

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2020

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: 001-38807

Anchiano Therapeutics Ltd.

(Exact Name of Registrant as Specified in its Charter)

Israel
(State or other jurisdiction of
incorporation or organization)

81-3676773
(I.R.S. Employer
Identification No.)

**One Kendall Square
Building 400
Suite 14-105
Cambridge, MA 02139**
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (857) 259-4622

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing five ordinary shares, no par value per share	ANCN	Nasdaq Capital Market
Ordinary shares, no par value per share	n/a	Nasdaq Capital Market*

*Not for trading; only in connection with the registration of American Depositary Shares

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, 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
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

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

As of May 7, 2020, the registrant had 37,099,352 ordinary shares outstanding.

ANCHIANO THERAPEUTICS LTD.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2020

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NOTE ABOUT FORWARD-LOOKING STATEMENTS

This quarterly report contains forward-looking statements. All statements other than statements of historical fact are “forward-looking statements” for purposes of this Quarterly Report on Form 10-Q. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” and similar expressions intended to identify forward-looking statements, but these are not the only ways these statements are identified. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties.

As used in this Quarterly Report on Form 10-Q, unless the context otherwise requires:

- references to “Anchiano Therapeutics Ltd.,” “Anchiano,” the “Company,” “us,” “we” and “our” refer to Anchiano Therapeutics Ltd. an Israeli company and its consolidated subsidiaries;
- references to “ordinary shares,” “our shares” and similar expressions refer to the Company’s ordinary shares, no nominal (par) value;
- references to “ADS” refer to the American Depositary Shares listed on the Nasdaq Capital Market (“Nasdaq”) under the symbol “ANCN,” each representing five ordinary shares of the Company;
- references to “dollars,” “U.S. dollars” and “\$” are to U.S. Dollars;
- references to “NIS” are to New Israeli Shekels; and
- references to the “SEC” are to the U.S. Securities and Exchange Commission.

PART I. – FINANCIAL INFORMATION

Item 1. Financial Statements

**ANCHIANO THERAPEUTICS LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, in thousands, except share and per share data)**

	<u>March 31, 2020</u>	<u>December 31, 2019</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,009	\$ 17,575
Restricted cash	126	-
Prepaid expenses and other	542	636
Total current assets	<u>14,677</u>	<u>18,211</u>
Property and equipment, net	121	158
Operating lease right-of-use	339	1,199
Other non-current assets	46	187
Total assets	<u>\$ 15,183</u>	<u>\$ 19,755</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Trade payables	\$ 602	\$ 875
Accrued expenses and other	2,681	2,855
Operating lease liability	188	391
Total current liabilities	<u>3,471</u>	<u>4,121</u>
Non-current operating lease liability	152	725
Total liabilities	<u>3,623</u>	<u>4,846</u>
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares, no par value - authorized 100,000,000 shares as of March 31, 2020 and December 31, 2019; issued and outstanding 37,099,352 shares at March 31, 2020 and December 31, 2019	-	-
Paid-in capital	119,654	119,468
Currency translation differences reserve	872	872
Accumulated deficit	(108,966)	(105,431)
Total shareholders' equity	<u>11,560</u>	<u>14,909</u>
Total liabilities and shareholders' equity	<u>\$ 15,183</u>	<u>\$ 19,755</u>

See accompanying notes to unaudited condensed consolidated financial statements

ANCHIANO THERAPEUTICS LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited, in thousands, except share and per share data)

	Three months ended March 31,	
	2020	2019
Operating expenses:		
Research and development	\$ 1,050	\$ 4,135
General and administrative	1,825	1,291
Restructuring expense	670	-
Total operating expenses	<u>3,545</u>	<u>5,426</u>
Finance (income) expense, net	<u>(10)</u>	<u>4,487</u>
Net loss and comprehensive loss	<u>\$ (3,535)</u>	<u>\$ (9,913)</u>
Basic and diluted loss per share	<u>\$ (0.10)</u>	<u>\$ (0.38)</u>
Weighted average number of shares outstanding - basic and diluted	<u>37,099,352</u>	<u>26,337,517</u>

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

ANCHIANO THERAPEUTICS LTD.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(Unaudited, in thousands, except share data)

	<u>Ordinary shares</u>		<u>Paid-in capital</u>	<u>Currency translation differences reserve</u>	<u>Accumulated deficit</u>	<u>Total</u>
	<u>Number of shares</u>	<u>Amounts (*)</u>				
Balance at January 1, 2020	37,099,352	\$ -	\$ 119,468	\$ 872	\$ (105,431)	\$ 14,909
Share-based compensation	-	-	186	-	-	186
Net loss	-	-	-	-	(3,535)	(3,535)
Balance at March 31, 2020	<u>37,099,352</u>	<u>\$ -</u>	<u>\$ 119,654</u>	<u>\$ 872</u>	<u>\$ (108,966)</u>	<u>\$ 11,560</u>
Balance at January 1, 2019	15,575,682	\$ -	\$ 87,240	\$ 872	\$ (78,307)	\$ 9,805
Issuance of shares, net	21,523,670	-	26,500	-	-	26,500
Reclassification of warrants due to reassessment	-	-	(3,628)	-	-	(3,628)
Reclassification of warrants due to modification	-	-	8,198	-	-	8,198
Share-based compensation	-	-	380	-	-	380
Net loss	-	-	-	-	(9,913)	(9,913)
Balance at March 31, 2019	<u>37,099,352</u>	<u>\$ -</u>	<u>\$ 118,690</u>	<u>\$ 872</u>	<u>\$ (88,220)</u>	<u>\$ 31,342</u>

(*) No par value

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

ANCHIANO THERAPEUTICS LTD.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	Three months ended March 31,	
	2020	2019
Operating activities:		
Net loss	\$ (3,535)	\$ (9,913)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Financing costs, net	-	4,565
Depreciation	71	21
Share-based payments	186	380
Write-off of right-of-use related to restructuring	84	-
Changes in operating asset and liabilities:		
Prepaid and other current	94	1,498
Other non-current assets	11	(157)
Trade payables	(273)	704
Accrued expenses and other	(174)	(220)
Net cash used in operating activities	<u>(3,536)</u>	<u>(3,122)</u>
Investing activities:		
Purchase of property and equipment	(34)	(75)
Net cash used in investing activities	<u>(34)</u>	<u>(75)</u>
Financing activities:		
Proceeds from issuance of ordinary shares and warrants	-	30,500
Issuance costs	-	(2,681)
Net cash provided by financing activities	<u>-</u>	<u>27,819</u>
Increase (decrease) in cash, cash equivalents and restricted cash	(3,570)	24,622
Cash, cash equivalents and restricted cash at, beginning of period	17,705	7,640
Cash, cash equivalents and restricted cash at, end of period	<u>\$ 14,135</u>	<u>\$ 32,262</u>
Reconciliation in amounts on consolidated balance sheets:		
Cash and cash equivalents	\$ 14,009	\$ 32,132
Restricted cash	126	130
Total cash, cash equivalents and restricted cash	<u>\$ 14,135</u>	<u>\$ 32,262</u>
Supplemental disclosure of cash flow information:		
Reclassification of warrants due to reassessment	\$ -	\$ 3,628
Reclassification of warrants due to modification	\$ -	\$ 8,198
Taxes paid in cash	\$ -	\$ 244
Interest paid in cash	\$ -	\$ 22

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

Anchiano Therapeutics Ltd.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. The Company and Basis of Presentation

Anchiano Therapeutics Ltd. is an early-stage preclinical biopharmaceutical company committed to discovering and developing new cancer therapies designed to target the products of mutated genes that are drivers of human malignancies. The Company is developing small-molecule pan-mutant RAS inhibitors and inhibitors of PDE10 and the β -catenin pathway.

In November 2019, the Company discontinued clinical development of inodiftagene vixteplasmid. After a thorough evaluation of the available data, the Company determined there was a low probability of surpassing the pre-defined futility threshold at the planned interim analysis of its Phase 2 Codex study, which was evaluating inodiftagene vixteplasmid in patients with BCG-unresponsive non-muscle-invasive bladder cancer ("NMIBC"), and announced the discontinuation of the study.

In January 2020, the Board of Directors of the Company approved management's recommendation to close the Company's office and laboratories located in Israel. Following the closure of the Israeli facilities, the Company's sole remaining office will be located in Cambridge, Massachusetts (for details, see Note 4 below). During the last two years, there has been a significant increase in the Company's activities in the United States, resulting from the Company's management's strategic decision to shift its development, financing and ongoing operations from Israel to the United States.

The Company is incorporated and registered in Israel. The Company's American Depositary Shares ("ADSs"), each representing five ordinary shares of the Company with no par value (the "ordinary shares"), began trading on the Nasdaq Capital Market ("Nasdaq") in February 2019 under the symbol "ANCN". The Company's ordinary shares traded on the Tel Aviv Stock Exchange ("TASE") between August 2006 and June 2019, at which time the Company voluntarily delisted from the TASE. The Company wholly owns a subsidiary, Anchiano Therapeutics Israel Ltd., which itself wholly owns a Delaware-incorporated subsidiary, Anchiano Therapeutics, Inc.

Liquidity

The condensed consolidated 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. As shown in the accompanying consolidated financial statements, the Company has incurred losses and cash flow deficits from operations since inception, resulting in an accumulated deficit at March 31, 2020 of \$109.0 million. The Company has financed operations to date primarily through public and private placements of equity securities. The Company anticipates that it will continue to incur net losses for the foreseeable future. The Company believes that its existing cash and cash equivalents will only be sufficient to fund its projected cash needs until the first quarter of 2021. Accordingly, these factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. To meet future capital needs, the Company would need to raise additional capital through equity or debt financing or other strategic transactions. However, any such financing may not be on favorable terms or may not be available to the Company on any terms. The failure of the Company to obtain sufficient funds on commercially-acceptable terms when needed, would have a material adverse effect on the Company's business, results of operations and financial condition. The forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of the Company's expenses could vary materially and adversely as a result of a number of factors. The Company has based its estimates on assumptions that may prove to be wrong, and the Company's expenses could prove to be significantly higher than it currently anticipates. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Unaudited Interim Financial Information

The interim condensed consolidated financial statements included in this quarterly report are unaudited. The unaudited interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and applicable rules and regulations of the SEC regarding interim financial reporting and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for a fair statement of the Company's financial position as of March 31, 2020, and its results of operations for the three months ended March 31, 2020 and 2019, changes in shareholders' equity for the three months ended March 31, 2020 and 2019, and cash flows for the three months ended March 31, 2020 and 2019. The results of operations for the three months ended March 31, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020 or for any other future annual or

interim period. The December 31, 2019 balance sheet was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. These financial statements should be read in conjunction with the audited financial statements included in the Company's Form 10-K for the year ended December 31, 2019 as filed with the SEC. The Company's significant accounting policies are disclosed in the audited financial statements for the year ended December 31, 2019 included in the Company's Form 10-K. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies.

2. Summary of Significant Accounting Policies

a. Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. The Company evaluates its assumptions on an ongoing basis, including those related to share-based compensation, leases and derivatives. The Company's management believes that the estimates, judgment and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting periods. Actual results could differ from those estimates.

b. Reclassifications

Certain prior year amounts shown in the accompanying unaudited condensed consolidated financial statements have been reclassified to conform to the 2020 presentation. These reclassifications did not have any effect on total current assets, total assets, total current liabilities, total liabilities, total shareholders' equity, net loss, or loss per share.

c. Recent Accounting Pronouncements

Recent accounting pronouncements, other than below, issued by the FASB (including its Emerging Issues Task Force), the AICPA and the SEC did not or are not believed by management to have a material effect on the Company's present or future financial statements.

In December 2019, the FASB issued "ASU 2019-12, Simplifying the Accounting for Income Taxes." The objective of the standard is to improve areas of GAAP by removing certain exceptions permitted by ASC 740 and clarifying existing guidance to facilitate consistent application. The standard will become effective for us beginning on January 1, 2021. The Company is currently evaluating the new standard to determine the potential impact on its financial condition, results of operations, cash flows, and financial statement disclosures.

3. Accrued expenses and other

Accrued and other current liabilities consist of the following for the periods indicated (in thousands):

	March 31, 2020	December 31, 2019
Accrued expenses	\$ 935	\$ 372
Restructuring accrual	1,322	2,161
Payroll and related	170	60
Liability for employee rights upon retirement	254	262
	<u>\$ 2,681</u>	<u>\$ 2,855</u>

4. Leases

In January 2018, the Company signed an agreement to rent a laboratory and offices in Jerusalem through May 2023. The Company had an option to extend the agreement by another five years. The annual rent (including management fees) is approximately \$0.4 million and is linked to the Israeli Consumer Price Index. Pursuant to the agreement, bank guarantees of \$0.1 million were provided to the property owner. In January 2020, pursuant to the Company's decision to close its Israeli operations, the agreement was modified such that the Company will vacate the facilities on May 31, 2020 but will continue to make scheduled lease payments through October 31, 2020. The Company recorded restructuring expense of \$247,000 related to the modification of the Israeli lease agreement and other closure activities.

In May 2018, the Company signed an agreement to rent space for its headquarter offices in Cambridge, Massachusetts. This agreement was amended in October 2019 to reflect relocating to a new 2,400 square foot suite within the same facility effective February 1, 2020. The annual rent is approximately \$0.2 million. The amended lease term ends January 31, 2022 and there are no options to extend the lease.

5. License Agreement

In September 2019, the Company announced that it entered into an option to license agreement with ADT Pharmaceuticals, LLC ("ADT"). Pursuant to the terms and conditions set forth in the agreement, the parties agreed to conduct research and development activities of novel small-molecule inhibitors (RAS and PDE10/β-catenin). As part of the arrangement, the Company is primarily responsible for the research, development, manufacturing and regulatory activities and ADT assists with the research activities as necessary in exchange for a quarterly fee from the Company. In connection with the agreement, ADT also granted the Company exclusive rights to research, develop, manufacture and commercialize the aforementioned compounds relating to patents owned by ADT and any products containing such compounds worldwide. In consideration for the rights granted under the agreement, the Company committed to pay ADT (i) a \$3 million upfront fee; (ii) a fee upon transfer of the know-how and intellectual property rights to the Company; and then (iii) additional payments, including milestone and royalty payments. The Company has the ability to terminate the agreement at any time in its entirety or on a compound-by-compound basis after providing 90 days written notice to ADT. The upfront payment was paid in the third quarter of 2019. The Company accounted for the upfront fee and additional payments as research and development expense.

6. Restructuring

Restructuring provisions are recognized for the direct expenditures arising from restructuring initiatives, where the plans are sufficiently detailed and where appropriate communication has been made to those affected.

The Company has recorded restructuring expenses related principally to contract termination costs due to the discontinuation of the clinical trials to CROs and manufacturers and contractual involuntary termination benefits to employees which have been accounted for as ongoing benefit arrangements and associated termination costs related to the reduction of its workforce.

One-time termination benefits are expensed at the date the employees are notified, unless the employees must provide future services beyond a minimum retention period, in which case the benefits are expensed ratably over the future service periods. A provision for contract termination costs, in which a contract is terminated or the entity will continue to incur costs pursuant to contract for its remaining term without economic benefit, is recognized only when the contract is terminated or when the entity permanently ceases using the rights granted under the contract.

In November 2019, the Company decided to discontinue its Phase 2 Codex study in patients with BCG-unresponsive NMIBC. In connection with this decision, the Company is required to make certain payments under contracts with CROs and with manufactures of the drug in order to terminate the contracts and close the trials. This restructuring plan included a reduction in the workforce of seven employees.

In January 2020, the Board of Directors approved management's recommendation to close the Company's office and laboratories located in Israel. In connection with this restructuring, the employment of the remaining five Israeli employees will be terminated in the second quarter of 2020.

As noted above, in conjunction with this decision the Company renegotiated its lease for Israeli laboratory and office space. In connection with this decision, the Company expects to vacate the facilities on May 30, 2020 but continue to make scheduled lease payments through October 31, 2020. In the first quarter of 2020, the Company recorded a restructuring charge to adjust its operating lease right of use asset and operating lease liability to reflect the loss on the early termination of the Israeli lease obligation.

The following table represents a roll forward of the restructuring and other activities noted above (in thousands):

	CRO, Manufacturing and other related	Severance- related	Facility and Leases	Total
Balance, January 1, 2020	\$ 2,572	\$ 336	\$ -	\$ 2,908
Expenses	423	-	247	670
Paid or consumed	(1,881)	(69)	(216)	(2,166)
Balance, March 31, 2020	<u>\$ 1,114</u>	<u>\$ 267</u>	<u>\$ 31</u>	<u>\$ 1,412</u>

Outstanding liabilities for restructuring related activities at March 31, 2020 included in trade payables and accrued expenses and other were \$90,000 and \$1,322,000, respectively.

7. Shareholders' Equity

a. 2018 Private Placement

In June 2018, the Company completed a \$22.9 million fundraising round from investors in the United States and Israel. In consideration for the investment, the Company issued 5,960,787 ordinary shares at a price per share of approximately \$3.842, as well as 2,713,159 warrants to acquire additional shares equal to 80% of the shares issued, at an exercise price per share of NIS 16.20 (approximately \$4.32). The warrants are exercisable for five years from December 31, 2018, the closing date of the transaction, and may be exercised on a cashless basis.

In addition, the investors were granted price protection rights (to shares and warrants) in the event of a future share issuance by the Company wherein the price does not increase by at least approximately 42.86% over the price per share in the fundraising (or is less than the adjusted price per share, if the price has already been adjusted). For details of an allocation that took place in 2019 pursuant to these rights, see Note 7b below. The warrants and shares were recorded within equity on the issuance date.

Effective January 1, 2019, the Company changed its functional currency from NIS to USD. Due to this change, the exercise price of the warrants was no longer denominated in the Company's functional currency and therefore not considered indexed to the Company's own stock according to ASC 815-40. Accordingly, the Company recorded the fair value of the warrants as a liability at January 1, 2019.

Subsequently, upon the Company's Nasdaq initial public offering on February 14, 2019, the warrants' term was modified such that the exercise price currency was changed to USD. As a result, the warrants were once again considered indexed to the Company's own stock according to ASC 815-40. Accordingly, the fair value of the warrants at February 14, 2019 was reclassified from a liability to equity on that date.

The following table summarizes the activity for the warrants whose fair value measurements are estimated utilizing Level 3 inputs (in thousands):

	2019
Fair value on January 1, 2019	\$ 3,628
Adjustments-finance expenses	4,570
Fair value on February 14, 2019	<u>\$ 8,198</u>

The Company has determined the fair value of the warrants (a Level 3 valuation) as of January 1, 2019 and February 14, 2019. The fair value of these warrants was estimated by implementing the Probability-Weighted Expected Return Method or the Black-Scholes Method. The following parameters were used:

	Derivative Financial Instrument	
	February 14, 2019	January 1, 2019
Stock price	\$1.84	\$2.50
Expected term	End of 2022	End of 2022
Risk free rate	2.49%	1.37%
Volatility	52%	48%

b. Public Offering

On February 14, 2019, the Company raised gross proceeds of \$30.5 million in its Nasdaq initial public offering (“IPO”), allocating 2,652,174 ADSs, each representing five ordinary shares of the Company. The ADSs are listed under the symbol “ANCN.” In accordance with price protection rights granted in 2018 and activated in the offering (see Note 7a above for details and accounting treatment), the Company issued an additional 8,262,800 ordinary shares (equivalent to 1,652,560 ADSs) to rights holders and adjusted their warrants to be exercisable for an additional 6,207,330 ordinary shares (equivalent to 1,241,466 ADSs).

c. Share-based compensation

The Company has two share-based compensation plans under which share options or other share-based awards have been granted: the 2011 Share Option Plan and the 2017 Share Option Plan (the “2017 Plan”). The 2017 Plan replaced the 2011 Share Option Plan with respect to future grants; and, therefore, no further awards may be made under 2011 Share Option Plan. The Compensation Committee of the Board of Directors and the Board of Directors administer these plans.

The fair value of each option granted is estimated using the Black-Scholes option pricing method. The volatility is based on the Company’s historical volatility. The risk-free interest rate assumption is based on observed Treasury yields over the expected term of the options granted with USD-denominated exercise prices (options granted in the past with NIS-denominated exercise prices used the equivalent Israeli government bond yields). The Company’s management uses the mid-point between the vesting date and the contractual term for each vesting tranche or its expectations, as applicable, of each option as its expected term. The expected term of the options granted represents the period of time that granted options are expected to remain outstanding

The fair value of each option granted in the three months ended March 31, 2019 was estimated on the grant date using the Black-Scholes option pricing model with the following assumptions:

	Three months ended March 31, 2019
Value of ordinary share	\$1.54
Dividend yield	0%
Expected volatility	52.3% - 68.6%
Risk-free interest rate	2.4% - 2.5%
Expected term (years)	5.5 - 6.9

The were no grants of stock options in the three months ended March 31, 2020.

The following table summarizes the number of options outstanding and exercisable as of March 31, 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years
Options outstanding - January 1, 2020	3,822,374	\$ 2.50	8.5
Forfeited/expired/cancelled	(120,106)		
Options outstanding - March 31, 2020	<u>3,702,268</u>	\$ 2.52	8.3
Options exercisable - March 31, 2020	<u>1,893,715</u>		

The aggregate intrinsic value of both outstanding and exercisable options at March 31, 2020 is \$0.

The following table illustrates the effect of share-based compensation on the statements of operations (in thousands):

	Three months ended March 31,	
	2020	2019
Research and development	\$ 73	\$ 142
General and administrative	113	238
	<u>\$ 186</u>	<u>\$ 380</u>

8. Net Loss per share

Basic loss per share is computed on the basis of the net loss for the period divided by the weighted-average number of ordinary shares outstanding during the period. Diluted loss per share is based upon the weighted-average number of ordinary shares and of ordinary shares equivalents outstanding when dilutive. Ordinary share equivalents include outstanding stock options which are included under the treasury stock method when dilutive.

The following ordinary shares underlying stock options and warrants were excluded from the calculation of diluted net loss per ordinary share, because their effect would have been anti-dilutive for the years presented:

	Three months ended March 31,	
	2020	2019
Stock Options	3,702,268	2,405,642
Warrants	10,975,959	10,975,959

9. Subsequent events

COVID-19 Outbreak

In March 2020 the World Health Organization declared the global novel coronavirus (COVID-19) outbreak a pandemic. As of May 7, 2020, the Company's operations have not been significantly impacted by the COVID-19 outbreak. However, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on its financial condition and operations, including ongoing and planned pre-clinical development activities.

Share Capital

On April 23, 2020, in connection with the Annual General Meeting of Shareholders, the shareholders of the Company agreed to increase the authorized share capital from 100,000,000 ordinary shares to 500,000,000 ordinary shares.

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 our consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis, particularly with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read "Risk Factors" in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2019 as filed with the SEC for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a preclinical biotechnology company committed to discovering and developing new cancer therapies designed to target the products of mutated genes that are drivers of human malignancies. Throughout most of 2019, we ran a Phase 2 study, designated Codex, evaluating inodiftagene vixtepasmid in patients with BCG-unresponsive NMIBC. However, in November 2019, after a thorough evaluation of data, we determined there was a low probability of surpassing the pre-defined futility threshold at the planned interim analysis of the study, and announced the discontinuation of the study and of active clinical development of inodiftagene vixtepasmid.

We acquired the rights to two developmental programs targeting oncogenic pathways (small-molecule pan-mutant RAS inhibitors and inhibitors of PDE10 and the β -catenin pathway) pursuant to the Collaboration and License Agreement (the "License Agreement") into which we entered with ADT Pharmaceuticals, LLV ("ADT") on September 20, 2019. Our operations are focused on the successful development, regulatory approval and commercialization of products derived from the compounds conveyed and contemplated under the License Agreement, which are in the research stage. Under the agreement, we are primarily responsible for the research, development, manufacturing, regulatory and commercial activities with respect to the Compounds.

Our corporate structure consists of a parent company, Anchiano Therapeutics Ltd., incorporated in Israel, which wholly owns a subsidiary, Anchiano Therapeutics Israel Ltd, incorporated in Israel, which itself wholly owns a subsidiary, Anchiano Therapeutics, Inc. incorporated in Delaware. We currently maintain offices in Cambridge, MA and an office and laboratory in Jerusalem, Israel. However, in January 2020 our Board of Directors approved management's recommendation to close our Israeli office and laboratories in 2020, with our operations to continue from our Cambridge office. The closure is expected to be completed in the second quarter of 2020.

License Agreement

In September 2019, we publicly announced that we had entered into an option to license agreement with ADT. Pursuant to the terms and conditions set forth in the agreement, we have mutually agreed to use commercially reasonable efforts to conduct research and development activities of novel small-molecule inhibitors (RAS and PDE10/ β -catenin). As part of the arrangement, we will be primarily responsible for the research, development, manufacturing and regulatory activities and ADT will assist with the research activities as necessary in exchange for a quarterly fee. In connection with the agreement, ADT also granted us exclusive rights to research, develop, manufacture and commercialize the aforementioned compounds relating to patents owned by ADT and any products containing such compounds worldwide. In consideration for the rights granted under the agreement, we paid ADT a \$3 million upfront fee, and agreed to pay (i) a fee upon transfer of the know-how and intellectual property rights to us; and (ii) additional payments, including milestone and royalty payments. We have the ability to terminate the agreement at any time in its entirety or on a compound-by-compound basis after providing 90 days written notice to ADT. The upfront fee was paid in 2019. Since there is no alternative future use for the upfront fee, we accounted for it as a research and development expense.

Components of Operating Results

Revenues

To date, we have not generated any revenue. We do not expect to receive any revenue unless and until we obtain regulatory approval and commercialize a future product candidate, or until we receive revenue from a collaboration such as a co-development or out-licensing agreement. There can be no assurance that we will receive such regulatory approvals, and if a future product candidate is approved, that we will be successful in commercializing it.

Research and Development Expenses

Research and development activities are our primary focus. Due to the inherently unpredictable nature of preclinical and clinical development, we are unable to estimate with certainty the costs we will incur and the timelines that will be required in the continued development and approval of our product candidates. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, if and when such arrangements will be entered into, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We expect our research and development expenses to increase over the next several years as our development programs progress and as we seek to initiate clinical trials. We also expect to incur increased research and development expenses as we selectively identify and develop additional product candidates.

Research and development expenses include the following:

- employee-related expenses, such as salaries and share-based compensation;
- expenses relating to outsourced and contracted services, such as CROs, external laboratories and consulting, research and advisory services;
- supply, development and manufacturing costs relating to clinical trial materials;
- preclinical study expenses and related developmental costs; and
- costs associated with regulatory compliance.

We recognize research and development expenses as we incur them.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, including share-based compensation related to directors and employees, facility costs, patent application and maintenance expenses, and external professional service costs, including legal, accounting, audit, finance, business development, investor relations and human resource services, and other consulting fees.

Finance (Income) Expense, Net

Finance (Income) expense, net, consisted primarily of finance expenses recorded due to revaluation of investor warrants at fair value during a period where these could not be classified within equity (for more details, see Note 7a in “Item 1. Financial Statements Unaudited” above), offset by interest income received on the Company’s cash and cash equivalents and foreign currency exchange gains and losses.

Restructuring Expense

We have recognized restructuring provisions for the direct expenditures arising from restructuring initiatives, where the plans are sufficiently detailed and where appropriate communication to those affected has been made. To this end, we have recorded restructuring expenses comprised principally of contract termination costs, employee severance and associated termination costs related to the reduction of our workforce and costs associated with the early termination of facility leases.

One-time termination benefits are expensed at the date the employees are notified, unless the employees must provide future services beyond a minimum retention period, in which case the benefits are expensed ratably over the future service periods. A provision for contract termination costs, in which a contract is terminated or the entity will continue to incur costs under a contract for its remaining term without economic benefit (an onerous contract), is recognized only when the contract is terminated or when the entity permanently ceases using the rights granted under the contract.

Results of Operations

Below is a summary of our results of operations for the periods indicated:

	Three months ended		Increase/(decrease)	
	March 31,		\$	%
	2020	2019		
	<i>(in thousands)</i>			
Operating expenses:				
Research and development	\$ 1,050	\$ 4,135	\$ (3,085)	-75%
General and administrative	1,825	1,291	534	41%
Restructuring expense	670	-	670	-
Operating loss	<u>(3,545)</u>	<u>(5,426)</u>	<u>(1,881)</u>	<u>35%</u>
Financing (income) expense, net	(10)	4,487	(4,497)	-100%
Net loss	<u>\$ (3,535)</u>	<u>\$ (9,913)</u>	<u>\$ (6,378)</u>	<u>64%</u>

Our results of operations have varied in the past and can be expected to vary in the future due to numerous factors. We believe that period-to-period comparisons of our operating results are not necessarily meaningful and should not be relied upon as indications of future performance.

Three Months Ended March 31, 2020 Compared to the Three Months Ended March 31, 2019

Research and development expenses

Research and development expense decreased by approximately \$3.0 million, or 73%, in the three months ended March 31, 2020 from the comparable period of 2019. The decrease is primarily due to reductions in third-party clinical trial and manufacturing costs of approximately \$2.8 million associated with the Phase 2 Codex clinical trial which was discontinued in November 2019, partially offset by third-party development costs of \$0.3 million incurred in 2020 associated with the RAS program acquired in September 2019.

General and administrative expenses

General and administrative costs increased by approximately \$0.5 million, or 42%, in the three months ended March 31, 2020 from the comparable period of 2019. The increase is primarily due to increased personnel costs, insurance costs and professional fees associated with establishing an infrastructure to support a U.S. publicly traded company.

Restructuring expense

In November 2019, we decided to discontinue our Phase 2 Codex study in patients with BCG-unresponsive NMIBC. In connection with this decision, we are required to make certain payments under contracts with CROs and with other manufacturers of the drug in order to terminate the contracts and close the trials. Moreover, the restructuring plan included a reduction in the workforce of seven employees.

Separately, in January 2020 our board of directors approved management's recommendation to close our office and laboratories located in Israel. The closure resulted in the termination of employment of the Company's remaining five Israeli employees.

Restructuring expenses incurred during the first quarter of 2020 were comprised principally of contract termination costs, employee severance and associated termination costs related to the reduction of our workforce, and costs associated with the early termination of our lease facility.

Financing (income) expense, net

Financing (income) expense, net decreased by approximately \$4.5 million.

For the three months ended March 31, 2020, finance expense was primarily interest income and foreign currency exchange rate gains.

For the three months ended March 31, 2019, finance expense of \$4.5 million was primarily related to the revaluation of investor warrants at fair value during a period where these could not be classified within shareholders' equity, due to the following circumstances:

On initial measurement, the warrants together with their price protections were classified as equity instruments that are not subsequently measured at fair value, and thus we allocated the proceeds according to the relative fair value of the instruments. However, we changed our functional currency from NIS to USD as of January 1, 2019. Due to this change from this date, the exercise price of the warrants was no longer denominated in our functional currency and the warrants were therefore not considered indexed to our own stock according to ASC 815-40 and no longer met all the criteria to be classified within equity. Therefore, the warrants were reclassified as a liability at their fair value as of January 1, 2019, and any difference was accounted for as an adjustment to equity. Upon our Nasdaq initial public offering of February 14, 2019, the warrants' exercise price currency was changed to USD. As a result, the warrants were reclassified within equity. Consequently, the warrants were measured at fair value from January 1, 2019 until February 14, 2019, with resulting finance expenses of \$4.6 million, until they were reclassified within equity.

Cash Flows

The table below shows a summary of our cash flow activities for the periods indicated:

	Three months ended		Increase/(decrease)	
	March 31,		\$	%
	2020	2019		
	<i>(in thousands)</i>			
Net cash used in operating activities	\$ (3,536)	\$ (3,122)	\$ 414	13%
Net cash used in investing activities	(34)	(75)	(41)	-55%
Net cash provided by financing activities	-	27,819	(27,819)	-100%
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ (3,570)	\$ 24,622	\$ (28,192)	-114%

Operating activities

Net cash used in operating activities increased by \$0.4 million, or 14%, for the three months ended March 31, 2020 compared to the same period of 2019. Net loss adjusted for non-cash activities was \$3.2 million for the three months ended March 31, 2020 compared to \$4.9 million resulting in favorable cash flow of \$1.7 million. This was more than offset by unfavorable changes in working capital of approximately \$2.2 million.

Investing activities

Investing activities in the three months ended March 31, 2020 and 2019 are purchases of fixed assets.

Financing activities

Financing activities in the three months ended March 31, 2019 reflect the net proceeds from the Company's IPO on February 14, 2019. There were no financing activities in the three months ended March 31, 2020.

Contractual Commitments

The Company's contractual commitments are as follows at March 31, 2020 (in thousands):

Remainder of 2020	\$	164
2021		189
2022		16
Total	\$	<u>369</u>

Effects of Currency Fluctuation

Currency fluctuations could affect us through increased or decreased costs, mainly for goods and services acquired outside of the United States. Currency fluctuations have not had a material effect on our results of operations during the three months ended March 31, 2020 or 2019.

Off-Balance Sheet Arrangements

We have not entered into any transactions with unconsolidated entities as to which we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that would expose us to material continuing risks, contingent liabilities or any other obligation under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

Critical Accounting Policies

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. GAAP. Comparative figures, which were previously presented and publicly reported in accordance with IFRS as issued by the International Accounting Standards Board, have been adjusted as necessary to be compliant with our policies under U.S. GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail throughout this section. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

For a discussion of our critical accounting policies, please read Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our 2019 Form 10-K. There have been no material changes to these critical accounting policies since our 2019 Form 10-K.

Recently-Issued Accounting Pronouncements

Certain recently-issued accounting pronouncements are discussed in Note 2, Summary of Significant Accounting Policies, to the unaudited condensed consolidated financial statements included in "Item 1. Financial Statements Unaudited"

Liquidity and Capital Resources

The condensed consolidated 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. As shown in the accompanying consolidated financial statements, the Company has incurred losses and cash flow deficits from operations since inception, resulting in an accumulated deficit at March 31, 2020 of \$109.0 million. The Company has financed operations to date primarily through public and private placements of equity securities. The Company anticipates that it will continue to incur net losses for the foreseeable future. The Company believes that its existing cash and cash equivalents will only be sufficient to fund its projected cash needs until the first

quarter of 2021. Accordingly, these factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. To meet future capital needs, the Company would need to raise additional capital through equity or debt financing or other strategic transactions. However, any such financing may not be on favorable terms or even available to the Company. The failure of the Company to obtain sufficient funds on commercially-acceptable terms when needed, would have a material adverse effect on the Company's business, results of operations and financial condition. The forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of the Company's expenses could vary materially and adversely as a result of a number of factors. The Company has based its estimates on assumptions that may prove to be wrong, and the Company's expenses could prove to be significantly higher than it currently anticipates.

In April, as previously disclosed, the Company received a deficiency letter from the Nasdaq Stock Market regarding noncompliance with certain minimum bid price requirements. The Company will work to formulate a plan to regain compliance within the required time periods. An inability to regain compliance during the applicable time periods, and any subsequent extension periods, if any, would have a material adverse effect.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are an emerging growth company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and are not required to provide the information under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures as of March 31, 2020, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, 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 our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition or cash flows.

Item 1A. Risk Factors

As a smaller reporting company (as defined in Rule 12b-2 of the Exchange Act), we are not required to provide the information called for by this Item 1A.

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

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth below.

Exhibit Number	Description	Form	File No	Incorporate	Exhibit No.	Filed Herewith
				by Date of Filing		
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.					<input checked="" type="checkbox"/>
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.					<input checked="" type="checkbox"/>
32.1(1)	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					<input checked="" type="checkbox"/>
32.2(1)	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					<input checked="" type="checkbox"/>
101.INS	XBRL Instance Document					<input checked="" type="checkbox"/>
101.SCH	Inline XBRL Taxonomy Extension Schema Document					<input checked="" type="checkbox"/>
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					<input checked="" type="checkbox"/>
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					<input checked="" type="checkbox"/>
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					<input checked="" type="checkbox"/>
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					<input checked="" type="checkbox"/>

(1) The certifications on Exhibit 32 hereto are deemed not “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: May 7, 2020

ANCHIANO THERAPEUTICS LTD.

By: /s/ /Dr. Frank Haluska.

Dr. Frank Haluska.

Chief Executive Officer

(Principal Executive Officer)

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: May 7, 2020

ANCHIANO THERAPEUTICS LTD.

By: /s/ Stephen DiPalma

Stephen DiPalma

Chief Financial Officer

*(Principal Accounting Officer and Principal Financial Officer
and duly Authorized Signatory)*