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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2021

OR

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

For the transition period from to

Commission File Number 001-39069

Aprea Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**84-2246769**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
535 Boylston Street **Boston, Massachusetts**	**02116**
(Address of principal executive offices)	(Zip Code)

(617) 463-9385
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	**Trading Symbol**	**Name of exchange on which registered:**
Common stock, par value $0.001 per share	APRE	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 ☒

There were 21,465,140 shares of the registrant's common stock, $0.001 par value, outstanding as of November 8, 2021.

Aprea Therapeutics, Inc.
Quarterly Report on Form 10-Q
For the Quarter Ended September 30, 2021

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "designed," "would," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Quarterly Report on Form 10-Q and include statements regarding our current intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned development, prospects for commercialization, and market uptake of APR-246 or *eprenetapopt* and our other potential product candidates, the strength and breadth of our intellectual property, our ongoing and planned clinical trials and our ability to resolve any clinical holds, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the legal and regulatory landscape impacting our business, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our development and validation of manufacturing capabilities, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to future events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. We caution you that forward-looking statements are not guarantees, or predictive, of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- estimates of our expenses, capital requirements and our needs for additional financing;
- business interruptions, including delays in enrollment, patient follow-up and data collection of clinical trials, resulting from the outbreak of the novel coronavirus, COVID-19;
- the prospects of eprenetapopt and other product candidates, which are still in development;
- outcome and results of ongoing or future preclinical studies and clinical trials of eprenetapopt or APR-548;
- the design of our multiple clinical trials, including the sample size, trial duration, endpoint definition, event rate assumptions and eligibility criteria;
- our expectations regarding the timing of data from our clinical trials;
- market acceptance or commercial success of eprenetapopt or any other product candidate we develop and the degree of acceptance among physicians, patients, patient advocacy groups, healthcare payors and the medical community;
- our expectations regarding competition, potential market size, the size of the patient populations for eprenetapopt and our other product candidates, if approved for commercial use, and market acceptance;
- our ability to obtain regulatory approval of eprenetapopt and our other product candidates, and any restrictions, limitations and/or warnings in their labels, if approved;
- the scope of protection we are able to establish and maintain for intellectual property rights covering eprenetapopt and our other product candidates;

- potential claims relating to our intellectual property and third-party intellectual property;
- the duration of our intellectual property estate that will provide protection for eprenetapopt and our other product candidates;
- developments relating to our competitors and our industry;
- our sales, marketing or distribution capabilities and our ability to commercialize eprenetapopt and our other product candidates, if we obtain regulatory approval;
- current and future agreements with third parties in connection with the manufacturing, commercialization, packaging and distribution of eprenetapopt and our other product candidates;
- our expectations regarding the ability of our current contract manufacturing partners to produce eprenetapopt and our other product candidates in the quantities and timeframe that we will require;
- our expectations regarding our future costs of goods;
- our ability to attract, retain and motivate key personnel and increase the size of our organization;
- our ability to establish collaborations in lieu of obtaining additional financing;
- the impact of government laws and regulations;
- our financial performance; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act or a smaller reporting company under the Exchange Act.

Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q. You should also read carefully the factors described in the “Risk Factors” included in Part II, Item 1A of this Quarterly Report and in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020 to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

This Quarterly Report on Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

This Form 10-Q may include trademarks, tradenames, and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this Form 10-Q may appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

Aprea Therapeutics, Inc.
Part I – Financial Information

Item 1. Financial Statements

Aprea Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 61,428,404	$ 89,017,686
Prepaid expenses and other current assets	750,929	3,399,019
Total current assets	62,179,333	92,416,705
Property and equipment, net	27,318	38,515
Right of use lease asset	248,834	320,616
Other noncurrent assets	29,375	29,383
Total assets	$ 62,484,860	$ 92,805,219
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,548,388	$ 4,503,619
Accrued expenses	6,267,429	10,571,237
Lease liability—current	223,999	256,309
Total current liabilities	9,039,816	15,331,165
Lease liability—noncurrent	29,773	78,847
Total liabilities	9,069,589	15,410,012
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock, $0.001 par value, 400,000,000 shares authorized, 21,360,140 and 21,186,827 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively.	21,360	21,187
Additional paid-in capital	237,227,804	231,418,356
Accumulated other comprehensive loss	(10,454,699)	(10,037,261)
Accumulated deficit	(173,379,194)	(144,007,075)
Total stockholders' equity	53,415,271	77,395,207
Total liabilities and stockholders' equity	$ 62,484,860	$ 92,805,219

See accompanying notes to unaudited condensed consolidated financial statements.

Aprea Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 6,015,616	$ 8,761,095	$ 19,433,721	$ 28,551,246
General and administrative	3,414,795	3,473,210	10,183,953	10,036,564
Total operating expenses	9,430,411	12,234,305	29,617,674	38,587,810
Other income (expense):				
Interest (expense) income, net	(33)	(9,212)	(1,678)	217,908
Foreign currency (loss) gain	(21,907)	(74,565)	247,233	283,636
Total other (expense) income	(21,940)	(83,777)	245,555	501,544
Net loss	$ (9,452,351)	$ (12,318,082)	$ (29,372,119)	$ (38,086,266)
Other comprehensive loss:				
Foreign currency translation	(207,608)	(168,982)	(417,438)	(836,852)
Total comprehensive loss	(9,659,959)	(12,487,064)	(29,789,557)	(38,923,118)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.45)	$ (0.58)	$ (1.39)	$ (1.80)
Weighted-average common shares outstanding, basic and diluted	21,231,584	21,186,827	21,201,910	21,115,797

See accompanying notes to unaudited condensed consolidated financial statements.

Aprea Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

	Common Stock		Additional Paid-in Capital	Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount				
Balance, December 31, 2019	21,022,752	$ 21,023	$ 226,284,548	$ (11,533,778)	$ (90,528,263)	$ 124,243,530
Exercise of stock options	164,075	164	150,785	—	—	150,949
Stock-based compensation	—	—	2,161,931	—	—	2,161,931
Foreign currency translation	—	—	—	(667,870)	—	(667,870)
Net loss	—	—	—	—	(25,768,184)	(25,768,184)
Balance, June 30, 2020	21,186,827	$ 21,187	$ 228,597,264	$ (12,201,648)	$ (116,296,447)	$ 100,120,356
Stock-based compensation	—	—	1,389,647	—	—	1,389,647
Foreign currency translation	—	—	—	(168,982)	—	(168,982)
Net loss	—	—	—	—	(12,318,082)	(12,318,082)
Balance, September 30, 2020	21,186,827	$ 21,187	$ 229,986,911	$ (12,370,630)	$ (128,614,529)	$ 89,022,939
Balance, December 31, 2020	21,186,827	$ 21,187	$ 231,418,356	$ (10,037,261)	$ (144,007,075)	$ 77,395,207
Stock-based compensation	—	—	3,686,060	—	—	3,686,060
Foreign currency translation	—	—	—	(209,830)	—	(209,830)
Net loss	—	—	—	—	(19,919,768)	(19,919,768)
Balance, June 30, 2021	21,186,827	$ 21,187	$ 235,104,416	$ (10,247,091)	$ (163,926,843)	$ 60,951,669
Exercise of stock options	93,894	94	86,876	—	—	86,970
Vesting of restricted stock units	79,419	79	(79)	—	—	—
Stock-based compensation	—	—	2,036,591	—	—	2,036,591
Foreign currency translation	—	—	—	(207,608)	—	(207,608)
Net loss	—	—	—	—	(9,452,351)	(9,452,351)
Balance, September 30, 2021	21,360,140	$ 21,360	$ 237,227,804	$ (10,454,699)	$ (173,379,194)	$ 53,415,271

See accompanying notes to unaudited condensed consolidated financial statements.

Aprea Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (29,372,119)	$ (38,086,266)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	9,860	12,177
Stock-based compensation	5,722,651	3,551,578
Amortization of right of use lease asset	195,825	160,540
Foreign currency (gain)	(247,233)	(283,636)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,648,090	1,698,801
Accounts payable	(1,955,231)	2,173,125
Accrued expenses and other liabilities	(4,303,808)	2,441,836
Lease liability	(205,427)	(271,625)
Net cash used in operating activities	(27,507,392)	(28,603,470)
Cash flows from investing activities:		
Purchases of property and equipment	—	(9,419)
Net cash used in investing activities	—	(9,419)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	86,970	150,949
Net cash provided by financing activities	86,970	150,949
Decrease in cash and cash equivalents	(27,420,422)	(28,461,940)
Effect of exchange rate changes on cash	(168,860)	(480,296)
Cash and cash equivalents—beginning of year	89,017,686	130,088,869
Cash and cash equivalents—end of period	$ 61,428,404	$ 101,146,633
Non-cash investing and financing activities:		
Operating lease liabilities arising from obtaining right-of-use assets	$ 124,043	$ -

See accompanying notes to unaudited condensed consolidated financial statements.

Aprea Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Nature of business and basis of presentation

Nature of business—Aprea Therapeutics, Inc. (or the "Company") is a clinical-stage biopharmaceutical company focused on developing and commercializing novel cancer therapeutics that reactivate the mutant tumor suppressor protein p53. p53 is the protein expressed from the *TP53* gene, the most commonly mutated gene in cancer. The Company began principal operations in 2006 and is headquartered in Boston, Massachusetts with research facilities in Stockholm, Sweden.

Corporate reorganization - In September 2019, the Company completed a corporate reorganization whereby Aprea Therapeutics AB became a wholly-owned subsidiary of the Company. In connection with the corporate reorganization, each issued and outstanding share of Series A, Series B and Series C convertible preferred stock of Aprea Therapeutics AB was exchanged on a one for one basis into shares of Series A, Series B and Series C convertible preferred stock of the Company.

Each share of common stock of Aprea Therapeutics AB ($0.11 par value) was also exchanged on a one for one basis into shares of common stock of the Company ($0.001 par value).

Basis of presentation and management plans—The accompanying financial statements are prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP"). The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and raising capital, and has financed its operations through the issuance of convertible preferred stock and common stock.

The Company is subject to risks common to companies in the biopharmaceutical industry. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be maintained, that any therapeutic products developed will obtain required regulatory approval or that any approved or consumer products will be commercially viable. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will generate significant product sales.

The Company believes that the September 30, 2021 cash balance of approximately $61.4 million will be sufficient to fund the Company's operations into 2023. In the event that additional funds are not available thereafter, management would expect to significantly reduce expenditures to conserve cash, which would involve scaling back or curtailing new development activity.

2. Summary of significant accounting policies

The Company's complete listing of significant accounting policies are described in Note 2 to the Company's audited consolidated financial statements as of December 31, 2020 included in its annual report on Form 10-K filed with the Securities and Exchange Commission (or the "SEC").

Principles of consolidation—The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries Aprea Therapeutics AB and Aprea US, Inc., which was incorporated in June 2016. Management has concluded it has a single reporting segment for purposes of reporting financial condition and results of operations. All intercompany transactions and balances have been eliminated.

Unaudited interim consolidated financial statements—The accompanying unaudited interim condensed consolidated financial statements have been prepared by the Company in accordance with U.S. GAAP for interim information and pursuant to the rules and regulations of the SEC for reporting on Form 10-Q. Accordingly, certain information and

Aprea Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. These unaudited condensed interim financial statements should be read in conjunction with the audited financial statements and related notes included in the Company's annual report on Form 10-K for the year ended December 31, 2020 filed with the SEC.

The unaudited interim consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements, and in management's opinion, include all adjustments, consisting of only normal recurring adjustments, necessary for the fair presentation of the financial information for the interim periods have been made. The results of operations for the three and nine months ended September 30, 2021 are not necessarily indicative of the results to be expected for the full fiscal year or any future period.

Use of estimates—The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses as of and during the reporting period. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company assesses estimates on an ongoing basis; however, actual results could materially differ from those estimates. Significant items subject to such estimates and assumptions include stock-based compensation expense.

Foreign currency and currency translation—The functional currency for Aprea Therapeutics AB is the Swedish Krona. Assets and liabilities of Aprea Therapeutics AB are translated into United States dollars at the exchange rate in effect on the balance sheet date. Operating expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated statements of stockholders' equity as a component of accumulated other comprehensive loss. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other income (expense), net in the condensed consolidated statements of operations and comprehensive loss as incurred.

Cash and cash equivalents— The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents.

Fair value of financial instruments—The accounting standard for fair value measurements provides a framework for measuring fair value and requires expanded disclosures regarding fair value measurements. Fair value is defined as the price that would be received upon sale of an asset or paid to transfer a liability between market participants at measurement dates. ASC Topic 820, Fair Value Measurement ("ASC 820"), establishes a three-level valuation hierarchy for instruments measured at fair value. The hierarchy is based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The hierarchy defines three levels of valuation inputs, of which the first two are considered observable and the last is considered unobservable:

- Level 1 inputs: Quoted prices in active markets for identical assets or liabilities.
- Level 2 inputs: Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.
- Level 3 inputs: Unobservable inputs developed using estimates or assumptions developed by the Company, which reflect those that a market participant would use in pricing the asset or liability.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Aprea Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

The Company's financial instruments consist of cash and cash equivalents and accounts payable. The carrying amount of accounts payable is considered a reasonable estimate of fair value due to the short-term maturity.

Accounting for leases—The Company adopted the Lease standard (ASC 842) effective January 1, 2019, using the modified retrospective method. The new standard provided a number of optional practical expedients in transition. The Company elected to apply the 'package of practical expedients' which allowed them to not reassess (i) whether existing or expired arrangements contain a lease, (ii) the lease classification of existing or expired leases, or (iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. The Company also elected to apply (i) the practical expedient which allows them to not separate lease and non-lease components, for new leases entered into after adoption and (ii) the short-term lease exemption for all leases with an original term of less than 12 months, for purposes of applying the recognition and measurements requirements in the new standard.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on specific facts and circumstances, the existence of an identified asset(s), if any, and the Company's control over the use of the identified asset(s), if applicable. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of future lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. The Company's incremental borrowing rate ranged from approximately 3.0% to 4.3% based on the remaining lease term of the applicable leases.

The Company has elected not to separate lease and non-lease components as a single component. Operating leases are recognized on the balance sheet as ROU lease assets, lease liabilities current and lease liabilities non-current. Fixed rents are included in the calculation of the lease balances while variable costs paid for certain operating and pass-through costs are excluded. Lease expense is recognized over the expected term on a straight-line basis.

Stock-based compensation—The Company measures stock options and other stock-based awards granted to employees and directors based on their fair value on the date of the grant and recognize compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. The Company applies the straight-line method of expense recognition to all awards with only service based vesting conditions.

For stock-based awards granted to non-employees, compensation expense is recognized over the period during which services are rendered by such non-employees until completed in accordance with the FASB issued ASU No. 2018-07, Compensation Stock Compensation (Topic 718): Improvements to Nonemployee Share Based Payment Accounting. The new standard largely aligns the accounting for share based payment awards issued to employees and nonemployees by expanding the scope of ASC 718 to apply to nonemployee share based transactions, as long as the transaction is not effectively a form of financing.

The Company estimates the fair value of each stock option grant on the date of grant using the Black Scholes option pricing model, which uses as inputs the fair value of the Company's common stock and assumptions the Company makes for the volatility of its common stock, the expected term of its stock options, the risk-free interest rate for a period that approximates the expected term of its stock options and its expected dividend yield.

The Company also awards restricted stock units ("RSUs") to employees and directors. RSUs are generally subject to forfeiture if employment terminates prior to the completion of the vesting restrictions. The Company expenses the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse.

Net loss per share—The Company has reported losses since inception and has computed basic net loss per share attributable to common stockholders by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. The

Aprea Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Company computes diluted net loss per common share after giving consideration to all potentially dilutive common shares, including options to purchase common stock, outstanding during the period determined using the treasury-stock and if-converted methods, except where the effect of including such securities would be antidilutive. Because the Company has reported net losses since inception, these potential common shares have been anti-dilutive and basic and diluted loss per share have been the same.

The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to include them would be anti-dilutive (in common stock equivalent shares):

	Nine months ended September 30,	
	2021	2020
Options to purchase common stock	4,719,115	3,771,459
Unvested restricted stock units	399,719	—
Total shares of common stock equivalents	5,118,834	3,771,459

Recently issued accounting pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies that the Company adopts as of the specified effective date.

Management does not believe that any recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying financial statements.

3. Leases

The Company is party to two operating leases for office and laboratory space. The Company’s finance leases are immaterial both individually and in the aggregate. The Company has elected to apply the short-term lease exception to all leases of one year or less. Rent expense for three and nine months ended September 30, 2021 was $81,657 and $257,744, respectively. Rent expense for the three and nine months ended September 30, 2020 was $84,482 and $241,807, respectively.

The Company has an operating lease in Boston, Massachusetts for office space which was amended effective July 1, 2021. The lease will now expire on December 31, 2022 and does not have any renewal options. The Company also has an operating lease for office and laboratory space in Solna, Sweden that expires in June 2022.

Quantitative information regarding the Company’s leases for the three and nine months ended September 30, 2021 and 2020 is as follows:

	Three months ended September 30,		Nine months ended September 30,	
Lease Cost	2021	2020	2021	2020
Operating lease cost	$ 59,700	$ 56,834	$ 176,104	$ 168,900
Other Information				
Operating cash flows paid for amounts included in the measurement of lease liabilities	$ 64,056	$ 62,909	$ 191,022	$ 188,727
Operating lease liabilities arising from obtaining right-of-use assets	$ 124,043	$ —	$ 124,043	$ —
Weighted average remaining lease term (years)	0.75 - 1.25	1.25 - 1.75	0.75 - 1.25	1.25 - 1.75
Weighted average discount rate	3.0 - 4.3%	3.0 - 4.3%	3.0 - 4.3%	3.0 - 4.3%

Aprea Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Future lease payments under noncancelable leases are as follows at September 30, 2021:

Future Lease Payments	Operating Leases
2021	$ 65,800
2022	195,861
Total Lease Payments	$ 261,661
Less: Imputed Interest	(7,889)
Total Lease Liabilities	$ 253,772

As most of the Company's leases do not provide an implicit rate, the Company used its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The Company uses the incremental borrowing rate on January 1, 2019 for operating leases that commenced prior to that date.

4. Accrued expenses

Accrued expenses consist of the following:

	September 30, 2021	December 31, 2020
Professional fees	$ 168,485	$ 224,424
Compensation and benefits	1,115,320	1,515,312
Research and development	4,424,556	8,158,302
Other	559,068	673,199
Total accrued expenses	$ 6,267,429	$ 10,571,237

5. Stockholders' equity

The total number of shares of all classes of capital stock that the Company is authorized to issue is 440,000,000 shares, consisting of 400,000,000 shares of common stock, par value $0.001 per share and 40,000,000 shares of preferred stock, par value $0.001 per share.

Common Stock

The holders of common stock are entitled to one vote for each share of common stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, after the payment or provision for payment of all debts and liabilities of the Company, the holders of common stock shall be entitled to share in the remaining assets of the Company available for distribution, if any.

Shelf Registration Statement

On November 12, 2020, the Company filed a universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, rights, debt securities and units up to an aggregate of $350.0 million. On November 30, 2020, the Shelf Registration Statement was declared effective by the SEC. The universal shelf registration statement includes an at-the-market ("ATM") offering program for the sale of up to $50.0 million of shares of the Company's common stock. As of September 30, 2021, no sales of any of the Company's common stock occurred under the ATM program.

Aprea Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense of $2,036,591, and $5,722,651 for the three and nine months ended September 30, 2021, respectively. The Company recorded stock-based compensation expense of $1,389,647 and $3,551,578 for the three and nine months ended September 30, 2020, respectively.
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6. Income Taxes

The Company has no income tax expense due to operating losses incurred for the three and nine months ended September 30, 2021 and 2020. The Company has provided a valuation allowance for the full amount of the net deferred tax assets as, based on all available evidence, it is considered more likely than not that all the recorded deferred tax assets will not be realized in a future period.

Realization of the future tax benefits is dependent on may factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. Under the provisions of the U.S. Internal Revenue Code and Sweden tax law, certain substantial changes in the Company's ownership, including a sale of the Company or significant changes in ownership due to sales of equity, may have limited, or may limit in the future, the amount of net operating loss carryforwards that could be used annually to offset future taxable income. For U.S. and Swedish income tax purposes, the Company has not completed a study to assess whether a change of control has occurred or whether there have been changes of control since the Company's formation due to the complexity and cost associated with such study and because there could be additional changes of control in the future. As a result, the Company is not able to estimate the effect of the change in control, if any, on the Company's ability to utilize U.S. or Swedish net operating losses or other tax attribute carryforwards in the future. For Swedish income tax purposes, the Company's net operating losses may be subject to limitations in accordance with the country's group contribution restriction laws.

The Company files tax returns in Sweden, the United States and Massachusetts, and all tax years since inception remain open to examination by the major taxing jurisdictions to which the Company is subject, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service (IRS) or other authorities if they have or will be used in a future period. The Company is not currently under examination by the IRS or any other jurisdictions for any tax years.

As tax law is complex and often subject to varied interpretations, it is uncertain whether some of the Company's tax positions will be sustained upon examination. Tax liabilities associated with uncertain tax positions represent unrecognized tax benefits, which arise when the estimated benefit recorded in the Company's financial statements differs from the amounts taken or expected to be taken in a tax return because of the uncertainties described above. If recognized, the Company's uncertain tax positions would all be absorbed by net operating losses.

As of September 30, 2021 and December 31, 2020, the Company had approximately $0.8 million of liabilities related to uncertain tax positions. As the Company's uncertain tax positions can be offset by available net operating losses, the Company did not recognize interest and penalties for 2021 and 2020.

7. Commitments and contingencies

The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. As of September 30, 2021, the Company has not recorded a provision for any contingent losses.

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

You should read the following discussion and analysis of our financial condition and results of operations together with the unaudited financial information and notes thereto included in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business and related financing, including forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report and in our Annual Report on Form 10-K for the year ended December 31, 2020, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing novel cancer therapeutics that reactivate the mutant p53 tumor suppressor protein. p53 is the protein expressed from the *TP53* gene, the most commonly mutated gene in cancer. We believe that mutant p53 is an attractive therapeutic target due to the high incidence of p53 mutations across a range of cancer types and its involvement in key cellular activities such as apoptosis. Cancer patients with mutant p53 face a significantly inferior prognosis even when treated with the current standard of care, and a large unmet need for these patients remains.

Our lead product candidate, APR-246, or *eprenetapopt*, is a small molecule p53 reactivator that is in clinical development for hematologic malignancies, including myelodysplastic syndromes, or MDS, and acute myeloid leukemia, or AML. Eprenetapopt has received orphan drug and fast track designations from the FDA for MDS, orphan drug and fast track designations from the FDA for AML and orphan drug designation from the European Commission for MDS and AML, and we believe eprenetapopt will be a first-in-class therapy if approved by applicable regulators. We are conducting, supporting and planning multiple clinical trials of eprenetapopt and APR-548.

On August 4, 2021, the U.S. Food and Drug Administration (FDA) placed a partial clinical hold on the clinical trials of eprenetapopt in combination with azacitidine in our myeloid malignancy programs. The FDA's concerns referred to the safety and efficacy data from the Phase 3 frontline MDS clinical trial. In particular, the FDA requested more information related to a potential risk-reward imbalance between the combination of eprenetapopt and azacitidine versus azacitidine alone as it relates to increased adverse events in our Phase 3 frontline clinical trial in MDS.

There are approximately 9 patients currently receiving eprenetapopt in combination with azacitidine in our myeloid malignancy programs, which includes the MDS, AML and post-transplant maintenance trials, all of which have completed enrollment. Patients who are benefiting from treatment can continue to receive study treatment. As part of the partial clinical hold, no additional patients can be enrolled to these clinical trials until the partial clinical hold is resolved. We intend to work with the FDA to analyze the data, address the specific questions raised, and seek to resolve the partial clinical hold as soon as possible.

On August 11, 2021, the FDA placed a clinical hold on our clinical trial evaluating eprenetapopt with acalabrutinib or with venetoclax and rituximab in lymphoid malignancies. The FDA's concerns referred to the safety and efficacy data from the Phase 3 frontline MDS clinical trial. There are no patients currently receiving study treatment in this trial and no additional patients can be enrolled until the clinical hold is resolved. We intend to work with the FDA to address the specific questions raised and seek to resolve the clinical hold as soon as possible.

Our current clinical trials are as follows:

- **Phase 3 Frontline MDS Trial --** In June 2020, we completed full enrollment of 154 patients in a pivotal Phase 3 trial of eprenetapopt with azacitidine for frontline treatment of *TP53* mutant MDS. The pivotal Phase 3 trial is supported by data from two Phase 1b/2 investigator-initiated trials, one in the U.S. and one in France, testing eprenetapopt with azacitidine as frontline treatment in *TP53* mutant MDS and AML patients. The data from the U.S. and French Phase 1b/2 trials were published in *The Journal of Clinical Oncology* in January 2021 and February 2021, respectively. In December 2020, we announced that our pivotal Phase 3 trial failed to meet

its predefined primary endpoint of complete remission (CR) rate. Analysis of the primary endpoint at this data cut demonstrated a higher CR rate (53% more patients achieving a CR) in the experimental arm receiving eprenetapopt with azacitidine versus the control arm receiving azacitidine alone but did not reach statistical significance. Based on a thorough analysis of the current Phase 3 trial data and comparisons to the U.S. and French Phase 1b/2 trials, we believe that despite similar types and frequency of adverse events observed in the Phase 3 experimental arm and the Phase 1b/2 trials, patients in the Phase 3 experimental arm experienced substantially more study treatment dose modifications compared to the experience in the U.S. and French Phase 1b/2 trials. We believe that the dose modifications of eprenetapopt and azacitidine led to undertreatment in the Phase 3 experimental arm that negatively impacted efficacy, particularly the primary endpoint of CR rate. We continue to follow patients who remain on-study. Based on initial feedback from the FDA and the partial clinical hold on our myeloid malignancy programs, we believe that there is no registrational pathway for this Phase 3 trial and we have voluntarily withdrawn our Breakthrough Therapy designation.

- **Phase 2 MDS/AML Post-Transplant Trial --** In July 2021, we announced positive results from a single-arm, open-label Phase 2 clinical trial evaluating eprenetapopt with azacitidine as post-transplant maintenance therapy in *TP53* mutant MDS and AML patients who have received an allogeneic stem cell transplant. The primary endpoint of the trial is the rate of relapse-free survival (RFS) at 12 months. In 33 patients enrolled in the trial, the RFS at 1-year post-transplant was 58% and the median RFS was 12.1 months. The overall survival (OS) at 1-year post-transplant was 79%, with a median OS of 19.3 months. Prior clinical trials evaluating post-transplant outcomes in *TP53* mutant MDS and AML patients have reported a 1-year post-transplant RFS of ~30% and a median OS of ~5-8 months. As part of our plan to seek to resolve the partial clinical hold, we plan to share data with the FDA. Data from this clinical trial has been accepted for oral presentation at the 63rd American Society of Hematology (ASH) Annual Meeting on December 12, 2021 (abstract #409) and we may also present data from this clinical trial at additional future scientific or medical conferences.

- **Phase 1/2 AML Trial** -- We are currently conducting a Phase 1/2 clinical trial, which is currently subject to a partial clinical hold, evaluating the safety, tolerability, and preliminary efficacy of eprenetapopt therapy in *TP53* mutant AML patients. The lead-in portion of the trial evaluated the tolerability of eprenetapopt with venetoclax, with or without azacitidine, and no dose-limiting toxicities were observed in 12 patients receiving either regimen. Based on these results, we have expanded the trial to treat 33 additional frontline *TP53* mutant AML patients with the combination of eprenetapopt, venetoclax and azacitidine. In June 2021, we announced that the regimen of eprenetapopt with venetoclax and azacitidine met the CR primary efficacy endpoint. In 30 patients who were evaluable for efficacy at the time of the analysis, the CR rate was 37% and the composite response rate of CR plus CR with incomplete hematologic recovery (CRi), CR/CRi, was 53%. The trial met the primary efficacy endpoint of CR, which is based on a Simon 2-stage design. We plan to continue collecting data from this Phase 2 clinical trial and share data with the FDA as part of our effort to resolve the partial clinical hold. Data from this clinical trial has been accepted for poster presentation at the 63rd American Society of Hematology (ASH) Annual Meeting on December 13, 2021 (abstract #3409) and we may also present data from this clinical trial at additional future scientific or medical conferences.

- **Phase 1 NHL Trial** -- We have initiated a Phase 1 clinical trial, which is currently subject to a clinical hold, in relapsed/refractory *TP53* mutant chronic lymphoid leukemia (CLL) assessing eprenetapopt with venetoclax and rituximab and eprenetapopt with acalabrutinib in order to further assess eprenetapopt in hematological malignancies. The first patient was enrolled in the first quarter of 2021. The Company intends to work with the FDA to address the specific questions raised, and seek to resolve the clinical hold as soon as possible.

- **Phase 1/2 Solid Tumor Trial** – We are currently conducting a Phase 1/2 clinical trial in relapsed/refractory gastric, bladder and non-small cell lung cancers assessing eprenetapopt with anti-PD-1 therapy. The dose-escalation phase of the trial enrolled 6 patients with advanced solid tumors and no dose-limiting toxicities were observed. Based on these results, we enrolled additional patients into expansion cohorts for advanced gastric, bladder and non-small cell lung cancers. Data from this trial was presented at the European Society of Medical Oncology (ESMO) Congress 2021 (Presentation #516MO) and reported interim results for 31 patients who had initiated treatment, including three gastric/GFJ, three bladder/urothelial cancer and 19 non-small lung cancer (NSCLC) patients. In the bladder/urothelial cohort, one patient with localized *TP53* mutant high-grade

transitional cell bladder cancer had achieved complete remission (CR) by RECIST criteria at the first response assessment at 9 weeks. In the NSCLC cohort, two patients with *TP53* mutant squamous NSCLC had reductions in target lesions of 26.7% and 8.2%, respectively, from baseline by RECIST criteria at the first response assessment at 9 weeks.

- **APR-548 Phase 1 Trial** – Our second product candidate, APR-548, is a next generation p53 reactivator that is being developed in an oral dosage form. We are currently enrolling a Phase 1 dose-escalation clinical trial evaluating safety, tolerability, and preliminary efficacy of APR-548 with azacitidine in frontline and relapsed/refractory MDS patients. The trial is open and patients are enrolled in the first dosing cohort.

Aprea Therapeutics AB, or Aprea AB, was originally incorporated in 2002 and commenced principal operations in 2006. We incorporated Aprea Therapeutics, Inc. (the "Company") in May 2019. In September 2019 we completed a corporate reorganization and, as a result, all of the issued and outstanding stock of Aprea AB was exchanged for common stock, preferred stock or options, as applicable, of the Company As a result of such transactions, Aprea AB became a wholly-owned subsidiary of the Company.

We have devoted substantially all of our resources to developing our product candidates, including eprenetapopt, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. To date, we have financed our operations through private placements of preferred stock and the net proceeds received from the initial public offering (IPO) of our common stock. Through September 30, 2021, we had received net proceeds of approximately $224.0 million from our sales of preferred and common stock.

Since our inception, we have incurred significant losses on an aggregate basis. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our product candidates. Our net losses were $9.5 million and $29.4 million for the three and nine months ended September 30, 2021, respectively, $12.3 million and $38.1 million for the three and nine months ended September 30, 2020, respectively, and $53.5 million, $28.1 million and $15.5 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of September 30, 2021, we had an accumulated deficit of $173.4 million. These losses have resulted primarily from costs incurred in connection with research and development activities, patent investment, and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

We anticipate that our expenses will increase substantially if and as we:

- conduct our current and future clinical trials and additional preclinical research of eprenetapopt;
- initiate and continue research and preclinical and clinical development of our other product candidates;
- seek to identify and develop additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing, manufacturing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- require the manufacture of larger quantities of our product candidates for clinical development and potential commercialization;
- maintain, expand, protect and enforce our intellectual property portfolio;
- acquire or in-license other drugs and technologies;
- defend against any claims of infringement, misappropriation or other violation of third-party intellectual property;

- hire and retain additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our drug development, any future commercialization efforts and our operation as a public company.

Furthermore, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

As a result, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. We may be unable to raise additional funds or enter into other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2021, we had cash and cash equivalents of $61.4 million. We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “—Liquidity and Capital Resources.”

The COVID-19 pandemic

The novel coronavirus outbreak (COVID-19) has been declared a “Public Health Emergency of International Concern” by the World Health Organization. COVID-19 has spread to the countries in which we, our suppliers, and our other business partners conduct business. Governments in affected regions have implemented, and may continue to implement or re-implement, safety precautions, including quarantines, travel restrictions, business closures, cancellations of public gatherings, and other measures they deem necessary. Like many other organizations and individuals, the Company and our employees are taking additional steps to avoid or reduce infection, including limiting travel and implementing remote work arrangements. We will continue to actively monitor the situation and may take further actions that could alter our business operations as may be required by national, state, or local authorities, or that we determine are in the best interests of our employees and stockholders.

Together with our investigators and clinical sites, we continue to assess the impact of the coronavirus pandemic on data integrity, patient enrollment, the ability to maintain patients in our clinical trials and, the corresponding impact on the timing of the completion of our clinical trials.

We have assessed both capacity and the current clinical supply chain associated with the production of eprenetapopt and APR-548 and have observed no disruptions to date in our clinical supply chain and our ability to provide supply for our on-going clinical trials. We will continue to monitor and assess the potential impact of the COVID-19 pandemic on our clinical trial supply chain.

There are many uncertainties regarding the COVID-19 pandemic, and we are closely monitoring the impact of the pandemic on all aspects of our business, including how it will impact our clinical trials, employees, suppliers, vendors and business partners. While the pandemic did not materially affect our financial results and business operations for the three and nine months ended September 30, 2021, we are unable to predict the impact that COVID-19 will have on our financial position and operating results at this time due to numerous uncertainties such as the duration and spread of the outbreak. We will continue to assess the evolving impact of the COVID-19 pandemic and will make adjustments to our operations if necessary.

Components of our results of operations

Revenue

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for eprenetapopt or other product candidates that we may develop in the future are successful and result in marketing approval or collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements that we may enter into with third parties.

Operating expenses

Our expenses since inception have consisted solely of research and development costs and general and administrative costs.

Research and development expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of our product candidates, and include:

- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct research, preclinical activities and clinical trials on our behalf as well as contract manufacturing organizations, or CMOs, that manufacture our product candidates for use in our preclinical and clinical trials;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- expenses related to compliance with regulatory requirements; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid or accrued research and development expenses.

We typically use our employee and infrastructure resources across our development programs. We track outsourced development costs and payments made to our research partners by product candidate or development program, but we do not allocate personnel costs or other internal costs to specific development programs or product candidates.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase for the foreseeable future as we initiate additional clinical trials of eprenetapopt, pursue later

stages of clinical development of eprenetapopt, initiate clinical trials for product candidates other than eprenetapopt and continue to discover and develop additional product candidates.

We cannot determine with certainty the duration and costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenue from the commercialization and sale of any our product candidates for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of our ongoing clinical trials of eprenetapopt and APR-548, as well as of any future clinical trials of eprenetapopt, APR-548, or other product candidates and other research and development activities that we may conduct;
- our ability to resolve the partial clinical hold on our clinical trials of eprenetapopt in combination with azacitidine in our myeloid malignancy programs;
- our ability to resolve the clinical hold on our clinical trial of eprenetapopt with acalabrutinib or with venetoclax and rituximab in lymphoid malignancies;
- uncertainties in clinical trial design and patient enrollment rates;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of, and any limitations imposed by regulatory bodies on, any marketing approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the U.S. Food and Drug Administration, or FDA, or another regulatory authority in a foreign jurisdiction were to require us to conduct clinical trials beyond the scope we currently anticipate, or additional clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant trial delays due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

We are currently conducting multiple clinical trials of eprenetapopt: a Phase 3 trial in the United States for the treatment of *TP53* mutant MDS with azacitidine which is supported by published data from two Phase 1b/2 investigator-initiated trials, one in the U.S. and one in France testing eprenetapopt with azacitidine as frontline treatment in *TP53* mutant MDS and AML patients; a Phase 2 trial of post-transplant maintenance therapy with azacitidine in *TP53* mutant MDS and AML; a Phase 1b/2 trial for the treatment of *TP53* mutant AML with venetoclax and azacitidine; a Phase 1/2 solid tumor trial assessing eprenetapopt with anti-PD-1 therapy; and a Phase 1/2 trial for the treatment of *TP53* mutant relapsed/refractory CLL with venetoclax and rituximab or with ibrutinib. We are currently conducting a Phase 1 trial of APR-548 with azacitidine in *TP53* mutant frontline and relapsed/refractory MDS. At this time, we cannot reasonably estimate the cost for initiating and completing other clinical trials or preclinical studies of eprenetapopt or other product candidates, as it will be highly dependent on the clinical data from ongoing clinical trials as well as any target disease subpopulations chosen for further evaluation. On August 4, 2021, the FDA placed a partial clinical hold on our clinical trials of eprenetapopt in combination with azacitidine in our myeloid malignancy programs. We intend to work with the FDA to analyze the data, address the specific questions raised, and seek to resolve the partial clinical hold as soon as possible. On August 11, 2021, the FDA placed a clinical hold on our clinical trial of eprenetapopt with acalabrutinib or with venetoclax and rituximab in lymphoid malignancies. We intend to work with the FDA to address the specific questions raised and seek to resolve the clinical hold as soon as possible.

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our headcount to support personnel in research and development and to support our operations generally as we increase our research and development activities and activities related to the potential commercialization of our product candidates. We also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements; director and officer insurance costs; and investor and public relations costs.

Other income and expense

Interest income and expense

Interest income consists of income earned on our cash and cash equivalents. Interest expense consists of the interest component associated with our facility leases. Our interest income initially increased as our cash and cash equivalents were higher due to the cash proceeds received from our IPO. Such interest income is subsequently decreasing as (i) our cash balance decreases as we continue to fund operations and (ii) a decrease in interest rates.

Foreign currency gain

Our consolidated financial statements are presented in U.S. dollars, which is our reporting currency. The financial position and results of operations of our subsidiary Aprea AB is measured using the foreign subsidiary's local currency as the functional currency. Aprea AB cash accounts holding U.S. dollars are remeasured based upon the exchange rate at the date of remeasurement with the resulting gain or loss included in the consolidated statement of operations and comprehensive loss. Expenses of such subsidiaries have been translated into U.S. dollars at average exchange rates prevailing during the period. Assets and liabilities have been translated at the rates of exchange on the consolidated balance sheet date. The resulting translation gain and loss adjustments are recorded directly as a separate component of stockholders' equity and as other comprehensive loss on the consolidated statement of operations and comprehensive loss.

Income taxes

We have not recorded any U.S. federal, state or foreign income tax expense or benefits for the net losses we have incurred in any year, due to our uncertainty of realizing a benefit from those items. We have provided a valuation allowance for the full amount of the net deferred tax assets as, based on all available evidence, it is considered more likely than not that all the recorded deferred tax assets will not be realized in a future period.

Critical accounting policies and use of estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

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

Accrued research and development expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses at each balance sheet. This process involves reviewing open contract and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research activities on our behalf and conducting preclinical studies and clinical trials on our behalf;
- investigative sites or other service providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing and development and distribution of preclinical and clinical supplies.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Stock-based compensation

We measure stock options and other stock-based awards granted to employees and directors based on their fair value on the date of the grant and recognize compensation expense of those awards, over the requisite service period, which is generally the vesting period of the respective award. We apply the straight-line method of expense recognition to all awards with only service-based vesting conditions and apply the graded-vesting method to all awards with performance-based vesting conditions or to awards with both service-based and performance-based vesting conditions.

For stock-based awards granted to non-employees, compensation expense is recognized over the period during which services are rendered by such non-employees until completed in accordance with the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. The new standard largely aligns the accounting for share-based payment awards issued to employees and nonemployees by expanding the scope of ASC 718 to apply to nonemployee share-based transactions, as long as the transaction is not effectively a form of financing.

We estimate the fair value of each stock option grant on the date of grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield.

We also award restricted stock units ("RSUs") to employees and directors. RSUs are generally subject to forfeiture if employment terminates prior to completion of the vesting restrictions. We expense the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse.

Emerging growth company and smaller reporting company status

We are an emerging growth company (EGC), as defined in the JOBS Act. Under this act, emerging growth companies are permitted to delay adopting new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We may remain classified as an EGC until the end of the fiscal year in which the fifth anniversary of our IPO occurs, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last trading day of the second quarter before that time or if we have annual gross revenues of $1.07 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than $1 billion of non-convertible debt over a three-year period.

We are also a "smaller reporting company," as such term is defined in Rule 12b-2 of the Exchange Act, meaning that the market value of our common stock held by non-affiliates is less than $700 million and our annual revenue is less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our common stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Results of operations

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

	Three months ended September 30,		
	2021	2020	Change
Operating expenses:			
Research and development	$ 6,015,616	$ 8,761,095	$ (2,745,479)
General and administrative	3,414,795	3,473,210	(58,415)
Total operating expenses	9,430,411	12,234,305	(2,803,894)
Other income (expense):			
Interest (expense) income, net	(33)	(9,212)	9,179
Foreign currency gain	(21,907)	(74,565)	52,658
Total other (expense) income	(21,940)	(83,777)	61,837
Net loss	$ (9,452,351)	$ (12,318,082)	$ 2,865,731

Research and development expenses

	Three months ended September 30, 2021	2020	Change
Eprenetapopt (APR-246)	$ 3,378,188	$ 7,923,977	$ (4,545,789)
Other early-stage development programs	1,067,960	428,485	639,475
Unallocated research and development expenses	1,569,468	408,632	1,160,835
Total research and development expenses	$ 6,015,616	$ 8,761,095	$ (2,745,479)

Research and development expenses for the three months ended September 30, 2021 were $6.0 million, compared to $8.7 million for the three months ended September 30, 2020. The overall decrease of $2.7 million was primarily due to the continued development of our lead product candidate, eprenetapopt, as follows:

- a decrease of $2.3 million related to our pivotal Phase 3 clinical trial of eprenetapopt with azacitidine for frontline treatment of *TP53* mutant MDS which completed enrollment in Q2 2020. The $2.3 million decrease included $1.0 million related to the development of an in vitro companion diagnostic test for eprenetapopt during the three months ended September 30, 2020 for which there were no comparable costs during the three months ended September 30, 2021;

- a decrease of $0.5 million related to the development of a Phase 1/2 clinical trial in relapsed/refractory *TP53* mutant chronic lymphoid leukemia (CLL) assessing eprenetapopt with venetoclax and rituximab and eprenetapopt with ibrutinib in order to further assess eprenetapopt in hematological malignancies; and

- a decrease of $0.3 million in manufacturing expenses related to the pausing of scale-up of manufacturing activities for the anticipated commercial production of eprenetapopt.

The above decreases were offset, in part by the following:

- an increase of $0.3 million related to pre-clinical activities; and

- an increase of $0.1 million related to the development of a Phase 1 dose-escalation clinical trial of APR-548, a next generation p53 reactivator being developed in an oral dosage form.

General and administrative expenses

General and administrative expenses for the three months ended September 30, 2021 were $3.4 million, compared to $3.5 million for the three months ended September 30, 2020. The decrease of $0.1 million was primarily related to decreases in commercial development expense of $0.8 million, offset in part, by an increase of $0.2 million in non-cash stock-based compensation expense, an increase of $0.2 million in legal expenses and an increase of $0.2 million in personnel costs. The decrease in commercial development expense was related to the initiation of certain pre-commercialization activities such as market research and brand building in the three months ended September 30, 2020 for which there was no comparable expense for the comparable period in 2021. The increase in non-cash stock-based compensation expense was primarily related to stock option and RSU grants made in February 2021 in connection with the Company’s annual compensation review for employees and stock option and RSU grants made in June 2021 in connection with the Company’s annual compensation review for its non-employee board members.

Other income and expense

Foreign currency loss for the three months ended September 30, 2021 was $21,907 compared to a foreign currency loss of $74,565 for the three months ended September 30, 2020. The decrease in the foreign currency loss of $52,658 was primarily due to a strengthening of the U.S. dollar against the Swedish Krona during the three months ended September 30, 2021. Interest expense for the three months ended September 30, 2021 consisted of interest expense associated with our facility leases, offset in part, by interest earned on our cash and cash equivalents.

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

	Nine months ended September 30,		
	2021	2020	Change
Operating expenses:			
Research and development	$ 19,433,721	$ 28,551,246	$ (9,117,525)
General and administrative	10,183,953	10,036,564	147,389
Total operating expenses	29,617,674	38,587,810	(8,970,136)
Other income (expense):			
Interest (expense) income	(1,678)	217,908	(219,586)
Foreign currency gain	247,233	283,636	(36,403)
Total other (expense) income	245,555	501,544	(255,989)
Net loss	$ (29,372,119)	$ (38,086,266)	$ 8,714,147

Research and development expenses

	Nine months ended September 30,		
	2021	2020	Change
Eprenetapopt (APR-246)	$ 10,843,510	$ 22,529,194	$ (11,685,684)
Other early-stage development programs	3,493,027	1,405,402	2,087,625
Unallocated research and development expenses	5,097,184	4,616,650	480,534
Total research and development expenses	$ 19,433,721	$ 28,551,246	$ (9,117,525)

Research and development expenses for the nine months ended September 30, 2021 were $19.4 million, compared to $28.5 million for the nine months ended September 30, 2020. The overall decrease of $9.1 million was primarily due to the continued development of our lead product candidate, eprenetapopt as follows:

- a decrease of $8.6 million related to our pivotal Phase 3 clinical trial of eprenetapopt with azacitidine for frontline treatment of *TP53* mutant MDS which completed enrollment in Q2 2020. The $8.6 million decrease included $2.2 million related to the development of an in vitro companion diagnostic test for eprenetapopt during the nine months ended September 30, 2020 for which there were no comparable costs during the nine months ended September 30, 2021;

- a decrease of $1.4 million related to our Phase 2 post-transplant MDS/AML clinical trial; and

- a decrease of $0.7 million in manufacturing expenses related to the pausing of scale-up of manufacturing activities for the anticipated commercial production of eprenetapopt.

The above decreases were offset, in part by the following:

- an increase of $1.0 million related to our Phase 1/2 clinical trials in relapsed/refractory gastric, bladder and non-small cell lung cancers assessing eprenetapopt with anti-PD-1 therapy which enrolled its first patient in Q3 2020; and

- an increase of $0.6 million related to the development of a Phase 1 dose-escalation clinical trial of APR-548, a next generation p53 reactivator being developed in an oral dosage form.

General and administrative expenses

General and administrative expenses for the nine months ended September 30, 2021 were $10.2 million, compared to $10.0 million for the nine months ended September 30, 2020. The increase of $0.2 million was primarily related to increases of $1.4 million in non-cash stock-based compensation expense, $0.3 million in legal expense and $0.2 million in insurance expense, offset in part by decreases in commercial development expense of $1.1 million and $0.7 million of consulting expense. The increase in non-cash stock-based compensation expense was primarily related to stock option and RSU grants made in February 2021 in connection with the Company's annual compensation review for employees and stock option and RSU grants made in June 2021 in connection with the Company's annual compensation review for its non-employee board members. The decrease in commercial development expense was related to the initiation of certain pre-commercialization activities such as market research and brand building in the nine months ended September 30, 2020 for which there was no comparable expense for the comparable period in 2021. The decrease in consulting expense was related to decreased recruiting and search fees.

Other income and expense

Foreign currency gain for the nine months ended September 30, 2021 was $0.2 million compared to a foreign currency gain of $0.3 million for the nine months ended September 30, 2020. The decrease in foreign currency gain of $0.1 million was primarily due to a weakening of the U.S. dollar against the Swedish Krona during the nine months ended September 30, 2021. Interest expense for the nine months ended September 30, 2021 consisted of interest expense associated with our facility leases, offset in part, by interest earned on our cash and cash equivalents.

Liquidity and capital resources

Since our inception, we have incurred significant losses on an aggregate basis. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. To date, we have financed our operations through private placements of our preferred and common stock and the net proceeds received from the initial public offering (IPO) of our common stock. Through September 30, 2021, we had received net proceeds of $224.0 million from our sales of preferred and common stock. As of September 30, 2021, we had cash and cash equivalents of $61.4 million.

Cash flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Nine months ended September 30,	
	2021	2020
Net cash provided by (used in):		
Operating activities	$(27,507,392)	$ (28,603,470)
Investing activities	--	(9,419)
Financing activities	86,970	150,949
Net decrease in cash and cash equivalents	$(27,420,422)	$ (28,461,940)

Operating activities.

Cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities was $27.5 million for the nine months ended September 30, 2021 compared to $28.6 million for the nine months ended September 30, 2020. The decrease in cash used in operating activities of $1.0 million was primarily attributable to a decrease in our net loss of $8.7 million and a decrease in operating assets and liabilities of $9.9 million, partially offset by an increase in non-cash stock-based compensation of $2.2 million.

Investing activities.

No cash was used in investing activities for the nine months ended September 30, 2021, while $9,419 was used in investing activities for the nine months ended September 30, 2020. Cash used in investing activities for the nine months ended September 30, 2020 represented the acquisition of property and equipment.

Financing activities.

Cash provided by financing activities was $86,970 and $150,949 for the nine months ended September 30, 2021 and 2020, respectively and represented proceeds received from the exercise of stock options.

Funding requirements

We expect our expenses to increase substantially in connection with our ongoing development activities related to eprenetapopt, APR-548 and other product candidates and programs which are still in the early stages of clinical development. In addition, we have incurred and continue to incur additional costs associated with operating as a public company. We expect that our expenses will increase substantially if and as we:

- conduct our current and future clinical trials and additional preclinical research of eprenetapopt and APR-548;
- decide to continue with the development of an in vitro companion diagnostic test for eprenetapopt;
- initiate and continue research and preclinical and clinical development of our other product candidates;
- seek to identify and develop additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing, manufacturing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- require the manufacture of larger quantities of our product candidates for clinical development and potentially commercialization;
- maintain, expand, protect and enforce our intellectual property portfolio;
- acquire or in-license other drugs and technologies;
- defend against any claims of infringement, misappropriation or other violation of third-party intellectual property;
- hire and retain additional clinical, quality control and scientific personnel;
- build out new facilities or expand existing facilities to support our ongoing development activity;
- add operational, financial and management information systems and personnel, including personnel to support our drug development, any future commercialization efforts and our transition to a public company; and
- continue to operate as a public company.

As of September 30, 2021, we had cash and cash equivalents of $61.4 million. We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with the development of eprenetapopt and other product candidates and programs and because the extent to which we may enter into collaborations with third parties for development of our product candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of our current and future clinical trials of eprenetapopt for our current targeted indications;
- the scope, progress, results and costs of drug discovery, preclinical research and clinical trials for eprenetapopt and our other product candidates;
- the number of future product candidates that we pursue and their development requirements;
- the costs, timing and outcome of regulatory review of our product candidates;
- the extent to which we acquire or invest in businesses, products and technologies, including entering into or maintaining licensing or collaboration arrangements for product candidates on favorable terms, and although we may explore such opportunities from time to time during the normal course of business, we have no commitments or agreements to complete any such transactions;
- the costs and timing of future commercialization activities, including drug sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval, to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of any collaborator that we may have at such time;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the impact of COVID-19 on the financial markets in general and on our business in particular;
- the costs of preparing, filing and prosecuting patent applications, maintaining, protecting and enforcing our intellectual property rights and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and our research and development activities; and
- the costs of operating as a public company.

Developing drug products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any product candidates or generate revenue from the sale of any products for which we may obtain marketing approval. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests in our securities may be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholders. Additional debt or preferred equity financing, if available, may involve agreements that include restrictive covenants that may limit our ability to take specific actions, such as incurring debt, making capital

expenditures or declaring dividends, which could adversely impact our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute existing ownership interest.

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

Contractual obligations and commitments

For additional details regarding our contractual obligations, see Note 3 “Leases” to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Shelf Registration Statement

On November 12, 2020, we filed a universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, rights and debt securities and units up to an aggregate of $350.0 million. On November 30, 2020, the Shelf Registration Statement was declared effective by the SEC. The universal shelf registration statement includes an at-the-market offering program for the sale of up to $50.0 million of shares of our common stock. As of September 30, 2021, no sales of our common stock occurred under the at-the-market offering program.

Recent accounting pronouncements

See Note 2 to our condensed consolidated financial statements which discusses new accounting pronouncements.

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 in the rules and regulations of the SEC.

Item 3. Quantitative and qualitative disclosures about market risk

Interest Rate Risk

We are exposed to market risk related changes in interest rates. As of September 30, 2021, our cash equivalents consisted of bank deposits and money market accounts. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, historical fluctuations in interest income have not been significant for us.

Foreign Currency Exchange Rate Risk

We face market risk to the extent that changes in foreign currency exchange rates affect our non-U.S. dollar functional currency foreign subsidiaries’ revenues, expenses, assets and liabilities. The financial position and results of operations of our subsidiary Aprea AB is measured using the foreign subsidiary’s local currency as the functional currency. Aprea AB cash accounts holding U.S. dollars are remeasured based upon the exchange rate at the date of remeasurement with the resulting gain or loss included in the consolidated statement of operations and comprehensive loss.

Our investments in foreign subsidiaries with a functional currency other than the U.S. dollar are generally considered long-term. In addition, we do not believe that we currently have any significant direct foreign exchange risk. Accordingly, we have not used any derivative financial instruments to hedge exposure to such risk.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, mean controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company on the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including, our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgement in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2021, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable level.

Changes in Internal Control

There has been no change in our internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act 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 subject to any material legal proceedings.

Item 1A. Risk Factors.

Our business is subject to substantial risks and uncertainties. Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors below, the risk factors in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020, together with the information contained elsewhere in this Quarterly Report on Form 10-Q, including Part I, Item 1 "Financial Statements" and Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in our other public filings in evaluating our business, including our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on March 16, 2021. Any of the risks and uncertainties described below and in our other filings with the SEC, either alone or taken together, could materially and adversely affect our business, financial condition, results of operations, prospects for growth, and the value of an investment in our common stock. In addition, these risks and uncertainties could cause actual results to differ materially from those expressed or implied by forward looking statements contained in this Form 10-Q (please read the Cautionary Note Regarding Forward-Looking Statements in this Form 10-Q).

Risks related to our financial position and need for additional capital

We have incurred significant losses in each year since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since our inception, we have incurred significant losses on an aggregate basis. Our net loss was $9.5 million and $29.4 million for the three and nine months ended September 30, 2021, respectively, and $53.5 million, $28.1 million and $15.5 million for the years ended December 31, 2020, 2019 and 2018, respectively. Our accumulated deficit was $173.4 million and $144.0 million as of September 30, 2021 and December 31, 2020, respectively. We have not generated any revenue to date from sales of any drugs and have financed our operations principally through private placements of our preferred stock and the net proceeds received from the initial public offering (IPO) of our common stock. We have devoted substantially all of our efforts to research and development. Our lead product candidate, eprenetapopt or APR-246, is in clinical development. A second generation compound, APR-548, is also in clinical development, and we are developing other product candidates currently in preclinical research. In December 2020, we announced that our pivotal Phase 3 trial failed to meet its predefined primary endpoint of complete remission (CR) rate. In August 2021, we announced the FDA placed a partial hold on the clinical trials of eprenetapopt in combination with azacitidine in our myeloid malignancy program and placed a clinical hold on our clinical trial evaluating eprenetapopt with acalabrutinib or with venetoclax and rituximab in lymphoid malignancies. As a result, it could be several years, if ever, before we have any product candidates ready for commercialization. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter.

To become and remain profitable, we must develop, obtain approval for and eventually commercialize a drug or drugs with significant market potential, either on our own or with a collaborator. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those drugs for which we may obtain marketing approval and establishing and managing any collaborations for the development, marketing and/or commercialization of our product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business and/or continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if at all. If we are unable to obtain product approvals or generate significant commercial revenues, our business will be materially harmed.

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

Unregistered sales of equity securities

None.

Use of proceeds from registered securities

On October 7, 2019, we completed our IPO, in which we sold 6,516,667 shares of common stock, $0.001 par value per share, which included the exercise in full by the underwriters of their option to purchase an additional 850,000 shares of common stock, at a price to the public of $15.00 per share. The offer and sale of the shares in the IPO was registered under the Securities Act pursuant to registration statements on Form S-1 (File No. 333-233662), which was filed with the SEC on September 6, 2019 and amended subsequently and declared effective on October 2, 2019, and Form S-1MEF, which was filed and declared effective with the SEC on October 2, 2019. The underwriters of the offering were J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC and RBC Capital Markets, LLC.

Our registration statements relating to the IPO registered common stock with a maximum aggregate offering price of up to $103,500,005. We raised approximately $90.9 million in net proceeds after deducting underwriting discounts and commissions of $6.8 million but before deducting other offering expenses. No offering expenses were paid directly or indirectly to any of our directors of officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Through September 30, 2021, we have used approximately $29.3 million of the net proceeds from our IPO for matters described in our final IPO prospectus filed with the SEC on October 4, 2019, or our IPO prospectus. There has been no material change in the planned use of the remaining proceeds from our IPO, as described in our IPO prospectus.

Repurchases of equity securities by the issuer

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits.

Exhibit Index

Exhibit Number	Description of Document
31.1	Certification of the Registrant's Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Registrant's Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Registrant's Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of the Registrant's Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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.
101.SCH	XBRL Schema Document.
101.CAL	XBRL Calculation Linkbase Document.
101.DEF	XBRL Definition Linkbase Document.
101.LAB	XBRL Label Linkbase Document.
101.PRE	XBRL Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101).

* The certifications furnished in Exhibit 32.1 and Exhibit 32.2 hereto are deemed to accompany this Quarterly Report and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 8, 2021

Aprea Therapeutics, Inc.

By: /s/ Christian S. Schade
Christian S. Schade
Chairman and Chief Executive Officer (Principal Executive Officer)

Date: November 8, 2021

By: /s/ Scott M. Coiante
Scott M. Coiante
Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Christian S. Schade, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Aprea Therapeutics, 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 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) 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;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2021

/s/ Christian S. Schade
Christian S. Schade
Chief Executive Officer

CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott M. Coiante, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Aprea Therapeutics, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2021

/s/ Scott M. Coiante
Scott M. Coiante
Chief Financial Officer

STATEMENT OF CHIEF EXECUTIVE OFFICER OF
APREA THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Aprea Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021 as filed with the Securities and Exchange Commission (the "Report"), I, Christian S. Schade, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: November 8, 2021

/s/ Christian S. Schade
Christian S. Schade
Chief Executive Officer

STATEMENT OF CHIEF ACCOUNTING OFFICER OF
APREA THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Aprea Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021 as filed with the Securities and Exchange Commission (the "Report"), I, Scott M. Coiante, Chief Accounting Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: November 8, 2021

/s/ Scott M. Coiante
Scott M. Coiante
Chief Financial Officer