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, 2021

☐ **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	**26-3744114**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10222 Barnes Canyon Road, Bldg. #2, San Diego, California	**92121**
(Address of principal executive offices)	**(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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of October 31, 2021, the registrant had 47,499,886 shares of common stock ($0.001 per share par value) outstanding.

CRINETICS PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q
For the Quarter Ended September 30, 2021

TABLE OF CONTENTS

PART I — FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

Crinetics Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets

(In thousands)

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 161,536	$ 93,087
Investment securities	31,789	77,793
Prepaid expenses and other current assets	10,648	6,612
Total current assets	203,973	177,492
Property and equipment, net	2,903	3,181
Operating lease right-of-use asset	1,983	2,232
Restricted cash	500	500
Other assets	—	40
Total assets	$ 209,359	$ 183,445
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,153	$ 5,588
Accrued compensation and related expenses	5,375	4,066
Other current liabilities	912	835
Total current liabilities	12,440	10,489
Operating lease liability, non-current	3,322	4,014
Unvested stock liability	7	23
Total liabilities	15,769	14,526
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par; 10,000 shares authorized; no shares issued or outstanding at September 30, 2021 or at December 31, 2020	—	—
Common stock and paid-in capital, $0.001 par; 200,000 shares authorized; 38,624 shares issued and 38,620 shares outstanding at September 30, 2021; 33,017 shares issued and 33,001 shares outstanding at December 31, 2020	438,063	336,508
Accumulated other comprehensive income	(12)	25
Accumulated deficit	(244,461)	(167,614)
Total stockholders' equity	193,590	168,919
Total liabilities and stockholders' equity	$ 209,359	$ 183,445

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,	
	2021	2020	2021	2020
Grant revenues	$ —	$ —	$ —	$ 71
Operating expenses:				
Research and development	21,580	13,699	59,651	40,168
General and administrative	6,227	4,752	17,163	13,065
Total operating expenses	27,807	18,451	76,814	53,233
Loss from operations	(27,807)	(18,451)	(76,814)	(53,162)
Other income (expense):				
Interest income	24	122	77	938
Other income (expense), net	(68)	9	(110)	53
Total other income (expense), net	(44)	131	(33)	991
Net loss	(27,851)	(18,320)	(76,847)	(52,171)
Other comprehensive income (loss):				
Unrealized (loss) on investment securities	(22)	(83)	(37)	(104)
Comprehensive loss	$ (27,873)	$ (18,403)	$ (76,884)	$ (52,275)
Net loss per share:				
Net loss per share – basic and diluted	$ (0.73)	$ (0.56)	$ (2.13)	$ (1.76)
Weighted average shares outstanding – basic and diluted	38,309	32,890	36,147	29,608

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

Crinetics Pharmaceuticals, Inc.

Condensed Consolidated Statements of Stockholders' Equity

(In thousands)
(Unaudited)

	Common Stock Shares	Common stock and Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance at July 1, 2021	37,680	$ 418,040	$ 10	$ (216,610)	$ 201,440
Issuance of common stock, net of transaction costs	851	14,976	—	—	14,976
Vesting of shares subject to repurchase	4	5	—	—	5
Exercise of stock options	85	487	—	—	487
Stock-based compensation	—	4,555	—	—	4,555
Comprehensive loss	—	—	(22)	—	(22)
Net loss	—	—	—	(27,851)	(27,851)
Balance at September 30, 2021	38,620	$ 438,063	$ (12)	$ (244,461)	$ 193,590
Balance at January 1, 2021	33,001	$ 336,508	$ 25	$ (167,614)	$ 168,919
Issuance of common stock, net of transaction costs	5,413	87,534	—	—	87,534
Stock issued under Stock Purchase Plan	47	522	—	—	522
Vesting of shares subject to repurchase	12	16	—	—	16
Exercise of stock options	147	1,289	—	—	1,289
Stock-based compensation	—	12,194	—	—	12,194
Comprehensive loss	—	—	(37)	—	(37)
Net loss	—	—	—	(76,847)	(76,847)
Balance at September 30, 2021	38,620	$ 438,063	$ (12)	$ (244,461)	$ 193,590
Balance at July 1, 2020	32,882	$ 330,300	$ 127	$ (127,653)	$ 202,774
Vesting of shares 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	32,921	$ 333,151	$ 44	$ (145,973)	$ 187,222
Balance at January 1, 2020	24,263	$ 210,793	$ 148	$ (93,802)	$ 117,139
Issuance of common stock, net of transaction costs	8,223	107,856	—	—	107,856
Stock issued in at-the-market offering, net of costs	276	6,427	—	—	6,427
Vesting of shares subject to repurchase	13	21	—	—	21
Exercise of stock options	119	191	—	—	191
Stock issued 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	32,921	$ 333,151	$ 44	$ (145,973)	$ 187,222

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,	
	2021	**2020**
Operating activities:		
Net loss	$ (76,847)	$ (52,171)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation	12,194	7,456
Depreciation and amortization	687	723
Noncash lease expense	249	204
Accretion of purchase discounts and amortization of premiums on investment securities, net	236	(293)
Other, net	8	(18)
Increase (decrease) in cash resulting from changes in:		
Prepaid expenses and other assets	(3,996)	(2,269)
Accounts payable and accrued expenses, compensation and related expenses	2,395	808
Operating lease liability	(615)	(529)
Net cash used in operating activities	(65,689)	(46,089)
Investing activities:		
Purchases of investment securities	(23,380)	(113,762)
Maturities of investment securities	69,113	123,040
Purchases of property and equipment	(418)	(169)
Net cash provided by investing activities	45,315	9,109
Financing activities:		
Proceeds from issuance of common stock, net	87,534	107,856
Proceeds from issuance of common stock in at-the-market offering, net	-	6,427
Proceeds from exercise of stock options	1,289	191
Net cash provided by financing activities	88,823	114,474
Net change in cash, cash equivalents and restricted cash	68,449	77,494
Cash, cash equivalents and restricted cash at beginning of period	93,587	40,826
Cash, cash equivalents and restricted cash at end of period	$ 162,036	$ 118,320
Components of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 161,536	$ 117,820
Restricted cash	500	500
Cash, cash equivalents and restricted cash at end of period	$ 162,036	$ 118,320
Noncash investing and financing activities:		
Change in unvested stock liability	$ 16	$ 21
Amounts accrued for purchases of property and equipment	$ —	$ 6
Stock issued under Stock Purchase Plan	$ 522	$ 407

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. In October 2021, the Company formed Radionetics Oncology, Inc., or Radionetics, together with 5AM Ventures and Frazier Healthcare Partners. Radionetics aims to develop a deep pipeline of novel, targeted, nonpeptide radiopharmaceuticals for the treatment of a broad range of oncology indications. The Company maintains an equity interest in Radionetics

Unaudited Interim Financial Information

The accompanying interim condensed consolidated balance sheet as of September 30, 2021, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2021 and 2020, the condensed consolidated statements of stockholders' equity for the three and nine months ended September 30, 2021 and 2020, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2021 and 2020, 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 and the results of its operations and cash flows 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, 2021 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, 2021, the Company had $193.3 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 $244.5 million as of September 30, 2021. 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. To the extent possible, and consistent with applicable guidance from federal, state and local authorities, the Company is conducting business as usual, with necessary or advisable modifications to employee travel. The Company will continue to actively monitor the evolving situation related to COVID-19 and may take further actions that alter its operations, including those that may be required by federal, state or local authorities, or that the Company determines are in the best interests of its employees and other third parties with whom the Company does business. While the pandemic has not yet had a material effect on the Company's financial results, the degree to which COVID-19, including he impact of new variants of the virus that causes COVID-19, may impact the Company's future financial condition or 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 did not have a material impact on the Company's income tax provision for 2020 or for the nine months ended September 30, 2021.

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, 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 $3.1 million at September 30, 2021 and $2.1 million at December 31, 2020 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 $0.1 million and $0.3 million for the three and nine months ended September 30, 2021, respectively; for the three and nine months ended September 30, 2020, the Company recognized a reduction to R&D expense of $0.2 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):

	September 30,	
	2021	2020
Common stock options	6,606	4,224
Unvested common stock subject to repurchase	5	20
	6,611	4,244

Recently Adopted Accounting Pronouncements

ASU 2020-06

In August 2020, the Financial Accounting Standards Board ("FASB') issued Accounting Standards Update ("ASU') 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40) ("ASU 202*0-06'). ASU 2020-06 eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, ASU 2020-06 modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. The amendments in ASU 2020-06 are effective for smaller reporting companies as defined by the SEC for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company adopted ASU 2020-06 as of January 1, 2021, which did not have an impact on its 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, 2021 and December 31, 2020 (*in thousands*):

	As of September 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Available-for-sale investment securities:				
U.S. government and agency obligations	$ 15,579	$ 1	$ (6)	$ 15,574
Certificates of deposit	2,391	5	—	2,396
Corporate debt securities	13,830	—	(11)	13,819
Total	$ 31,800	$ 6	$ (17)	$ 31,789

	As of December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Available-for-sale investment securities:				
U.S. government and agency obligations	$ 74,222	$ 6	$ (5)	$ 74,223
Certificates of deposit	2,161	14	—	2,175
Corporate debt securities	1,385	10	—	1,395
Total	$ 77,768	$ 30	$ (5)	$ 77,793

All available-for-sale investment securities held at September 30, 2021 and December 31, 2020, 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, 2021 or December 31, 2020. 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, 2021 and December 31, 2020 were as follows (*in thousands*):

	As of September 30, 2021			
	Level 1	Level 2	Level 3	Total
Investment securities:				
U.S. government and agency obligations	$ —	$ 15,574	$ —	$ 15,574
Certificates of deposit	—	2,396	—	2,396
Corporate debt securities	—	13,819	—	13,819
Total assets measured at fair value	$ —	$ 31,789	$ —	$ 31,789

	As of December 31, 2020			
	Level 1	Level 2	Level 3	Total
Investment securities:				
U.S. government and agency obligations	$ 60,222	$ 14,001	$ —	$ 74,223
Certificates of deposit	—	2,175	—	2,175
Corporate debt securities	—	1,395	—	1,395
Total assets measured at fair value	$ 60,222	$ 17,571	$ —	$ 77,793

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, 2021.

5. BALANCE SHEET DETAILS

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

	September 30, 2021	December 31, 2020
Prepaid research and development costs	$ 7,385	$ 3,062
Australian tax incentive receivable	954	1,720
Prepaid insurance	1,264	693
Interest receivable	86	113
Prepaid expenses and other assets	959	1,024
Total	$ 10,648	$ 6,612

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

	September 30, 2021	December 31, 2020
Leasehold improvements	$ 3,516	$ 3,494
Lab equipment	1,759	1,551
Office equipment	700	653
Construction in progress	132	-
Computers and software	41	41
Property and equipment at cost	6,148	5,739
Less accumulated depreciation and amortization	3,245	2,558
Total	$ 2,903	$ 3,181

6. 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.

7. STOCKHOLDERS' EQUITY

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.

On April 12, 2021, the Company completed an underwritten follow-on offering of 4,562,044 shares of its common stock at a price to the public of $16.44 per share. Proceeds from the offering were approximately $72.6 million, net of underwriting discounts and commissions and offering costs of $2.4 million. The shares were registered pursuant to the Company's 2019 Shelf Registration Statement discussed below.

On July 28, 2021, the Company entered into a stock purchase agreement for the private placement of 851,306 shares of its common stock at a price of $17.62 per share (the "private placement"), which shares were issued on July 30, 2021. The private placement yielded gross proceeds of $15.0 million.

On October 21, 2021, the Company completed an underwritten follow-on offering of 8,712,400 shares of its common stock at a price to the public of $19.80 per share. Proceeds from the offering were approximately $161.9 million, net of underwriting discounts and commissions and offering costs of $10.6 million. The shares were registered pursuant to the Company's 2021 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 "2019 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 10, 2021, the Company filed a registration statement on Form S-3 (the "2021 Shelf Registration Statement"), which became immediately effective upon filing, covering the offering of common stock, preferred stock, debt securities, warrants and units and the resale of up to 851,306 shares by the accredited investor who purchased shares in the private placement.

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 2019 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 2019 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 did not issue any additional shares of common stock in the ATM Offering during the remainder of 2020 or in the nine months ended September 30, 2021.

8. 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, 2021, 1,286,672 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, 2021, an additional 1,650,846 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, 2021, 4,909 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 $7,000 as of September 30, 2021.

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, 2021, an aggregate of 897,048 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, 2021, an additional 330,169 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, 2021 was as follows:

	Options Outstanding (000's)	Weighted-Average Exercise Price	Weighted-Average Remaining Term	Aggregate Intrinsic Value (000's)
Balance at December 31, 2020	4,422	$ 14.42		
Granted	2,591	$ 17.36		
Exercised	(147)	$ 8.77		
Forfeited and expired	(260)	$ 18.96		
Balance at September 30, 2021	6,606	$ 15.52	8.2	$ 41,984
Vested and expected to vest at September 30, 2021	6,606	$ 15.52	8.2	$ 41,984
Exercisable at September 30, 2021	2,834	$ 12.74	7.1	$ 26,161

Aggregate intrinsic value is calculated as the difference at a specific point in time 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, 2021 was $1.6 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:

Stock Option Plans	2021	2020
Expected option term	6.0 years	6.0 years
Expected volatility	86%	78%
Risk free interest rate	1.0%	0.9%
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, 2021 and 2020 was $12.47 and $13.55 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):

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Research and development	$ 2,579	$ 1,376	$ 6,748	$ 3,689
General and administrative	1,976	1,406	5,446	3,767
Total stock-based compensation expense	$ 4,555	$ 2,782	$ 12,194	$ 7,456

As of September 30, 2021, unrecognized stock-based compensation cost related to option awards and to the ESPP was $44.8 million and $1.2 million, respectively, which is expected to be recognized over a remaining weighted-average period of approximately 2.1 years and 1.3 years, respectively.

9. SUBSEQUENT EVENT

Radionetics Oncology, Inc.

On October 18, 2021, the Company, together with 5AM Ventures and Frazier Healthcare Partners, announced the formation of Radionetics. Radionetics aims to develop a deep pipeline of novel, targeted, nonpeptide radiopharmaceuticals for the treatment of a broad range of oncology indications.

The Company entered into an exclusive world-wide license to its radiotherapeutics technology platform and associated intellectual property for use in developing radiotherapeutics and related radio-imaging agents, including exclusive rights to the underlying intellectual property on certain preclinical drug candidates. In exchange, the Company received 50,500,000 shares of common stock of Radionetics, which represents an initial majority stake in Radionetics, and a warrant to purchase additional shares of common stock designed to maintain a minimum equity interest for the Company in Radionetics of at least an aggregate of 22% of the fully diluted capitalization of Radionetics in connection with its sale, initial public offering, or SPAC transaction. In addition, we may receive potential sales milestones in excess of $1.0 billion and single-digit royalties on net sales. Radionetics completed a $30 million private financing with 5AM Ventures and Frazier Healthcare Partners as the sole participants. In addition, Radionetics and the Company may also engage in a research collaboration to identify drug candidates for multiple additional targets.

R. Scott Struthers, Ph.D. the Company’s President and Chief Executive Officer, will serve as chairman of the Radionetics board of directors. The Company has no obligation to fund the operations of Radionetics.

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, 2020.

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 function, 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 in clinical development for the treatment of acromegaly and neuroendocrine tumors, or NETs, including NETs complicated by carcinoid syndrome and nonfunctional NETs. Our other product candidates include CRN04777, which is in clinical development for the treatment of congenital hyperinsulinism, or HI, and CRN04894, which is in clinical development for the treatment of diseases of excess adrenocorticotrophic hormone, or ACTH, including Cushing's Disease and congenital adrenal hyperplasia, or CAH. We are advancing additional product candidates through preclinical discovery and development 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 the following product candidates:

Paltusotine (SST2 Agonist)

Paltusotine, our lead product candidate, establishes a new class of oral selective nonpeptide somatostatin receptor type 2, or SST2, agonists designed for the treatment of acromegaly and NETs. Somatostatin is a neuropeptide hormone that broadly inhibits the secretion of other hormones, including growth hormone, or GH, from the pituitary gland. Acromegaly arises from a benign pituitary tumor that secretes excess GH that, in turn, causes excess secretion of insulin-like growth factor-1, or IGF-1, by the liver. This loss of homeostasis in the GH axis results in excess tissue growth and other adverse metabolic effects throughout the body. Approximately 26,000 people in the United States suffer from acromegaly, and depending on surgical success, many are candidates for chronic pharmacological

intervention, of which somatostatin peptide analogs are the primary pharmacotherapy. NETs originate from neuroendocrine cells commonly found in the gut, lung, or pancreas. Typically, NETs are only diagnosed at a time of extensive metastatic disease and will often progress to liver failure. NETs are present in approximately 171,000 adults in the United States. Of these, approximately 33,000 patients have carcinoid syndrome, which occurs when the tumors secrete hormones or other chemical substances into the bloodstream that cause severe flushing or diarrhea, among other symptoms. Most NETs overexpress SST2 receptors and injected depots of peptide somatostatin analogs have become the first-line standard of care for many NETs patients. In 2020, injected somatostatin peptide drugs accounted for approximately $3.2 billion in global sales for the treatment of acromegaly, NETs, and other uses. These drugs require painful monthly or daily injections and, in the case of somatostatin peptide drugs, often fail to fully control the disease in many acromegaly patients.

We have initiated a Phase 3 development program for paltusotine in acromegaly which consists of two placebo-controlled clinical trials. The first of these, the PATHFNDR-1 trial, is designed as a double-blind, placebo-controlled, nine-month clinical trial of paltusotine in acromegaly patients with average IGF-1 levels less than or equal to 1.0 times the upper limit of normal, or ULN, and who are on stable doses of SRL monotherapy (octreotide LAR or lanreotide depot). If successful, we believe the PATHFNDR-1 study could support registration of paltusotine for acromegaly patients switching from other therapies. We also plan to conduct a second study, the PATHFNDR-2 trial, which is designed as a double-blind, placebo-controlled, six-month clinical trial of acromegaly patients with elevated IGF-1 levels. We expect to initiate this trial by the end of 2021. We believe that, if successful, the PATHFNDR-2 trial will support a more expansive registration of paltusotine for untreated acromegaly patients who require pharmacotherapy.

The primary endpoint of both PATHFNDR studies will be the proportion of patients with IGF-1 ≤ 1.0 × ULN at the end of the treatment period on paltusotine as compared to placebo. We expect top line data from both studies in 2023. We believe that, if successful, the two trials could support registration of paltusotine for all acromegaly patients who require pharmacotherapy, including untreated patients and those switching from other therapies. The FDA has granted orphan drug designation for paltusotine for the treatment of acromegaly

We are also conducting a Phase 2 trial with paltusotine in patients with NETs complicated by carcinoid syndrome, which is currently in start-up phase in 2021.

CRN04777 (SST5 Agonist)

CRN04777 is our investigational, oral, nonpeptide somatostatin receptor type 5, or SST5, agonist designed for the treatment of congenital HI and other syndromic forms of hyperinsulinism. Congenital HI is a devastating rare genetic disease associated with dysregulated insulin production, in which excess insulin produces life-threatening hypoglycemia (low blood glucose) beginning at birth. This loss of homeostatic control of blood glucose levels can lead to seizures, developmental disorders, learning disabilities, coma, and even death. Congenital HI occurs in approximately 1 in 25,000 to 50,000 new births in the United States. We are currently conducting a double-blind, randomized, placebo-controlled Phase 1 study of CRN04777 in healthy volunteers to assess the safety and tolerability of single and multiple doses of CRN04777. In addition, the study is designed to evaluate the potential mechanism of action of CRN04777 by measuring the suppression of insulin secretion in healthy volunteers following stimulation with either glucose or a sulfonylurea, agents that increase the secretion of insulin. We announced positive topline data from the single ascending dose cohorts in September 2021 and expect data from the multiple ascending dose cohorts in the first quarter of 2022. The FDA has granted rare pediatric disease designation for CRN04777 for the treatment of congenital HI. In addition, the European Medicines Agency has granted orphan drug designation for CRN04777 for the treatment of congenital HI. We also expect CRN04777 can be broadly applicable to other diseases characterized by excess insulin secretion, including forms of syndromic hyperinsulinism. Rather than being caused by a single gene mutation confined to the pancreatic beta-cell, syndromic HI may occur as part of a constellation of clinical findings in diseases where genetic mutations have pleiotropic effects outside of the beta-cell. Sotos syndrome, Beckwith Wiedemann syndrome, Kabuki syndrome and Turner's syndrome are examples of disorders from which many patients suffer from HI. Because of SST5's role as a critical downstream regulator of insulin secretion, we would expect patients with these syndromes to respond to the SST5 agonism caused by CRN04777.

CRN04894 (ACTH Antagonist)

CRN04894 is our investigational, oral, nonpeptide product candidate designed to antagonize ACTH, intended for the treatment of diseases caused by excess ACTH, including Cushing's disease and CAH. Cushing's disease results from a pituitary tumor that secretes excess ACTH which, in turn, causes the downstream synthesis and over-secretion of cortisol by the adrenal glands. Cortisol is the body's main stress hormone and excess amounts can cause significant increases in mortality and morbidity. CAH encompasses a set of disorders that are caused by genetic mutations that result in impaired cortisol synthesis. A lack of cortisol leads to a loss of feedback mechanisms and results in persistently high levels of ACTH, which, in turn, causes overstimulation of the adrenal cortex. The resulting adrenal hyperplasia and over-secretion of other steroids (particularly androgens) and steroid precursors can lead to a variety of effects from improper gonadal development to life-threatening dysregulation of mineralocorticoids. We are currently conducting a double-blind, randomized, placebo-controlled Phase 1 study of CRN04894 in healthy volunteers to assess the safety and tolerability of single and multiple doses of CRN04894. In addition, the study is designed to measure the effect of CRN04894 on suppression of cortisol, cortisol precursors, and adrenal androgens following exogenous ACTH stimulation. In August 2021, we announced preliminary data from the single ascending dose cohorts of the Phase 1 study. Single doses of CRN04894 were well-tolerated and demonstrated dose-dependent increases in CRN04894 plasma concentrations as well as reductions of both basal cortisol and elevated cortisol following an ACTH challenge. All adverse events reported through the single ascending dose cohorts were considered mild and there were no serious adverse events. We will proceed with the multiple ascending dose cohorts of the Phase 1 study and expect preliminary data in the first quarter of 2022.

Parathyroid Hormone Antagonist

We are developing antagonists of the parathyroid hormone, or PTH, receptor for the treatment of Primary Hyperparathyroidism (PHPT) and Humoral Hypercalcemia of Malignancy (HHM) and other diseases of excess PTH. PTH regulates calcium and phosphate homeostasis in bone and kidney through activation of its receptor, PTHR1. Increased activation of PTHR1, either via PTH or PTH-related peptide (PTHrP, PTHLH) can lead to skeletal, renal, gastrointestinal, and neurological problems. Primary hyperparathyroidism arises from a small, benign tumor on one or more of the parathyroid glands, which results in over-secretion of PTH, leading to increased blood calcium levels (hypercalcemia). Some patients experience no symptoms, and many can have surgery to remove the tumor and/or hyperactive gland(s), while some require management with medical therapy. Symptomatic PHPT is characterized by skeletal, renal, gastrointestinal, and neurological manifestations with increased mortality. HHM typically arises in patients with advanced-stage cancers. In cases of HHM, over-secretion of PTHrP caused by the malignant tumor results in bone resorption and calcium reabsorption in the kidney, leading to hypercalcemia. We have identified potent and orally available nonpeptide PTH antagonists that exhibit efficacy in preclinical models, and appropriate drug-like properties. We are evaluating a subset of molecules to identify potential development candidates suitable for evaluation in human clinical trials.

Radionetics Oncology, Inc.

On October 18, 2021, we, together with 5AM Ventures and Frazier Healthcare Partners, announced the formation of Radionetics Oncology, Inc., or Radionetics. Radionetics aims to develop a deep pipeline of novel, targeted, nonpeptide radiopharmaceuticals for the treatment of a broad range of oncology indications and its initial drug development efforts are focused on advancing 10 preclinical product candidates and leads that we discovered. In connection with the formation of Radionetics, we entered into a Collaboration and License Agreement with Radionetics granting Radionetics an exclusive world-wide license to our technology for the development of radiotherapeutics and related radio-imaging agents in exchange for a majority equity stake in Radionetics, potential sales milestones in excess of $1.0 billion and single-digit royalties on net sales.

Research Discovery

Patients with many other debilitating endocrine diseases await new therapeutic options. We plan to continue our drug discovery efforts and leverage our expertise in the evaluation of additional conditions including hyperparathyroidism, nonfunctional pituitary adenomas and polycystic kidney disease, among other indications. All our product candidates have been discovered, characterized, and developed internally and are the subject of composition of matter patent applications, including issued U.S. patents covering paltusotine extending to 2037. We have retained worldwide rights to commercialize our product candidates and do not have any royalty obligations.

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 continue to assess any impacts of the ongoing COVID-19 global pandemic on our drug manufacturing, nonclinical activities, and clinical trials, expected timelines, and costs on an ongoing basis. In light of the COVID-19 pandemic, and consistent with the FDA's updated industry guidance for conducting clinical trials issued on March 18, 2020, and updated most recently on January 27, 2021, 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 offices. We will continue to evaluate the impact of the COVID-19 pandemic on our business.

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, 2021, we had unrestricted cash, cash equivalents, and investment securities of $193.3 million. On April 12, 2021, we completed a public offering of 4,562,044 shares of common stock at a price of $16.44 per share and raised gross proceeds of approximately $75.0 million. On July 28, 2021, we entered into a stock purchase agreement for the private placement of 851,306 shares of common stock at $17.62 per share, which shares were issued on July 30, 2021. The private placement yielded gross proceeds of $15.0 million. On October 21, 2021, we completed an underwritten public offering of 8,712,400 shares of common stock at a price to the public of $19.80 per share and raised gross proceeds of approximately $172.5 million.

We have incurred cumulative net losses since our inception and, as of September 30, 2021, we had an accumulated deficit of $244.5 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. Prior to 2021, revenues 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 nonclinical 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 2021 and 2020 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:

- 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 U.S. generally accepted accounting principles. The preparation of these condensed financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities at the date of our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and on various other factors 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.

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, 2020. There have not been any material changes to the critical accounting policies discussed therein during the three and nine months ended September 30, 2021.

Results of Operations

Comparison of the three months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020 (*in thousands*):

	Three months ended September 30,		Dollar
	2021	2020	Change
Grant revenues	$ —	$ —	$ —
Operating expenses:			
Research and development	21,580	13,699	7,881
General and administrative	6,227	4,752	1,475
Total operating expenses	27,807	18,451	9,356
Loss from operations	(27,807)	(18,451)	(9,356)
Other income (expense), net	(44)	131	(175)
Net loss	$ (27,851)	$ (18,320)	$ (9,531)

Research and development expenses. Research and development expenses were $21.6 million and $13.7 million for the three months ended September 30, 2021 and 2020, respectively. The increase was primarily due to increased spending on manufacturing and development activities of $4.3 million associated with our clinical and nonclinical activities for paltusotine and our other clinical and preclinical programs, and an increase in personnel costs of $3.2 million, of which stock-based compensation was $1.2 million.

General and administrative expenses. General and administrative expenses were $6.2 million and $4.8 million for the three months ended September 30, 2021 and 2020, respectively. The increase was primarily due to additional personnel costs of $1.0 million, of which stock-based compensation was $0.6 million.

Other income (expense). Other income (expense), net was $(44,000) and $131,000 for the three months ended September 30, 2021 and 2020, respectively. The decrease resulted from the impact of foreign currency fluctuations and a reduction of the income generated by our investment securities portfolio due to declining market yields available for such securities.

Comparison of the nine months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020 (*in thousands*):

	Nine months ended September 30,		Dollar
	2021	2020	Change
Grant revenues	$ —	$ 71	$ (71)
Operating expenses:			
Research and development	59,651	40,168	19,483
General and administrative	17,163	13,065	4,098
Total operating expenses	76,814	53,233	23,581
Loss from operations	(76,814)	(53,162)	(23,652)
Other income (expense), net	(33)	991	(1,024)
Net loss	$ (76,847)	$ (52,171)	$ (24,676)

Grant revenues. Grant revenues relate to reimbursable expenses incurred in connection with SBIR Grants. We had no active SBIR Grants and therefore had no grant revenue for the nine months ended September 30, 2021, while such grant revenues were $71,000 for the nine months ended September 30, 2020. We completed activities under our 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 $59.7 million and $40.2 million for the nine months ended September 30, 2021 and 2020, respectively. The increase was primarily due to an increase in personnel costs of $8.8 million, of which stock-based compensation was $3.1 million, and increased spending on

manufacturing and development activities of $9.4 million associated with our clinical and nonclinical activities for paltusotine and our other clinical and preclinical programs.

General and administrative expenses. General and administrative expenses were $17.2 million and $13.1 million for the nine months ended September 30, 2021 and 2020, respectively. The increase was primarily due to additional personnel costs of $2.8 million, of which stock-based compensation was $1.7 million as well as an increase in legal and professional services expenses of $0.5 million.

Other income (expense). Other income (expense), net was $(33,000) and $1.0 million for the nine months ended September 30, 2021 and 2020, respectively. The decrease resulted from the impact of foreign currency fluctuations and a reduction of the income generated by our 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, 2021, we had unrestricted cash, cash equivalents and investment securities of $193.3 million and an accumulated deficit of $244.5 million.

The following table provides information regarding our cash flows for the nine months ended September 30, 2021 and 2020 (*in thousands*):

	Nine months ended September 30,	
	2021	2020
Net cash used in operating activities	$ (65,689)	$ (46,089)
Net cash provided by investing activities	45,315	9,109
Net cash provided by financing activities	88,823	114,474
Net change in cash, cash equivalents and restricted cash	$ 68,449	$ 77,494

Operating Activities. Net cash used in operating activities was $65.7 million and $46.1 million for the nine months ended September 30, 2021 and 2020, respectively. The increase in cash used in operations was primarily attributable to development and manufacturing activities associated with paltusotine and our other clinical and preclinical programs, and higher personnel costs. The net cash used in operating activities during the nine months ended September 30, 2021 was primarily due to our net loss of $76.8 million and a $2.2 million decrease in operating assets and liabilities, adjusted for $13.4 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, 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.

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 $45.3 million during the first nine months of 2021, compared to a net inflow of funds of approximately $9.1 million during the comparable period of 2020.

Financing activities. Net cash provided by financing activities was $88.8 million and $114.5 million for the nine months ended September 30, 2021 and 2020, respectively. The net cash provided by financing activities during 2021 was attributable to proceeds received from the sale of common stock in our underwritten follow-on offering in April 2021, our private placement of common stock in July 2021, and cash received from the exercise of stock options. The net cash provided by financing activities during the comparable period of 2020 was primarily the result of the proceeds received from the sale of common stock in our ATM Offering and in our public offering completed in April 2020.

Liquidity and Capital Resources

We believe that our existing capital resources, together with investment income, will be sufficient to satisfy our current and projected funding requirements for at least the next twelve months. 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;
- any delays and cost increases that result from the COVID-19 pandemic;
- 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;
- costs associated with any products or technologies that we may in-license or acquire;
- the funding of any co-development arrangements we enter into; and
- out ability to participate in future equity offering by Radionetics, including our option to exercise our warrant for the purchase of Radionetics stock.

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 three-month period ended March 31, 2020, we issued 275,764 shares of common stock in the ATM Offering for net proceeds of $6.4 million, after deducting commissions. We did not issue any additional shares of common stock in the ATM Offering during the remainder of 2020 or in the nine months ended September 30, 2021.

On August 10, 2021, we filed a registration statement on Form S-3, which became immediately effective upon filing, covering the offering of common stock, preferred stock, debt securities, warrants and units and the resale of up to 851,306 shares by the accredited investor who purchased shares in the private placement.

On October 21, 2021, we completed an underwritten public offering of 8,712,400 shares of common stock at a price to the public of $19.80 per share. We received proceeds of approximately $161.9 million, net of offering discounts and commissions and estimated offering costs of $10.6 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 comprehensive loss and totaled approximately $0.1 million and $0.1 million for the nine months ended September 30, 2021 and 2020, respectively.

As of September 30, 2021, 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, 2021 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.

PART II — OTHER INFORMATION

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

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, 2020.

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, 2021, we have used approximately $106.5 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.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation	8-K	001-38583	3.3	7/20/2018	
3.2	Amended and Restated Bylaws	8-K	001-38583	3.1	4/14/2020	
4.1	Specimen Stock Certificate Evidencing the Shares of Common Stock	S-1/A	333-225824	4.1	7/9/2018	
4.2	Amended and Restated Investor Rights Agreement, dated February 9, 2018, as amended, by and among the Registrant and certain of its stockholders	S-1	333-225824	4.2	6/22/2018	
31.1	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					X
31.2	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					X
32.1*	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					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 5, 2021

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

Date: November 5, 2021

By: /s/ Marc J.S. Wilson
Marc J.S. Wilson
Chief Financial Officer
(Principal financial and accounting officer)

Exhibit 31.1

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 5, 2021

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

R. Scott Struthers, Ph.D.
President and Chief Executive Officer

Exhibit 31.2

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 5, 2021

/s/ Marc J.S. Wilson

Marc J.S. Wilson
Chief Financial Officer

Exhibit 32.1

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, 2021 (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.
R. Scott Struthers, Ph.D.
President and Chief Executive Officer

Date: November 5, 2021

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, 2021 (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
Marc J.S. Wilson
Chief Financial Officer

Date: November 5, 2021