 142,101
Vesting of stock subject to repurchase	10	12	—	—	12
Exercise of stock options	13	22	—	—	22
Stock-based compensation	—	1,854	—	—	1,854
Comprehensive (loss)	—	—	(36)	—	(36)
Net loss	—	—	—	(14,430)	(14,430)
Balance at September 30, 2019	<u>24,218</u>	<u>\$ 208,578</u>	<u>\$ 198</u>	<u>\$ (79,253)</u>	<u>\$ 129,523</u>
Balance at January 1, 2019	24,061	\$ 203,544	\$ 61	\$ (43,380)	\$ 160,225
Vesting of stock subject to repurchase	56	83	—	—	83
Exercise of stock options	76	109	—	—	109
Issuance of stock under Stock Purchase Plan	25	379	—	—	379
Stock-based compensation	—	4,463	—	—	4,463
Comprehensive income	—	—	137	—	137
Net loss	—	—	—	(35,873)	(35,873)
Balance at September 30, 2019	<u>24,218</u>	<u>\$ 208,578</u>	<u>\$ 198</u>	<u>\$ (79,253)</u>	<u>\$ 129,523</u>

*See the accompanying notes to these unaudited condensed consolidated financial statements.*

Crinetics Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(In thousands)  
(Unaudited)

	Nine months ended September 30,	
	2020	2019
<b>Operating activities:</b>		
Net loss	\$ (52,171)	\$ (35,873)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation	7,456	4,463
Depreciation and amortization	723	658
Noncash lease expense	204	166
Accretion of purchase discounts and amortization of premiums on investment securities, net	(293)	(1,009)
Other, net	(18)	3
<b>Increase (decrease) in cash resulting from changes in:</b>		
Prepaid expenses and other current assets	(2,269)	(923)
Accounts payable and accrued expenses	808	22
Operating lease liability	(529)	(441)
Net cash used in operating activities	(46,089)	(32,934)
<b>Investing activities:</b>		
Purchases of investment securities	(113,762)	(67,070)
Maturities of investment securities	123,040	122,024
Purchases of property and equipment	(169)	(464)
Net cash provided by investing activities	9,109	54,490
<b>Financing activities:</b>		
Proceeds from issuance of stock in public offering, net	107,856	—
Proceeds from issuance of stock in at-the-market offering, net	6,427	—
Proceeds from exercise of stock options	191	109
Repurchase of unvested shares	—	(59)
Net cash provided by financing activities	114,474	50
<b>Net change in cash, cash equivalents and restricted cash</b>	<b>77,494</b>	<b>21,606</b>
<b>Cash, cash equivalents and restricted cash at beginning of period</b>	<b>40,826</b>	<b>45,473</b>
<b>Cash, cash equivalents and restricted cash at end of period</b>	<b>\$ 118,320</b>	<b>\$ 67,079</b>
<b>Components of cash, cash equivalents and restricted cash:</b>		
Cash and cash equivalents	\$ 117,820	\$ 66,579
Restricted cash	500	500
Cash, cash equivalents and restricted cash at end of period	\$ 118,320	\$ 67,079
<b>Noncash investing and financing activities:</b>		
Issuance of shares under Stock Purchase Plan	\$ 407	\$ 379
Amounts accrued for purchases of property and equipment	\$ 6	\$ —
Change in unvested stock liability	\$ 21	\$ 83

See the accompanying notes to these unaudited condensed consolidated financial statements.

**1. ORGANIZATION AND BASIS OF PRESENTATION****Description of Business**

Crinetics Pharmaceuticals, Inc. (the “Company”) is a clinical-stage pharmaceutical company incorporated in Delaware on November 18, 2008 and based in San Diego, California. The Company is focused on the discovery, development and commercialization of novel therapeutics for rare endocrine diseases and endocrine-related tumors. In January 2017, the Company established a wholly owned Australian subsidiary, Crinetics Australia Pty Ltd (“CAPL”), in order to conduct various preclinical and clinical activities for its development candidates.

**Unaudited Interim Financial Information**

The accompanying interim condensed consolidated balance sheet as of September 30, 2020, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2020 and 2019, the condensed consolidated statements of stockholders’ equity for the three and nine months ended September 30, 2020 and 2019, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2020 and 2019, and the related disclosures are unaudited. In management’s opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company’s financial position as of September 30, 2020 and the results of its operations and cash flows for the nine months ended September 30, 2020 and 2019 in accordance with accounting principles generally accepted in the United States of America (“GAAP”). The results for the three and nine months ended September 30, 2020 are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

**Principles of Consolidation and Foreign Currency Transactions**

The condensed consolidated financial statements include the accounts of the Company and CAPL. All intercompany accounts and transactions have been eliminated in consolidation. The functional currency of both the Company and CAPL is the U.S. dollar. Assets and liabilities that are not denominated in the functional currency are remeasured into U.S. dollars at foreign currency exchange rates in effect at the balance sheet date except for nonmonetary assets, which are remeasured at historical foreign currency exchange rates in effect at the date of transaction. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in other income (expense), in the condensed consolidated statements of operations and were not material for all periods presented.

**Segment Reporting**

Operating segments are identified as components of an enterprise about which discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

**Liquidity and Going Concern**

From inception, the Company has devoted substantially all of its efforts to drug discovery and development and conducting preclinical studies and clinical trials. The Company has a limited operating history and the sales and income potential of the Company’s business and market are unproven. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company’s cost structure.

As of September 30, 2020, the Company had \$186.8 million in unrestricted cash, cash equivalents and investment securities, which the Company believes is sufficient to meet its funding requirements for at least the next 12 months.

The Company has experienced net losses and negative cash flows from operating activities since its inception and has an accumulated deficit of \$146.0 million as of September 30, 2020. The Company expects to continue to incur net losses for the foreseeable future and believes it will need to raise substantial additional capital to accomplish its business plan over the next several years. The Company plans to continue to fund its losses from operations and capital funding needs through a combination of equity offerings, debt financings or other sources, including potential collaborations, licenses and other similar arrangements. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with

suppliers, liquidate assets where possible, or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations and future prospects. There can be no assurance as to the availability or terms upon which such financing and capital might be available in the future.

## **COVID-19**

The COVID-19 pandemic has caused significant business disruption around the globe. The extent of the impact of COVID-19 on the Company's operational and financial performance will depend on certain developments, including the duration and spread of the pandemic and the impact on the Company's clinical trials, employees and vendors. In response to the spread of COVID-19, we have restricted access to our offices to lab and a limited number of other personnel, while the remainder of our employees are continuing their work outside of our offices. At this point, the degree to which COVID-19 may impact the Company's financial condition or future results of operations is uncertain. A prolonged outbreak could have a material adverse impact on financial results and business operations of the Company, including the timing and ability of Company to complete certain clinical trials and other efforts required to advance the development of its drug candidates and raise additional capital.

In response to the pandemic, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was signed into law on March 27, 2020. The CARES Act, among other things, includes tax provisions relating to refundable payroll tax credits, deferment of employer's social security payments, net operating loss utilization and carryback periods, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The CARES Act has not had a material impact on our income tax provision for the nine months ended September 30, 2020. We will continue to evaluate the impact of the CARES Act on our financial position, results of operations and cash flows.

## **2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### **Use of Estimates**

The Company's condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of the Company's condensed consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's condensed consolidated financial statements and accompanying notes. The most significant estimates in the Company's condensed consolidated financial statements relate to accrued expenses and associated research and development expense, accrued amounts receivable under the Australian research and development tax incentive program, the assumptions underlying the determination of the estimated incremental borrowing rate for the determination of the Company's operating lease right-of-use asset, and the assumptions underlying the determination of the fair value of equity awards for purposes of determining stock-based compensation. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

### **Fair Value Measurements**

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The carrying amounts of the Company's current financial assets, restricted cash and current financial liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments.



### **Cash, Cash Equivalents and Restricted Cash**

Cash and cash equivalents include cash held in readily available checking and money market accounts, as well as short-term debt securities with maturities of three months or less when purchased. Restricted cash represents cash held as collateral for the Company's facility lease and is reported as a long-term asset in the accompanying condensed consolidated balance sheets.

### **Investment Securities**

All investments have been classified as "available-for-sale" and are carried at fair value as determined based upon quoted market prices or pricing models for similar securities at period end. Investments with contractual maturities less than 12 months at the balance sheet date are considered short-term investments. Investments with contractual maturities beyond one year are also classified as short-term due to the Company's ability to liquidate the investment for use in operations within the next 12 months.

Realized gains and losses on investment securities are included in earnings and are derived using the specific identification method for determining the cost of securities sold. The Company has not realized any significant gains or losses on sales of available-for-sale investment securities during any of the periods presented. As all the Company's investment holdings are in the form of debt securities, unrealized gains and losses that are determined to be temporary in nature are reported as a component of accumulated other comprehensive income (loss). A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the establishment of a new cost basis for the security. Interest income is recognized when earned and is included in investment income, as are the amortization of purchase premiums and accretion of purchase discounts on investment securities.

### **Concentrations of Credit Risk**

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and investment securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash balances due to the financial position of the depository institution in which those deposits are held. Additionally, the Company has established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

### **Leases**

The Company determines if an arrangement is a lease at the inception of the arrangement. Leases with a term longer than 12 months that are determined to be operating leases are included in operating lease assets, accrued expenses and other current liabilities and noncurrent operating lease liabilities in the condensed consolidated balance sheets based on the present value of the minimum lease payments called for under the arrangement. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

### **Research and Development Expenses**

Research and development ("R&D") expenses consist primarily of salaries, payroll taxes, employee benefits and stock-based compensation for individuals involved in R&D efforts, as well as consulting expenses, third-party R&D expenses, laboratory supplies, clinical materials and overhead, including facilities and depreciation costs, offset by the Australian Tax Incentive discussed below. R&D expenses are charged to expense as incurred. Payments made prior to the receipt of goods or services to be used in R&D are capitalized until the goods or services are received.

Costs incurred under contracts with contract research organizations that conduct and manage the Company's clinical trials are also included in research and development expenses. The financial terms and activities of these agreements vary from contract to contract and may result in uneven expense levels. Generally, these agreements set forth activities that drive the recording of expenses such as start-up and initiation activities, enrollment and treatment of patients, or the completion of other clinical trial activities. Expenses related to clinical trials are accrued based on estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies and progress of the clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the amounts that the Company is obligated to pay under its clinical trial agreements are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the Company adjusts its accruals accordingly on a prospective basis. Revisions to contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

Accrued R&D expenses were \$2.1 million at September 30, 2020 and \$2.8 million at December 31, 2019 and are included in accounts payable and accrued expenses in the condensed consolidated balance sheets.

#### **Australian Tax Incentive**

CAPL is eligible to obtain a cash refund from the Australian Taxation Office for eligible R&D expenditures under the Australian R&D Tax Incentive Program (the “Australian Tax Incentive”). The Australian Tax Incentive is recognized as a reduction to R&D expense when there is reasonable assurance that the Australian Tax Incentive will be received, the relevant expenditure has been incurred, and the amount can be reliably measured.

The Company recognized a reduction to R&D expense of \$0.2 million and \$0.6 million for the three and nine months ended September 30, 2020, respectively; for the three and nine months ended September 30, 2019, the Company recognized a reduction to R&D expense of \$0.3 million and \$0.6 million, respectively.

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

Stock-based compensation expense represents the estimated grant date fair value of the Company’s equity awards, consisting of stock options and shares issued under the Company’s Employee Stock Purchase Plan, recognized over the requisite service period of such awards (usually the vesting period) on a straight-line basis. For stock awards for which vesting is subject to performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable, or the performance condition has been achieved. The Company estimates the fair value of all stock option grants using the Black-Scholes option pricing model and recognizes forfeitures as they occur.

#### **Comprehensive Loss**

Comprehensive loss is comprised of the Company’s net loss and the unrealized gain or loss on the Company’s investment securities held for all periods presented.

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

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. Dilutive common stock equivalents are comprised of common stock subject to repurchase and stock options outstanding under the Company’s stock option plan. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive securities would be antidilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are shown below in common stock equivalent shares (in thousands):

	<u>September 30,</u>	
	<u>2020</u>	<u>2019</u>
Common stock options	4,224	3,107
Unvested common stock subject to repurchase	20	40
	<u>4,244</u>	<u>3,147</u>

#### **Recently Adopted Accounting Pronouncements**

##### *ASU 2018-13*

In August 2018, the FASB issued ASU 2018-13, “*Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*,” which improves the effectiveness of the disclosures required under ASC 820, “*Fair Value Measurements and Disclosures*” and modifies the disclosure requirements on fair value measurements, including the consideration of costs and benefits. The new standard is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The Company has prospectively adopted ASU 2018-13 as of January 1, 2020 for periods presented after adoption. The adoption of ASU 2018-13 did not have a material impact on the Company’s consolidated financial statements.

## Recent Accounting Pronouncements

### ASU 2016-13

In June 2016, the FASB issued ASU No. 2016-13, “Financial Instruments - Credit Losses (Topic 326): *Measurement of Credit Losses on Financial Instruments*” (“Topic 326”). Topic 326 amends guidance on reporting credit losses for assets held at amortized cost basis and available for sale debt securities. For assets held at amortized cost basis, Topic 326 eliminates the probable initial recognition threshold in current GAAP and, instead, requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For available for sale debt securities, credit losses should be measured in a manner similar to current GAAP, however Topic 326 will require that credit losses be presented as an allowance rather than as a write-down. This ASU update affects entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. This update is effective for the company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company is currently evaluating the impact of the pending adoption of this new standard on its consolidated financial statements.

### 3. INVESTMENT SECURITIES

The Company reports its available-for-sale investment securities at their estimated fair values based on quoted market prices for identical or similar instruments. The following is a summary of the available-for-sale investment securities held by the Company as of September 30, 2020 and December 31, 2019 (in thousands):

	As of September 30, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Available-for-sale investment securities:				
U.S. government and agency obligations	\$ 58,658	\$ 5	\$ (7)	\$ 58,656
Certificates of deposit	5,310	26	—	5,336
Corporate debt securities	4,992	20	—	5,012
Total	<u>\$ 68,960</u>	<u>\$ 51</u>	<u>\$ (7)</u>	<u>\$ 69,004</u>

	As of December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Available-for-sale investment securities:				
U.S. government and agency obligations	\$ 43,275	\$ 94	\$ (1)	\$ 43,368
Certificates of deposit	5,931	51	—	5,982
Commercial paper	17,645	—	—	17,645
Corporate debt securities	11,067	7	(3)	11,071
Total	<u>\$ 77,918</u>	<u>\$ 152</u>	<u>\$ (4)</u>	<u>\$ 78,066</u>

All available-for-sale investment securities held at September 30, 2020 and December 31, 2019, had maturity dates of less than 24 months.

None of the Company’s available-for-sale investment securities were in a material unrealized loss position at September 30, 2020 or December 31, 2019. As such, the Company has not recognized any impairment in its financial statements related to its available-for-sale investment securities.

### 4. FAIR VALUE MEASUREMENTS

The Company holds investment securities that consist of highly liquid, investment grade debt securities. The Company determines the fair value of its investment securities based upon one or more valuations reported by its investment accounting and reporting service provider. The investment service provider values the securities using a hierarchical security pricing model that relies primarily on valuations provided by an industry-recognized valuation service. Such valuations may be based on trade prices in active markets for identical assets or liabilities (Level 1 inputs) or valuation models using inputs that are observable either directly or indirectly (Level 2 inputs), such as

quoted prices for similar assets or liabilities, yield curves, volatility factors, credit spreads, default rates, loss severity, current market and contractual prices for the underlying instruments or debt, and broker and dealer quotes, as well as other relevant economic measures.

Financial assets measured at fair value on a recurring basis as of September 30, 2020 and December 31, 2019 were as follows (*in thousands*):

	As of September 30, 2020			
	Level 1	Level 2	Level 3	Total
<b>Investment securities:</b>				
U.S. government and agency obligations	\$ 50,157	\$ 8,499	\$ —	\$ 58,656
Certificates of deposit	—	5,336	—	5,336
Corporate debt securities	—	5,012	—	5,012
Total assets measured at fair value	<u>\$ 50,157</u>	<u>\$ 18,847</u>	<u>\$ —</u>	<u>\$ 69,004</u>

	As of December 31, 2019			
	Level 1	Level 2	Level 3	Total
<b>Investment securities:</b>				
U.S. government and agency obligations	\$ 15,478	\$ 27,890	\$ —	\$ 43,368
Certificates of deposit	—	5,982	—	5,982
Commercial paper	—	17,645	—	17,645
Corporate debt securities	—	11,071	—	11,071
Total assets measured at fair value	<u>\$ 15,478</u>	<u>\$ 62,588</u>	<u>\$ —</u>	<u>\$ 78,066</u>

The Company's policy is to recognize transfers between levels of the fair value hierarchy on the date of the event or change in circumstances that caused the transfer. There were no transfers into or out of Level 3 during the nine months ended September 30, 2020.

## 5. BALANCE SHEET DETAILS

Prepaid expenses and other current assets consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Prepaid research and development costs	\$ 3,848	\$ 2,478
Australian tax incentive receivable	1,644	929
Prepaid insurance	1,022	648
Interest receivable	125	224
Prepaid expenses and other assets	659	668
Total	<u>\$ 7,298</u>	<u>\$ 4,947</u>

Property and equipment, net consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Leasehold improvements	\$ 3,494	\$ 3,494
Lab equipment	1,534	1,468
Office equipment	653	567
Computers and software	41	41
Property and equipment at cost	5,722	5,570
Less accumulated depreciation and amortization	2,333	1,624
Total	<u>\$ 3,389</u>	<u>\$ 3,946</u>

## 6. OPERATING LEASE

*2018 Operating Lease.* In February 2018, as amended in March 2018, the Company entered into a non-cancelable operating lease for a facility in San Diego, California. The lease has an initial term of seven years which expires in August 2025, and the Company has an option to extend the term of the lease for an additional five years and has a termination option subject to early termination fees. The lease is subject to base lease payments and additional charges for common area maintenance and other costs and includes certain lease incentives and tenant improvement allowances. Rent expense is being recognized on a straight-line basis over the term of the lease. The Company's estimated incremental borrowing rate of 8.0% was used in its present value calculation as the facility lease does not have a stated rate, and the implicit rate was not readily determinable.

Under the terms of the lease, the Company provided the lessor with an irrevocable letter of credit in the amount of \$0.5 million. The lessor is entitled to draw on the letter of credit in the event of any default by the Company under the terms of the lease.

*Future Minimum Payments.* As of September 30, 2020, future minimum payments under non-cancellable operating leases were as follows (in thousands):

<b>Year ending December 31,</b>	<b>Minimum Payments</b>
2020 (3 months)	\$ 290
2021	1,173
2022	1,208
2023	1,244
2024	1,280
Thereafter	871
Total future minimum lease payments	6,066
Less imputed interest	1,022
Total operating lease liability	5,044
Less operating lease liability, current	810
Operating lease liability, non-current	\$ 4,234

Rent expense was \$0.3 million and \$0.8 million for the three and nine months ended September 30, 2020, respectively; for the three and nine months ended September 30, 2019, the Company recognized rent expense of \$0.2 million and \$0.7 million, respectively.

Cash paid for amounts included in the measurement of lease liabilities for operating cash flow from operating leases was \$0.8 million during each of the nine month periods ended September 30, 2020 and 2019, respectively.

## 7. COMMITMENTS AND CONTINGENCIES

### Litigation

From time to time, the Company may be subject to various claims and suits arising in the ordinary course of business. The Company does not expect that the resolution of these matters will have a material adverse effect on its financial position or results of operations.

## 8. STOCKHOLDERS' EQUITY

### Authorized Shares

In connection with the completion of the Company's initial public offering in July 2018, the Company amended and restated its certificate of incorporation to authorize 200,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share.

### Stock Offering

On April 17, 2020, the Company completed a public offering of 8,222,500 shares of its common stock at a public offering price of \$14.00 per share. Proceeds from the offering were approximately \$107.9 million, net of underwriting discounts and commissions and offering costs of \$7.3 million. The shares were registered pursuant to the Company's Shelf Registration Statement discussed below.

## **Shelf Registration Statement and ATM Offering**

On August 13, 2019, the Company filed a registration statement on Form S-3 (the “Shelf Registration Statement”), covering the offering of up to \$300.0 million of common stock, preferred stock, debt securities, warrants and units. The Registration Statement became effective on August 29, 2019.

On August 13, 2019 the Company also entered into a Sales Agreement (the “Sales Agreement”) with SVB Leerink LLC and Cantor Fitzgerald & Co. (collectively, the “Sales Agents”), under which the Company may, from time to time, sell shares of its common stock having an aggregate offering price of up to \$75.0 million through the Sales Agents (the “ATM Offering”). The Shelf Registration Statement included a prospectus covering the offering, issuance and sale of up to \$75.0 million of the Company’s common stock from time to time through the ATM Offering. The shares to be sold under the Sales Agreement may be issued and sold pursuant to the Shelf Registration Statement.

During the three-month period ended March 31, 2020, the Company issued 275,764 shares of common stock in the ATM Offering for net proceeds of \$6.4 million, after deducting commissions. The Company has not issued any additional shares of common stock in the ATM Offering since the first quarter of 2020.

## **9. EQUITY INCENTIVE PLANS**

### **2018 Incentive Award Plan**

In July 2018, the Company adopted the 2018 Incentive Award Plan (the “2018 Plan”). Under the 2018 Plan, which expires in July 2028, the Company may grant equity-based awards to individuals who are employees, officers, directors or consultants of the Company. Options issued under the 2018 Plan will generally expire ten years from the date of grant and vest over a four-year period. As of September 30, 2020, 2,216,046 shares were available for future issuance under the 2018 Plan.

The 2018 Plan contains a provision that allows annual increases in the number of shares available for issuance on the first day of each calendar year through January 1, 2028 in an amount equal to the lesser of: (i) 5% of the aggregate number of shares of the Company’s common stock outstanding on December 31 of the immediately preceding calendar year, or (ii) such lesser amount determined by the Company. Under this evergreen provision, on January 1, 2020, an additional 1,214,804 shares became available for future issuance under the 2018 Plan.

### **2015 Stock Incentive Plan**

In February 2015, the Company adopted the Crinetics Pharmaceuticals, Inc. 2015 Stock Incentive Plan (the “2015 Plan”), which provided for the issuance of equity awards to the Company’s employees, members of its board of directors and consultants. In general, options issued under this plan vest over four years and expire after 10 years. Subsequent to the adoption of the 2018 Plan, no additional equity awards can be made under the 2015 Plan.

Certain awards under the 2015 Plan allowed for exercise prior to vesting. Shares issued under such early-exercise provisions are subject to repurchase by the Company until they become fully vested. As of September 30, 2020, 19,630 unvested shares issued under early-exercise provisions were subject to repurchase by the Company. The condensed consolidated balance sheet reflects an unvested stock liability of \$28,000 as of September 30, 2020.

### **2018 Employee Stock Purchase Plan**

In July 2018, the Company adopted the 2018 Employee Stock Purchase Plan (the “ESPP”). The ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their eligible compensation. As of September 30, 2020, an aggregate of 638,720 shares of common stock were available for issuance under the ESPP.

The ESPP contains a provision that allows annual increases in the number of shares available for issuance on the first day of each calendar year through January 1, 2028 in an amount equal to the lesser of: (i) 1% of the aggregate number of shares of the Company’s common stock outstanding on December 31 of the immediately preceding calendar year, or (ii) such lesser amount determined by the Company. Under this evergreen provision, on January 1, 2020, an additional 242,961 shares became available for future issuance under the ESPP.

## Stock Options

Activity under the Company's stock option plans during the nine months ended September 30, 2020 was as follows:

	Options Outstanding (000's)	Weighted- Average Exercise Price	Weighted- Average Remaining Term	Aggregate Intrinsic Value (000's)
Balance at December 31, 2019	3,127	\$ 11.52		
Granted	1,342	\$ 20.28		
Exercised	(119)	\$ 1.60		
Forfeited and expired	(126)	\$ 19.35		
Balance at September 30, 2020	4,224	\$ 14.35	8.2	\$ 19,534
Exercisable at September 30, 2020	1,773	\$ 10.12	7.6	\$ 13,740

Aggregate intrinsic value is calculated as the difference at September 30, 2020 between the closing price of the Company's common stock and the exercise price of stock options that had exercise prices below the closing price.

The aggregate intrinsic value of options exercised during the nine months ended September 30, 2020 was \$2.0 million.

### Fair Value of Stock Option Awards

The Company utilizes the Black-Scholes option pricing model to value awards under its equity plans. The following table summarizes the weighted average assumptions used to estimate the fair value of stock options granted under the Company's stock option plans and the shares purchasable under the ESPP during the periods presented:

Stock Option Plans	2020	2019
Expected option term	6.0 years	5.9 years
Expected volatility	78%	78%
Risk free interest rate	0.9%	2.3%
Expected dividend yield	—%	—%
ESPP	2020	2019
Expected option term	2.0 years	1.3 years
Expected volatility	82%	62%
Risk free interest rate	0.0%	2.3%
Expected dividend yield	—%	—%

The key assumptions used in determining the fair value of equity awards, and the Company's rationale, were as follows: (i) *Expected option term* - the expected term represents the period that options are expected to be outstanding and has been estimated using the simplified method, which is an average of the contractual option term and its vesting period; (ii) *Expected volatility* - the expected volatility assumption is based on volatilities of a peer group of similar companies in the biotechnology industry whose share prices are publicly available; (iii) *Risk-free interest rate* - the risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities that approximate the expected terms of awards; and (iv) *Expected dividend yield* - the expected dividend yield assumption is zero as the Company has never paid dividends and has no present intention to do so in the future.

The weighted-average fair value of stock options awarded during the nine months ended September 30, 2020 and 2019 was \$13.55 and \$16.61 per share, respectively.

**Stock-Based Compensation Expense**

Stock-based compensation expense for the equity awards issued by the Company to employees and non-employees for the periods presented below was as follows (in thousands):

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2020</b>	<b>2019</b>	<b>2020</b>	<b>2019</b>
Included in research and development	\$ 1,376	\$ 864	\$ 3,689	\$ 2,242
Included in general and administrative	1,406	990	3,767	2,221
Total stock-based compensation expense	<u>\$ 2,782</u>	<u>\$ 1,854</u>	<u>\$ 7,456</u>	<u>\$ 4,463</u>

As of September 30, 2020, unrecognized stock-based compensation cost related to option awards and to the ESPP was \$27.4 million and \$0.7 million, respectively, which is expected to be recognized over a remaining weighted-average period of approximately 2.5 years and 1.5 years, respectively.



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

*You should read the following discussion of our financial condition and results of operations in conjunction with the unaudited condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2019.*

### **Forward Looking Statements**

*The following discussion and other parts of this quarterly report contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this quarterly report, including statements regarding our future results of operations and financial position, business strategy, the impact of the COVID-19 pandemic, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements are often identified by the use of words such as “may,” “will,” “expect,” “believe,” “anticipate,” “intend,” “could,” “should,” “estimate,” or “continue,” and similar expressions or variations. The forward-looking statements in this quarterly report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, operating results, business strategy, short-term and long-term business operations and objectives. These forward-looking statements speak only as of the date of this quarterly report and are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A, “Risk Factors.” The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.*

### **Overview**

We are a clinical-stage pharmaceutical company focused on the discovery, development, and commercialization of novel therapeutics for rare endocrine diseases and endocrine-related tumors. Endocrine pathways function to maintain homeostasis and commonly use peptide hormones acting through G-protein coupled receptors, or GPCRs, to regulate many aspects of physiology including growth, energy, metabolism, gastrointestinal functions and stress responses. We have assembled a seasoned team with extensive expertise in drug discovery and development in endocrine GPCRs and built a highly productive drug discovery organization. We have discovered a pipeline of oral nonpeptide (small molecule) new chemical entities that target peptide GPCRs to treat a variety of rare endocrine diseases where treatment options have significant efficacy, safety, and/or tolerability limitations. Our lead product candidate, paltusotine (formerly CRN00808), is currently in clinical development for the treatment of acromegaly, and we are advancing additional product candidates through clinical and preclinical studies in parallel. Our vision is to build the leading endocrine company which consistently pioneers new therapeutics to help patients better control their disease and improve their daily lives.

### **Our Pipeline**

We focus on the discovery and development of oral nonpeptide therapeutics that target peptide GPCRs with well-understood biological functions, validated biomarkers, and the potential to substantially improve the treatment of endocrine diseases and/or endocrine-related tumors. Our pipeline consists of paltusotine for acromegaly and neuroendocrine tumors, or NETs, and two preclinical programs for diseases of excess adrenocorticotrophic hormone, or ACTH, and congenital hyperinsulinism, or congenital HI.

#### ***Paltusotine***

Paltusotine, our lead product candidate, establishes a new class of oral selective nonpeptide somatostatin receptor type 2, or SST2, biased agonists designed for the treatment of acromegaly and NETs. The U.S. Food and Drug Administration, or FDA, has granted paltusotine orphan drug designation for the treatment of acromegaly.

We have completed two global Phase 2 clinical trials of paltusotine in acromegaly patients, the ACROBAT Edge, or Edge, and ACROBAT Evolve, or Evolve, trials. In addition, patients who completed the Edge and Evolve trials were eligible to enroll in the ACROBAT Advance trial, which is an open-label, long-term extension study designed to evaluate the safety and efficacy of paltusotine.

On October 26, 2020, we announced positive topline results from the ACROBAT Phase 2 program in acromegaly. The prespecified primary endpoint in Edge was achieved, showing that once daily oral paltusotine maintained insulin-like growth factor-1, or IGF-1, levels at Week 13 in acromegaly patients who were switched from an injected somatostatin receptor ligand, or SRL, depot of either octreotide or lanreotide monotherapy [change in IGF-1 = -0.034 (-0.107, 0.107), median (IQR)]. There were 25 patients enrolled in this prespecified primary analysis population (Group 1). During the four-week washout period after the 13-week treatment period, Group 1 patients showed a meaningful (>20%) and prompt (within two weeks) rise in IGF-1 levels from baseline, which characterized the magnitude of therapeutic activity of oral paltusotine in acromegaly patients. Edge also enrolled an additional 22 patients into four different exploratory populations (Groups 2-5).

As previously announced, the enrollment in Evolve was terminated early, enabling data to be available for the end of Phase 2 regulatory interactions on the Edge study. The reduced sample size did not allow for meaningful statistical comparisons between groups in the randomized withdrawal period. Data from these patients on lower doses of paltusotine were included in the post-hoc dose response analyses in combination with data from patients in the Edge study, most of whom received the higher doses.

Post-hoc analyses of patients in Edge (Group 1; n=25) and Evolve (n=13) were conducted in order to explore the effect of paltusotine dose on IGF-1 suppression. These analyses provided evidence of a dose response across the dose range of 10 to 40 mg. Dose-dependent results were observed when evaluating the effect on IGF-1 levels from: 1) switching from injectable SRL to paltusotine, and 2) withdrawing paltusotine during the washout phase. These data and ongoing exposure response analysis will inform the selection of doses to be included in the Phase 3 program that will be finalized after consultation with the FDA. We plan to meet with the FDA to share these results and finalize the protocol for our planned Phase 3 program, which remains on track to begin in the first half of 2021.

Paltusotine was generally well tolerated among the 60 ACROBAT participants (including both Edge and Evolve), which is consistent with prior clinical findings in healthy volunteers. There were no discontinuations due to drug-related adverse events, no safety signals seen in clinical laboratory analyses, no treatment-related serious adverse events, or SAEs, and no patients required rescue treatments with standard acromegaly medications during treatment. The most common treatment-emergent adverse events (>10%) included: headache, arthralgia, fatigue, peripheral swelling, paresthesia and hyperhidrosis.

#### ***ACTH Antagonist Program***

We are developing the first oral nonpeptide product candidate to antagonize ACTH action at the melanocortin 2 receptor, or MC2-R, that is designed for the treatment of Cushing's disease and other diseases caused by excess ACTH, including congenital adrenal hyperplasia and ectopic ACTH syndrome. We have completed first-in-human enabling studies with our lead ACTH antagonist development candidate. We plan to initiate a Phase 1 clinical trial in late 2020 or early 2021. If successful, we anticipate pharmacokinetic/pharmacodynamic, or PK/PD, data from this Phase 1 human proof-of-concept trial in 2021.

#### ***CRN04777, SST5 Agonist Program***

We are developing a new class of oral selective nonpeptide somatostatin receptor type 5, or SST5, agonists designed to treat congenital HI. We have completed first-in-human enabling studies with CRN04777, our lead SST5 agonist development candidate, and plan to initiate a Phase 1 clinical trial in early 2021. If successful, we anticipate PK/PD data from this Phase 1 human proof-of-concept trial in 2021. The FDA granted CRN04777 a rare pediatric disease designation for the treatment of congenital HI in September 2020.

#### **Australian operations**

In January 2017, we established Crinetics Australia Pty Ltd, or CAPL, a wholly-owned subsidiary which was formed to conduct various preclinical and clinical activities for our product and development candidates. We believe CAPL will be eligible for certain financial incentives made available by the Australian government for research and development expenses. Specifically, the Australian Taxation Office provides for a refundable tax credit in the form of a cash refund equal to 43.5% of qualified research and development expenditures under the Australian Research and Development Tax Incentive Program, or the Australian Tax Incentive, to Australian companies that operate the majority of their research and development activities associated with such projects in Australia. A wholly-owned Australian subsidiary of a non-Australian parent company is eligible to receive the refundable tax credit, provided that the Australian subsidiary retains the rights to the data and intellectual property generated in Australia, and provided that the total revenues of the parent company and its consolidated subsidiaries during the period for which

the refundable tax credit is claimed are less than \$20.0 million Australian dollars. If we lose our ability to operate CAPL in Australia, or if we are ineligible or unable to receive the research and development tax credit, or the Australian government significantly reduces or eliminates the tax credit, the actual refund amounts we receive may differ from our estimates.

## **COVID-19**

As we continue to actively advance our programs, we are in close contact with our principal investigators and clinical sites, and are assessing any impacts of COVID-19 on our drug manufacturing, nonclinical activities and clinical trials, expected timelines, and costs on an ongoing basis. In light of recent developments relating to the COVID-19 global pandemic, and consistent with the FDA's updated industry guidance for conducting clinical trials issued on March 18, 2020, clinical trials may be deprioritized in favor of treating patients who have contracted the virus or to prevent the spread of the virus. The direct and indirect impacts of COVID-19 on our business could alter our forecasted timelines. In addition, in response to the spread of COVID-19, we have limited the number of staff in our laboratory and offices. We will continue to evaluate the impact of the COVID-19 pandemic on our business and as we learn more about its impact on our industry.

## **Financial operations overview**

To date, we have devoted substantially all of our resources to drug discovery, conducting preclinical studies and clinical trials, obtaining and maintaining patents related to our product candidates, and the provision of general and administrative support for these operations. We have recognized revenues from various research and development grants, but do not have any products approved for sale and have not generated any product sales. We have funded our operations primarily through our grant revenues, the private placement of preferred stock, and sales of our common stock. As of September 30, 2020, we had unrestricted cash, cash equivalents, and investment securities of \$186.8 million.

We have incurred cumulative net losses since our inception and, as of September 30, 2020, we had an accumulated deficit of \$146.0 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and preclinical studies and our expenditures on other research and development activities. We expect our expenses and operating losses will increase substantially as we conduct our ongoing and planned clinical trials, continue our research and development activities, and conduct preclinical studies, hire additional personnel, protect our intellectual property and incur costs associated with being a public company, including audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission, or SEC, requirements, director and officer insurance premiums, and investor relations costs.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources including, potentially, collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, scale back or discontinue the development of our existing product candidates or our efforts to expand our product pipeline.

## ***Grant revenues***

To date, we have not generated any revenues from the commercial sale of approved products, and we do not expect to generate revenues from the commercial sale of our product candidates for at least the foreseeable future, if ever. Revenues for 2020 and 2019 were derived from Small Business Innovation Research Grants, or SBIR Grants, awarded to us by the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health. We do not currently have any active SBIR Grants nor do we expect grant revenues to be a material source of future funding.

## ***Research and development***

To date, our research and development expenses have related primarily to discovery efforts and preclinical and clinical development of our product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in research and development efforts;
- external research and development expenses incurred under agreements with contract research organizations, or CROs, investigative sites and consultants to conduct our clinical trials and preclinical and non-clinical studies;
- costs related to manufacturing our product candidates for clinical trials and preclinical studies, including fees paid to third-party manufacturers;
- costs related to compliance with regulatory requirements;
- laboratory supplies; and
- facilities, depreciation and other allocated expenses for rent, facilities maintenance, insurance, equipment and other supplies.

We recognize the Australian Tax Incentive as a reduction of research and development expense. The amounts are determined based on eligible research and development expenditures. The Australian Tax Incentive is recognized when there is reasonable assurance that the Australian Tax Incentive will be received, the relevant expenditure has been incurred, and the amount of the Australian Tax Incentive can be reliably measured.

Our direct research and development expenses consist principally of external costs, such as fees paid to CROs, investigative sites and consultants in connection with our clinical trials, preclinical and non-clinical studies, and costs related to manufacturing clinical trial materials. The majority of our third-party expenses during 2020 and 2019 related to the research and development of paltusotine. We deploy our personnel and facility related resources across all of our research and development activities.

Our clinical development costs may vary significantly based on factors such as:

- the number and scope of preclinical and IND-enabling studies;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- number of doses that patients receive;
- drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates; and
- the efficacy and safety profile of our product candidates.

We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of our product candidates and the discovery of new product candidates. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates 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 anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such

arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

### General and administrative

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for personnel in executive, finance and other administrative functions. Other significant costs include facility-related costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services, insurance costs, and commercial planning expenses. We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities and, if any of our product candidates receive marketing approval, commercialization activities. We also anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with operating as a public company.

### Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which we have prepared in accordance with United States generally accepted accounting principles. The preparation of these condensed financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting periods. We base our estimates on historical experience and on various other factors and assumptions that we believe are reasonable under the circumstances at the time the estimates are made, the results of which form the basis for making judgments about the book values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We periodically evaluate our estimates and judgments in light of changes in circumstances, facts and experience.

Our critical accounting policies are those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. For a description of our critical accounting policies, please see the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Significant Judgments and Estimates” contained in our Annual Report on Form 10-K for the year ended December 31, 2019. There have not been any material changes to the critical accounting policies discussed therein during the three and nine months ended September 30, 2020.

### Results of Operations

#### Comparison of the three months ended September 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended September 30, 2020 and 2019 (*in thousands*):

	Three months ended September 30,		Dollar Change
	2020	2019	
Grant revenues	\$ —	\$ 505	\$ (505)
Operating expenses:			
Research and development	13,699	11,823	1,876
General and administrative	4,752	3,911	841
Total operating expenses	18,451	15,734	2,717
Loss from operations	(18,451)	(15,229)	(3,222)
Other income (expense), net	131	799	(668)
Net loss	\$ (18,320)	\$ (14,430)	\$ (3,890)

*Grant revenues.* Grant revenues relate to reimbursable expenses incurred in connection with our SBIR Grants. We had no grant revenue for the three-month periods ended September 30, 2020, while such revenues were \$0.5 million for the three months ended September 30, 2019. We completed activities under our one remaining SBIR Grant during the first quarter of 2020 and we do not expect to generate grant revenues in future reporting periods.

*Research and development expenses.* Research and development expenses were \$13.7 million and \$11.8 million for the three months ended September 30, 2020 and 2019, respectively. The increase was primarily due to an increase in personnel and stock-based compensation costs of \$0.9 million and \$0.5 million, respectively, and a \$0.5 million increase in spending on outside services to support our development efforts.

*General and administrative expenses.* General and administrative expenses were \$4.8 million and \$3.9 million for the three months ended September 30, 2020 and 2019, respectively. The increase was primarily due to an increase in personnel costs of \$0.5 million and additional stock-based compensation of \$0.4 million.

*Other income (expense).* Other income (expense), net was \$0.1 million and \$0.8 million for the three months ended September 30, 2020 and 2019, respectively. The decrease resulted from a reduction of the income generated by our available-for-sale investment securities portfolio due to declining market yields available for such securities.

#### **Comparison of the nine months ended September 30, 2020 and 2019**

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019 (*in thousands*):

	<u>Nine months ended September 30,</u>		<u>Dollar Change</u>
	<u>2020</u>	<u>2019</u>	
Grant revenues	\$ 71	\$ 872	\$ (801)
Operating expenses:			
Research and development	40,168	29,363	10,805
General and administrative	13,065	10,127	2,938
Total operating expenses	<u>53,233</u>	<u>39,490</u>	<u>13,743</u>
Loss from operations	(53,162)	(38,618)	(14,544)
Other income (expense), net	991	2,745	(1,754)
Net loss	<u>\$ (52,171)</u>	<u>\$ (35,873)</u>	<u>\$ (16,298)</u>

*Grant revenues.* Grant revenues relate to reimbursable expenses incurred in connection with our SBIR Grants and totaled \$71,000 and \$0.9 million for the nine months ended September 30, 2020 and 2019, respectively. We completed activities under our one remaining SBIR grant during the first quarter of 2020.

*Research and development expenses.* Research and development expenses were \$40.2 million and \$29.4 million for the nine months ended September 30, 2020 and 2019, respectively. The increase was primarily due to increased spending on manufacturing and development activities of \$5.9 million associated with our clinical and nonclinical activities for paltusotine and our other clinical and preclinical programs. Additionally, our results for the nine months ended September 30, 2020 reflect an increase in personnel-related costs of \$2.8 million and additional stock-based compensation of \$1.4 million.

*General and administrative expenses.* General and administrative expenses were \$13.1 million and \$10.1 million for the nine months ended September 30, 2020 and 2019, respectively. The increase was primarily due to an increase in personnel-related costs of \$1.3 million and additional stock-based compensation of \$1.5 million.

*Other income (expense).* Other income (expense), net was \$1.0 million and \$2.7 million for the nine months ended September 30, 2020 and 2019, respectively. The decrease resulted from a reduction of the income generated by our available-for-sale investment securities portfolio due to declining market yields available for such securities.

#### **Cash Flows**

We have incurred cumulative net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of September 30, 2020, we had unrestricted cash, cash equivalents and investment securities of \$186.8 million and an accumulated deficit of \$146.0 million.

The following table provides information regarding our cash flows for the nine months ended September 30, 2020 and 2019 (*in thousands*):

	Nine months ended September 30,	
	2020	2019
Net cash used in operating activities	\$ (46,089)	\$ (32,934)
Net cash provided by investing activities	9,109	54,490
Net cash provided by financing activities	114,474	50
Net change in cash, cash equivalents and restricted cash	<u>\$ 77,494</u>	<u>\$ 21,606</u>

*Operating Activities.* Net cash used in operating activities was \$46.1 million and \$32.9 million for the nine months ended September 30, 2020 and 2019, respectively. The increase in cash used in operations was primarily attributable to development and manufacturing activities associated with paltusotine as well as our other clinical and preclinical programs, and higher personnel costs. The net cash used in operating activities during the nine months ended September 30, 2020 was primarily due to our net loss of \$52.2 million and a \$2.0 million increase in operating assets and liabilities, adjusted for \$8.1 million of noncash charges, primarily for stock-based compensation, depreciation and the accretion in value of our investment securities. Net cash used in operating activities during the nine months ended September 30, 2019 was primarily due to our net loss of \$35.9 million and a \$1.3 million increase in operating assets and liabilities, adjusted for \$4.3 million of noncash charges, primarily for stock-based compensation and depreciation.

*Investing activities.* Investing activities consist primarily of purchases and maturities of investment securities and, to a lesser extent, the cash outflow associated with purchases of property and equipment. Such activities resulted in a net inflow of funds of approximately \$9.1 million during the first nine months of 2020, compared to net inflow of funds of approximately \$54.5 million during the comparable period of 2019.

*Financing activities.* Net cash provided by financing activities was \$114.5 million and \$50,000 for the nine months ended September 30, 2020 and 2019, respectively. The net cash provided by financing activities during 2020 was primarily the result of the proceeds of \$107.9 million from the sale of shares of common stock in our public offering in April 2020, as well as \$6.4 million from the sale of shares in our ATM Offering, as defined below. The net cash provided by financing activities during the comparable period of 2019 resulted from the exercise of stock options.

### Liquidity and Capital Resources

We believe that our existing unrestricted cash, cash equivalents and investment securities, together with investment income, will be sufficient to satisfy our current and projected funding requirements into 2023. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future capital requirements will depend on many factors, including:

- the type, number, scope, progress, expansions, results, costs and timing of, our preclinical studies and clinical trials of our product candidates which we are pursuing or may choose to pursue in the future;
- the costs and timing of manufacturing for our product candidates, including commercial manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the timing and the extent of any Australian Tax Incentive refund and future grant revenues that we receive;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved;

- our ability to achieve sufficient market acceptance, adequate coverage and reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, licenses and other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings 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 our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

In August 2019, we entered into a Sales Agreement, or the Sales Agreement, with SVB Leerink LLC and Cantor Fitzgerald & Co., or collectively, the Sales Agents, under which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to \$75.0 million through the Sales Agents, or the ATM Offering. Sales of our common stock made pursuant to the Sales Agreement will be made directly on or through the Nasdaq Global Select Market under our effective shelf Registration Statement on Form S-3 filed on August 19, 2019 by means of ordinary brokers' transactions at market prices. Additionally, under the terms of the Sales Agreement, we may also sell shares of our common stock through the Sales Agents, on the Nasdaq Global Select Market or otherwise, at negotiated prices or at prices related to the prevailing market price. We are not obligated to, and we cannot provide any assurances that we will continue to, make any sales of the shares under the Sales Agreement. The Sales Agreement may be terminated by either Sales Agent (with respect to itself) or us at any time upon 10 days' notice to the other parties, or by either Sales Agent, with respect to itself, at any time in certain circumstances, including the occurrence of a material adverse change. We will pay the Sales Agents a commission for their services in acting as agent in the sale of common stock in an amount equal to 3% of the gross sales price per share sold.

During the nine months ended September 30, 2020, we issued 275,764 shares of common stock in the ATM Offering for net proceeds of \$6.4 million, after deducting commissions.

On April 17, 2020, we completed a public offering of 8,222,500 shares of our common stock at a public offering price of \$14.00 per share. We received proceeds of approximately \$107.9 million, net of offering discounts and commissions and offering costs of \$7.3 million.

#### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.



### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

#### ***Interest Rate Risk***

Our cash, cash equivalents and investment securities consist of cash held in readily available checking and money market accounts and short-term debt securities. We are exposed to market risk related to fluctuations in interest rates and market prices. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operations.

#### ***Foreign Currency***

We contract with vendors, CROs and investigational sites in several foreign countries, including countries in South America, Europe and the Asia Pacific. We are therefore subject to fluctuations in foreign currency rates in connection with these agreements. We do not hedge our foreign currency exchange rate risk. To date, we have not incurred any material adverse effects from foreign currency changes on these contracts.

In January 2017, we formed CAPL, a wholly-owned subsidiary in Australia, which exposes us to foreign currency exchange rate risk. The functional currency of CAPL is the United States dollar. Assets and liabilities of our foreign subsidiary that are not denominated in the functional currency are remeasured into U.S. dollars at foreign currency exchange rates in effect at the balance sheet date except for nonmonetary assets and capital accounts, which are remeasured at historical foreign currency exchange rates in effect at the date of transaction. Expenses are generally remeasured at foreign currency exchange rates which approximate average rates in effect during each period. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in other income (expense), net, in the consolidated statements of operations and totaled approximately \$61,000 for each of the nine months ended September 30, 2020 and 2019.

As of September 30, 2020, the impact of a theoretical 10% change in the exchange rate of the Australian dollar would not result in a material gain or loss. To date, we have not hedged exposures denominated in foreign currencies.

#### ***Inflation Risk***

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations for the periods presented.

### **Item 4. Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports 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 our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the 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, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2020 at the reasonable assurance level.

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 1. Legal Proceedings**

We are not currently a party to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

**Item 1A. Risk Factors**

Other than as set forth below, or as previously reported in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, there have been no material changes to the risk factors set forth in Part II, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2019.

*The FDA has granted rare pediatric disease designation for CRN04777, however, there is no guarantee that FDA approval of CRN04777 will result in a priority review voucher.*

In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a “rare pediatric disease” that meets certain criteria may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

The FDA has granted rare pediatric disease designation for CRN04777 for the treatment of congenital HI, however, there is no guarantee that we will be able to obtain a priority review voucher, even if CRN04777 is approved by the FDA. Moreover, Congress included a sunset provision in the statute authorizing the rare pediatric disease priority review voucher program. Specifically, FDA may not award the voucher to sponsors of marketing applications unless either (i) the drug has received rare pediatric disease designation as of December 11, 2020, and is then approved by the FDA no later than December 11, 2022; or (ii) Congress reauthorizes the program, for which legislation has been proposed in the current Congress. Even though we received rare pediatric disease designation for CRN04777 by the current statutory deadline of December 11, 2020, we may not receive the voucher if we do not obtain approval by December 11, 2022. Even if legislation is enacted that extends the date by which approval of the rare pediatric disease-designated drug must obtain approval to receive a priority review voucher, we may not obtain approval by that date, and even if we do, we may not obtain a priority review voucher.

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

None.

*Use of Proceeds*

On July 17, 2018, the SEC declared effective our registration statement on Form S-1 (File No. 333-225824), as amended, filed in connection with our IPO. The IPO closed on July 20, 2018 and we issued and sold 6,900,000 shares of our common stock at a price to the public of \$17.00 per share, which included the exercise in full of the underwriters’ option to purchase additional shares. We received gross proceeds from the IPO of \$117.3 million, before deducting underwriting discounts and commissions of approximately \$8.2 million and estimated offering expenses of approximately \$2.6 million. The managing underwriters of the offering were J.P. Morgan Securities LLC, Leerink Partners LLC and Piper Jaffray & Co. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

As of September 30, 2020, we have used approximately \$40.1 million of the proceeds from our IPO for general corporate purposes, including the development of paltusotine as well as for the preclinical and clinical development

of our other development programs. There has been no material change in the planned use of such proceeds from that described in the Prospectus.

**Item 3. Defaults upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

## EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	<a href="#">Amended and Restated Certificate of Incorporation</a>	S-1/A	333-225824	3.3	7/9/2018	
3.2	<a href="#">Amended and Restated Bylaws</a>	8-K	001-38583	3.1	4/14/2020	
4.1	<a href="#">Specimen Stock Certificate Evidencing the Shares of Common Stock</a>	S-1/A	333-225824	4.1	7/9/2018	
4.2	<a href="#">Amended and Restated Investor Rights Agreement, dated February 9, 2018, as amended, by and among the Registrant and certain of its stockholders</a>	S-1	333-225824	4.2	6/22/2018	
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Rule 13(a)-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002</a>					X
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Rule 13(a)-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002</a>					X
32.1*	<a href="#">Certification of Chief Executive Officer and Chief Financial Officer pursuant 18. U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002</a>					X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)					X

\* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Crinetics Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

## SIGNATURES

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

### **Crinetics Pharmaceuticals, Inc.**

Date: November 6, 2020

By: /s/ R. Scott Struthers, Ph.D.  
R. Scott Struthers, Ph.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: November 6, 2020

By: /s/ Marc J.S. Wilson  
Marc J.S. Wilson  
Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, R. Scott Struthers, Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Crinetics Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2020

/s/ R. Scott Struthers, Ph.D.

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R. Scott Struthers, Ph.D.

President and Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Marc J.S. Wilson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Crinetics Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2020

/s/ Marc J.S. Wilson

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Marc J.S. Wilson  
Chief Financial Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Crinetics Pharmaceuticals, Inc. (the “Company”) hereby certifies, to his knowledge, that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2020 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ R. Scott Struthers, Ph.D.

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R. Scott Struthers, Ph.D.

President and Chief Executive Officer

Date: November 6, 2020

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Crinetics Pharmaceuticals, Inc. (the “Company”) hereby certifies, to his knowledge, that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2020 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Marc J.S. Wilson

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Marc J.S. Wilson

Chief Financial Officer

Date: November 6, 2020