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

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

For the fiscal year ended December 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

001-38807
(Commission file number)

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 1400E** **Suite 14-105** **Cambridge, MA** **(Address of principal executive offices)**	**02139** **(Zip Code)**

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

Securities registered pursuant to Section 12(b) of the 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.

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 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 has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐ No ☒

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

The aggregate market value of ordinary shares held by non-affiliates of the registrant on the last business day of the registrant’s most recently completed second fiscal quarter was $16,607,978.24, based on the closing sale price of the registrant’s American Depositary Shares as reported on the Nasdaq Capital Market on June 28, 2019.

As of February 18, 2021, the registrant had 37,099,352 ordinary shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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PART I

In this Annual Report on Form 10-K, unless the context otherwise requires:

- references to "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 per share;
- references to "ADSs" 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 United States Dollars;
- references to "NIS" are to New Israeli Shekels;
- references to the "Companies Law" are to Israel's Companies Law, 5759-1999, as amended; and
- references to the "SEC" are to the U.S. Securities and Exchange Commission.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

The statements set forth under the captions "Business," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors," and other statements included elsewhere in this Annual Report on Form 10-K, which are not historical, constitute "forward-looking statements" within the meanings of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including statements regarding expectations, beliefs, intentions or strategies for the future. 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.

Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to:

- the results of the strategic review that our board of directors initiated;
- the composition of our board of directors;
- the initiation, timing, progress and results of our preclinical studies and other therapeutic candidate development efforts;
- our ability to develop and advance a future therapeutic candidate into clinical trial or to successfully complete our preclinical studies;
- our receipt of regulatory approvals for a future therapeutic candidate, and the timing of other regulatory filings and approvals;
- the clinical development, commercialization and market acceptance of a future therapeutic candidate;

- our ability to establish and maintain corporate collaborations and integrate new therapeutic candidates and new personnel;
- the interpretation of the properties and characteristics of a future therapeutic candidates;
- the implementation of our business model and strategic plans for our business and future therapeutic candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering future therapeutic candidates and our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- risks relating to our ability to finance our activities and research programs;
- our dependence on performance by third-party providers of services and supplies, including without limitation, clinical research organizations;
- the inherent risks and uncertainties in developing the types of preclinical products we are attempting to develop;
- competitive companies, technologies and our industry;
- risks related to our ability to maintain compliance with the continued listing standards of Nasdaq; and
- risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere.
- risks related to previous announced combination with Chemomab including with respect to the change of our business prospects, new product candidates, and clinical development plans following such combination.
- risks related to a failure to complete the previous announced combination with Chemomab, including our ability to support our operation with limited cash runway.

Item 1. Business

On December 14, 2020, we entered into an Agreement and Plan of Merger "(Merger Agreement") with Chemomab Ltd. ("Chemomab"), an Israeli limited company and a clinical-stage biotech company focusing on the discovery and development of innovative therapeutics for fibrosis-related diseases with high unmet need, which included the proposed business combination ("Merger") of CMB Acquisition Ltd., a wholly owned subsidiary of ours, with Chemomab as the surviving company, subject to shareholder approval. As a result, you should not place undue reliance on the plans discussed below relating to the pan-RAS and PDE10/ß-catenin programs as they are subject to change.

The merger is described in detail in a proxy statement / prospectus that we filed with the SEC on February 12, 2021 and that is available at this link: https://www.sec.gov/Archives/edgar/data/1534248/000110465921021553/tm211883-6_424b3.htm

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. These therapies are called small molecule targeted therapies. Our company has obtained the option to license small molecule technologies that we believe we can develop into product candidates that can deliver novel treatments for cancer patients whose cancers are caused by mutated genes and for whom existing therapies are limited in effectiveness. The first of these technologies comprises small molecules that potently inhibit the products of RAS oncogenes. RAS oncogenes are the most frequently mutated family of genes in human cancer, responsible for almost a third of all human malignancies, and almost half of the three most lethal cancers (*i.e*., lung cancer, colorectal cancer and pancreatic cancer). To date there are no approved therapies that are effective in countering their tumorigenic effects. Our second technology consists of small molecules that interfere with the Wnt/APC/β-catenin biochemical pathway through the inhibition of phosphodiesterase 10 ("PDE10"). Mutations in this pathway are involved in most human colorectal cancers, the second leading cause of cancer deaths in the United States, as well as in the hereditary cancer predisposition syndrome, familial adenomatous polyposis ("FAP"), which gives rise to colorectal cancer. As is true for RAS-driven cancers, to date there are no approved therapies specifically for cancers that carry mutations in the Wnt/APC/β-catenin pathway genes.

Previously we discovered and developed a gene therapy, inodiftagene vixteplasmid ("inodiftagene"), designed to treat early stage bladder cancer. We developed this gene therapy in six clinical trials in pancreatic cancer, ovarian cancer, and bladder cancer. Based on these preliminary clinical studies, we planned and initiated a clinical trial designed as the basis for potential regulatory approval of inodiftagene. This clinical trial, the Phase 2 Codex trial, was initiated in December 2018, enrolling patients through the following year. We terminated the program in November 2019 based on our assessment that the observed preliminary efficacy of inodiftagene in bladder cancer was insufficient to support regulatory approval.

In parallel to the now-terminated inodiftagene program, our corporate goals for 2019 called for the expansion of our pipeline, and we determined to move toward small molecule anti-cancer therapeutics. In September 2019, we entered into a collaboration and license agreement (the "Collaboration Agreement") with ADT Pharmaceuticals, LLC ("ADT") pursuant to which we agreed to use commercially reasonable efforts to conduct research and development activities with respect to the pan-RAS and PDE10/β-catenin programs under the oversight of a jointly established steering committee. In addition, ADT granted us an exclusive option to license its small molecule technologies. The Collaboration Agreement covers two proprietary classes of molecules: (1) inhibitors of RAS, and (2) inhibitors of the Wnt/APC/β-catenin pathway via PDE10. Pursuant to the Collaboration Agreement, we have an exclusive option to license the suite of intellectual property covering these molecules, with granted patents that extend to 2034.

We believe we will be able to develop these molecules into product candidates to provide new therapies for patients with cancers whose pathogenesis depends on mutant RAS oncogenes, or on mutations in the Wnt/APC/β-catenin pathway. Both of these genetic lesions cause enormous human suffering by reason of the cancers they cause. These genes are primarily responsible for lung, colorectal, and pancreatic cancers, the most common lethal cancers, among others. Mutations in one of the RAS genes are present in more than 30% of all human cancers, making these the most frequent oncogenic mutations in cancer. The Wnt/APC/β-catenin pathway genes are mutated in approximately 90% of colorectal cancers.

The impact of RAS and Wnt/APC/β-catenin mutations can be best understood by considering cancer incidence and death rates in the United States. According to the American Cancer Society, in 2020, it is expected that more than 1.8 million new cases of cancers will be diagnosed in the United States, and approximately 606,520 people in the United States are expected to die of cancer. More than 30% of these cancers have RAS mutations. The cancers with the highest estimated mortality rates in the United States for 2020 are lung cancer (approximately 136,000 deaths), colorectal cancer (approximately 53,000 deaths), and pancreatic cancer (approximately 47,000 deaths), which together are estimated to account for over 235,000 deaths in 2020 in the United States alone. These three cancer types are largely driven by mutant RAS. Globally, the epidemiologic profile is similar. The Wnt/APC/β-catenin pathway is similarly implicated in a large number of lethal cancers. Approximately 90% of colorectal cancers carry mutations in either the adenomatous polyposis coli ("APC") gene or in the CTNNB1 gene that encodes β-catenin. This translates into approximately 48,000 deaths due to colorectal cancer carrying Wnt/APC/β-catenin pathway mutations in the United States alone. Additionally, the involvement of the Wnt/APC/β-catenin pathway in the hereditary cancer syndrome FAP via mutations in the APC gene affects approximately 16,000 additional patients in the United States.

The RAS oncogenes are heavily implicated in the genesis of a broad spectrum of cancers as the most common oncogenic alterations known. There are three members of the RAS family of genes: KRAS, HRAS, and NRAS. Of the most frequently lethal cancer types, lung cancers (non-small cell lung cancers, "NSCLC") have mutations in one of the RAS family of genes in approximately 35% of cases; colorectal cancers carry RAS mutation in approximately 45% of cases; and pancreatic cancers carry RAS mutations in over 95% of cases. We estimate that the total addressable population of patients with RAS-mutation driven solid tumors alone is more than 165,000 patients per year in the US. This enormous toll of cancer morbidity and mortality suggests that therapies directed at tumors carrying mutated forms of RAS are urgently needed.

Treating cancers that carry mutated oncogenes by discovering and developing small molecule inhibitors of the mutated protein products of the oncogene is one of the most successful cancer treatment paradigms that exists. Approved small molecule targeted drugs include inhibitors of the oncogenic breakpoint cluster region-Abelson murine leukemia viral oncogene homolog 1 ("BCR-ABL") including imatinib, dasatinib, and ponatinib in leukemia; inhibitors of oncogenically mutated epidermal growth factor receptor ("EGFR") in NSCLC including erlotinib and osimertinib; inhibitors of mutated anaplastic leukemia kinase ("ALK") in NSCLC such as crizotinib and brigatinib; and many others. However, there are no approved inhibitors for mutated members of the RAS family of oncogenes. Until very recently, the unique biochemistry and biology of the RAS family had resisted efforts of cancer biologists to discover and develop drugs capable of inhibiting the activity of the mutated protein. However, in 2014 work by Shokat and others led to new approaches to the discovery of small molecules capable of inhibiting a particular mutated form of RAS, known as KRAS G12C. This designates a mutation in the KRAS member of the RAS family, in which an amino acid at position 12 is altered due to a mutation in the encoding gene. In 2019, this work led to the first demonstration in the clinic of anti-tumor response associated with treatment with KRAS G12C inhibitors under development by Amgen and Mirati Therapeutics. We believe the significance of these successes is field-altering, as for the first time there is evidence that inhibition of mutated RAS isoforms may be undertaken in the same manner as other successful small molecule targeted therapies had shown possible against other mutated oncogenes. In other words, RAS has become a clinically validated target. However, KRAS is only one of three mutated isoforms of the RAS family, and only approximately 11% of KRAS mutations are of the G12C type. This means that while these observations have proven that RAS-directed therapy using small molecule inhibitors is possible with clinical effect, results so far are confined to a small subset of patients carrying a particular mutation. That said, the values of the companies pursuing KRAS G12C inhibitors has grown by many billions of dollars during 2019.

Our lead focus is our pan-RAS program, which we believe is poised to take advantage both of the fact that RAS inhibition has been shown to be clinically valid, and initial successes by existing therapies have been confined to a fraction of tumors that carry RAS mutations. A broadly-acting pan-RAS inhibitor with the potential to treat RAS-driven cancers regardless of RAS isoform or mutation would be clinically useful. We believe our RAS-inhibitor molecules have potential for RAS inhibition in a broad variety of clinical settings.

The characteristics one would need in such inhibitors include: selectivity for activated RAS; potency against cells harboring mutant RAS; consistency of biochemical data with RAS inhibition (as opposed to other pathway points of inhibition); evidence for binding RAS directly; *in vivo* anti-tumor activity; and immunological stimulation *in vivo* consistent with other clinical RAS inhibitors.

Our small molecule inhibitors have been demonstrated to have these characteristics. Our lead RAS-inhibitor molecules are novel structures that share an indene core. These molecules potently inhibit growth of tumor cells harboring mutant RAS, while having greater than 100-fold selectivity over cells with normal RAS activity. Inhibitory activity has been observed with low nanomolar potency in KRAS-, HRAS-, and NRAS-driven tumor cell models with a variety of mutations across a variety of tumor types. This activity is observable in both monolayer cultures, and in 3-D spheroid cultures, which may have higher predictive value for anti-tumor activity. These compounds inhibit downstream signaling through RAF and PI3K pathways, which is consistent with their acting directly on RAS, as opposed to another pathway molecule. They initiate cell-cycle arrest and induce apoptosis, consistent with cell killing. Importantly, the inhibitors demonstrate blockade of GTP loading of RAS in the nucleotide-free state in cell-free biochemical assays, suggesting that their mechanism of action is through interference of GTP-mediated signaling. They have exhibited *in vivo* activity in RAS-mutant tumor models. Finally, an emerging characteristic of RAS inhibition is the stimulation of anti-tumor immunity. This has been shown with AMG 510, a KRAS G12C inhibitor presently in the clinic, and it suggests that effective RAS inhibition stimulates several anti-tumor immune mechanisms. Our inhibitors have been shown to similarly stimulate anti-tumor T-cell-mediated immune mechanisms, suggesting that their mechanism is indeed effected through RAS.

We have identified lead compounds with the desired biologic and biochemical characteristics with regard to effecting pan-RAS inhibition. We are undertaking additional structural studies and medicinal chemistry to identify a clinical lead compound. We anticipate that we will identify a clinical development lead compound in the next 12 to18 months, followed by 12 months of Investigational New Drug (“IND”) application-enabling studies. We believe this will allow us to initiate our first in human trial in 2022. Initial clinical studies will enroll patients with RAS mutations and advanced solid tumors. The clinical development of other targeted therapies in tumors with genetically defined driver mutations, including the development plans for the KRAS G12C inhibitors presently under investigation, suggests that there is a path to accelerated approval based on a single well-designed multi-center single-arm study. We would then pursue the expansion of indications to additional tumor types, earlier lines of therapy, and combination studies, with additional trials.

Our focus initially will be on the pan-RAS-inhibitor program. Our second program, the PDE10/β-catenin program, will proceed in collaboration with ADT. This program’s suite of small molecules selectively and potently inhibit PDE10 and suppress Wnt/APC/β-catenin signaling in preclinical models. PDE10 inhibition has been shown to downregulate β-catenin expression and inhibits polyp and tumor growth. We have identified molecules that are orally bioavailable, and, in our preliminary mouse models, have been shown to inhibit the development of intestinal polyposis and colon cancer, and the growth of pulmonary metastases. Initial plans for continued preclinical development of the PDE10/β-catenin program will be funded by ADT using Small Business Innovation Research (“SBIR”) grants to ADT.We believe we are positioned for the successful development of small molecule inhibitors. We believe that our pan-RAS and PDE10/β-catenin programs have substantial promise to lead to new development candidates with the potential to treat lethal tumors harboring RAS and Wnt/APC/β-catenin pathway mutations in the United States and globally.

In January 2020, our board of directors approved management’s recommendation to close our office and laboratories located in Israel. Following the closure of the Israeli facilities at the end of May 2020, our sole remaining office was located in Cambridge, Massachusetts. Under circumstances related our restructuring this office has not been in use for a large part of the year and our lease for this office in Cambridge, Massachusetts terminated on February 28, 2021. We are allowed, however, to continue using this address to receive mail.

On July 2, 2020, our Chief Executive Officer, Dr. Frank Haluska, sent a letter to the Chairman of our board of directors outlining Dr. Haluska’s belief that events had occurred that were sufficient to trigger his ability to resign for “Good Reason” under his employment agreement. Our board of directors informed Dr. Haluska that it disagreed with the letter’s assertions regarding “Good Reason” and treated the letter as a constructive resignation effective as of July 2, 2020. On July 12, 2020, Dr. Frank Haluska tendered his written resignation from our board of directors, effective immediately. Dr. Haluska referenced the matters articulated in his letter of July 2, 2020, and the Company’s response and actions following receipt of the letter as the basis for his resignation from the Board. It is our position, based on advice from our legal counsel, that Dr. Haluska resigned without Good Reason, is not entitled to severance, and we will contest any and all claims for severance. Prior to the appointment of Mr. Neil Cohen as interim Chief Executive Officer in October 2020 (see below), our board of directors handled all matters related to CEO duties.

On October 20, 2020, we appointed Mr. Neil Cohen as interim Chief Executive Officer of Anchiano, effective immediately. Mr. Cohen continues to serve as a member of our board of directors. The Company also appointed Andrew Fine to serve as our Chief Financial Officer, effective immediately. Mr. Fine previously served as our Interim Chief Financial Officer pursuant to a subcontracting agreement.

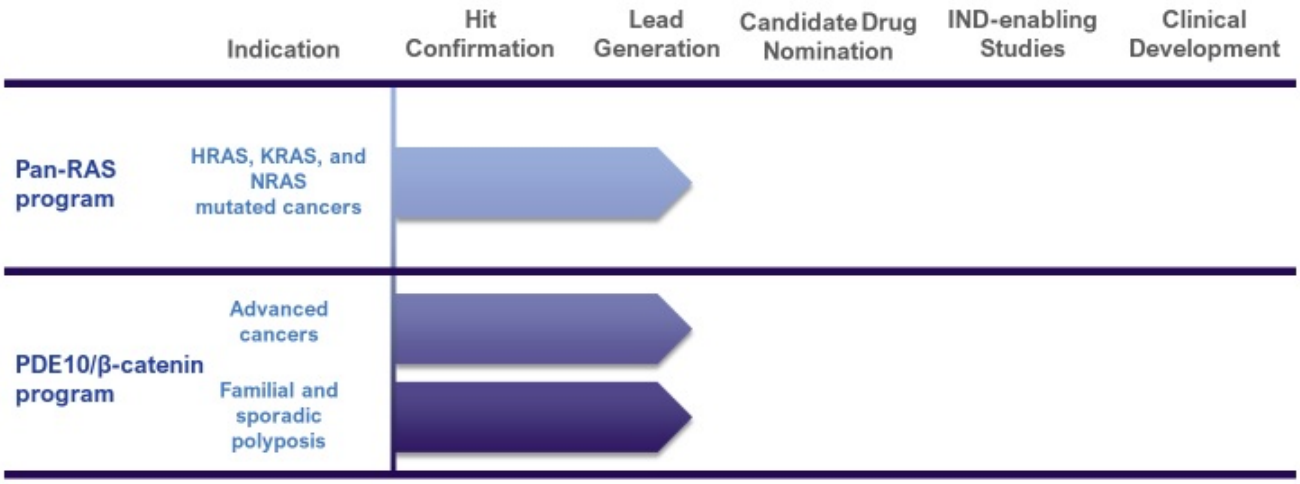
In light of business circumstances, and in order to conserve cash and preserve optionality while alternatives are being identified and assessed, we made a decision during July 2020 to undertake reductions in headcount and other cost saving measures. These included plans to temporarily reduce our internal and external research and development work on the Company’s pan-RAS-inhibitor program until there is greater clarity regarding Anchiano’s ability to fund the program. We continue to undertake actions for the promotion of the program and its assets and towards strengthening the protection of all related intellectual property.

On December 14, 2020 we entered into an Agreement and Plan of Merger with Chemomab, an Israeli limited company and a clinical-stage biotech company focusing on the discovery and development of innovative therapeutics for fibrosis-related diseases with high unmet need, which included the proposed Merger of CMB Acquisition Ltd., a wholly owned subsidiary of ours, with Chemomab as the surviving company, subject to shareholder approval. A shareholder meeting has been scheduled for March 15, 2021 to approve the Merger and related proposals. For more information regarding Chemomab and the proposed Merger, see the proxy statement/prospectus we filed with the SEC on February 12, 2021 and that can be found at this link: https://www.sec.gov/Archives/edgar/data/1534248/000110465921021553/tm211883-6_424b3.htm

Our Product Pipeline

Our preclinical programs are summarized below and consist of two preclinical programs. We have a partnership with ADT related to two small molecule development programs targeting oncogenic pathways, focused on RAS and PDE10/β-catenin, respectively.

Our Therapeutics Pipeline



Pan-RAS Program: Our highest priority program targets oncogenic mutations in the RAS family of genes (*i.e.*, KRAS, HRAS, and NRAS gene families), which are present in more than 30% of cancers. RAS plays a pivotal role in signal transduction pathways leading to tumor cell proliferation and survival. Our pan-RAS program has identified novel indene-based small molecules that exhibit potent and selective inhibition of activated RAS signaling regardless of isoform or mutation, or pan-RAS inhibition.

PDE10/ß-catenin Program: Genetic alterations in components that make up the Wnt signaling pathway, which includes APC and β-catenin, are prevalent in a number of cancer types, occurring in more than 80% of colorectal cancers. Our PDE10/ß-catenin program has identified small molecules that selectively and potently inhibit PDE10 and suppress Wnt/APC/β-catenin signaling in preclinical models. PDE10 inhibition has been shown to down regulate β-catenin expression and inhibits polyp and tumor growth. We believe it has potential for application in the treatment of cancer as well as spontaneous and familial polyposis syndromes.

Inodiftagene vixteplasmid: Previously we discovered and developed a gene therapy, inodiftagene, designed to treat non-muscle invasive bladder cancer ("NMIBC"). We had developed this gene therapy in six clinical trials in pancreatic cancer, ovarian cancer, and bladder cancer. Based on these preliminary clinical studies, we determined to test this product candidate in a clinical trial designed as the basis for potential regulatory approval. This clinical trial, the Codex trial, was initiated in December 2018, enrolling patients through the following year. In November 2019, we discontinued the pivotal Phase 2 Codex study. After a thorough analysis of the data, we determined that there was a low probability of surpassing the pre-defined futility threshold at the planned interim analysis, which required 10 complete responses in 35 patients. As of November 14, 2019, 16 patients were evaluable after the first disease assessment on treatment; of these, three, or 19%, had experienced a complete response. The data also indicated a low probability of achieving an efficacy profile that in our estimation would be necessary to support regulatory approval. The safety data on the investigational product were consistent with those observed in prior preliminary clinical trials. In April 2020 we notified Yissum Technology Transfer Company of the Hebrew University Ltd. ("Yissum") that as a result of our decision to discontinue clinical development of inodiftagene, we will cease payments to maintain intellectual property ("IP") we licensed from Yissum that supported the development and as related to a licensing and development agreement between the parties ("License Agreement"). In August 2020 we agreed with Yissum on termination of the License Agreement and return of the IP.

Pan-RAS Program

Background

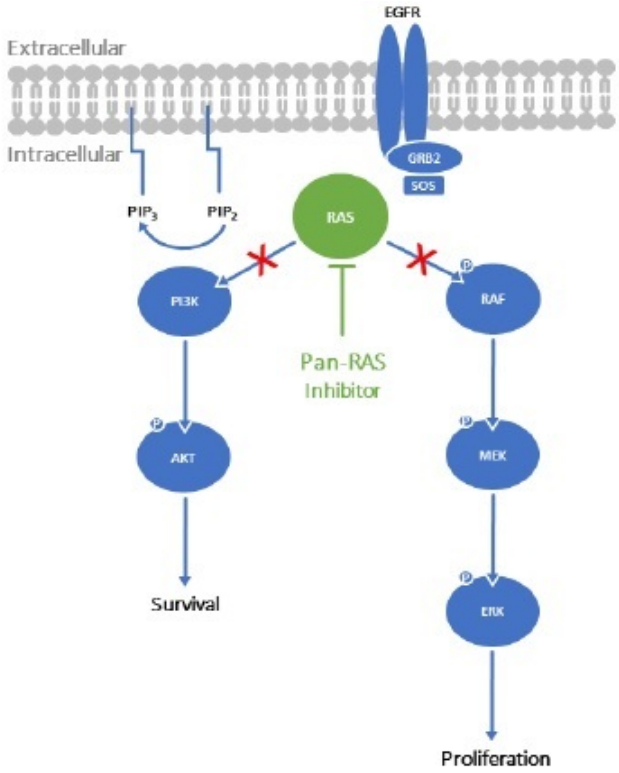
According to the National Cancer Institute, mutations in the RAS family of genes (*i.e.*, KRAS, HRAS, and NRAS) are the most frequent oncogenic mutations in cancer, present in over 30% of all cancers. These mutations are involved in more than 181,000 cancer deaths per year (more than 30% of 606,000 deaths) in the United States alone. The three most lethal cancers, lung cancer, colorectal cancer and pancreatic cancer, are driven largely by mutant RAS. Of these cancer types, non-small cell lung cancers ("NSCLC") have mutations in the RAS family of genes in approximately 35% of cases; colorectal cancers carry RAS mutation in approximately 45% of cases; and pancreatic cancers carry RAS mutations in over 95% of cases. Taken together, in these three cancer types, RAS mutations account for more than 100,000 lethal cases of cancer per year in the United States. The World Health Organization estimates that in 2018, the most common causes of cancer death are lung cancer (1.76 million deaths) and colorectal cancer (862,000 deaths). According to the National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) Program, five-year survival outcomes in advanced NSCLC, colorectal cancer and pancreatic cancer are particularly dismal - 5%, 14% and 3%, respectively.

We estimate that the total addressable population of patients with RAS-mutation driven solid tumors alone totals more than 165,000 patients per year in the United States. These morbidity and mortality rates suggest that therapies directed at tumors carrying mutated forms of RAS are urgently needed.

Taken together, these statistics suggest that the patient population that could benefit from effective therapy targeting RAS mutations is large. The U.S. annual incidence of NSCLC, colorectal cancer, and pancreatic cancer combined is approximately 395,000 patients, of which approximately 295,00 are advanced cases. We estimate that this translates into approximately 130,000 addressable patients annually with RAS-mutated advanced solid tumors in the United States in these three indications. We estimate that other solid tumors will add approximately 35,000 additional addressable patients for a total annual addressable patient population of 165,000 in the United States. RAS mutations are similarly frequent globally. Despite success in development of therapies targeting other genetic drivers in cancer, there have been no approved RAS inhibitors to date. The frequency of RAS mutations in cancer, the high mortality associated with the disease, and the lack of any approved targeted therapies creates a significant clinical need.

RAS plays a pivotal role in cell signal transduction pathways leading to tumor cell proliferation and survival. RAS, a membrane bound protein, resides in an inactive, or GDP-bound, state. Following stimulation, RAS releases guanosine triphosphate ("GDP") and forms a transient nucleotide-free state, subsequently binding with guanosine triphosphate ("GTP"). Active, or GTP-bound, RAS engages specific RAS effector proteins (*e.g.*, RAF, PI3K), resulting in activation of pathways leading to cell proliferation and survival. Oncogenic activation of RAS occurs mainly via mutations in codons 12, 13 and 61—with a shift to the GTP-bound state and constitutive activation of RAS effector pathways.

RAS Signaling Pathway



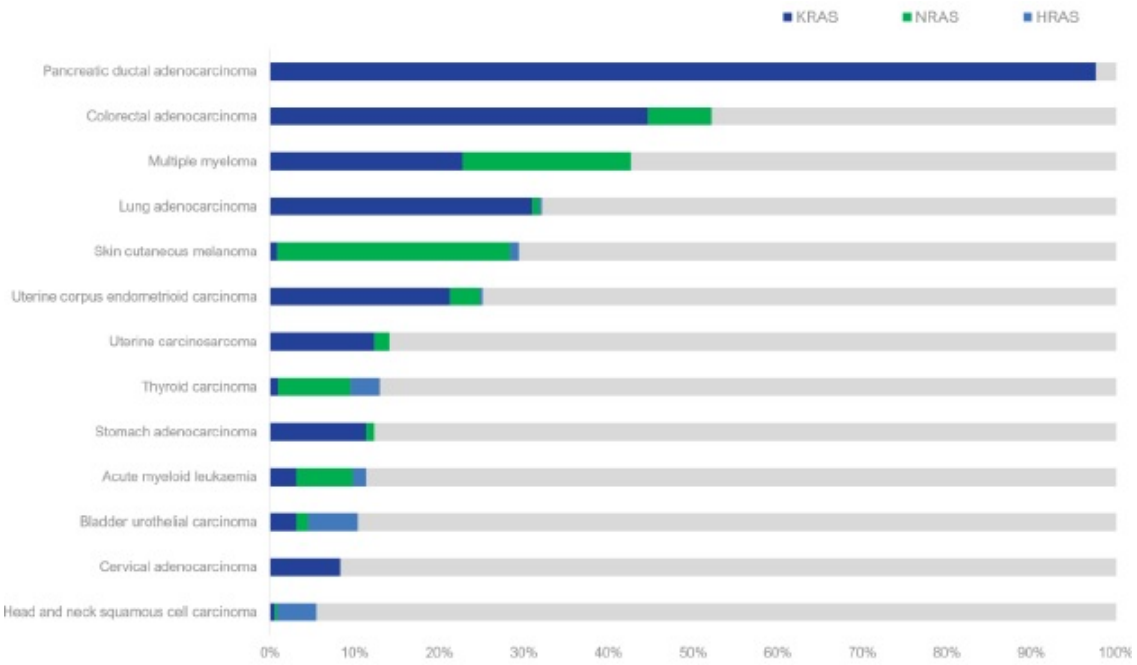
Abbreviations:

EGFR =	epidermal growth factor receptor,	ERK =	extracellular signal-regulated kinase
GRB2 =	growth factor receptor-bound protein 2	MEK =	mitogen activated protein kinase
P =	phosphorylated	PI3K =	phosphatidylinositol 3-kinase
PIP2 =	phosphatidylinositol (4,5)-bisphosphate	PIP3 =	phosphatidylinositol (3,4,5)-trisphosphate
SOS =	son of sevenless		

The understanding of the oncogenic properties of RAS has driven the search for anti-RAS therapeutics for several decades. However, mutant RAS has long been viewed as “undruggable” directly due to its minute structural differences from wild-type RAS, its smooth surface and lack of deep pockets for binding of small molecule inhibitors. Initial attempts to inhibit mutant RAS focused on inhibition of farnesyltransferase, responsible for posttranslational modifications associated with correct localization of the protein. However, this line of investigation has been unsuccessful to date in clinical trials. More recently, a previously unrecognized pocket of RAS—the Switch II Pocket (“SII-P”)—was discovered in the inactive GDP-bound form. Compounds have been identified that selectively target the cysteine mutation at codon 12 (also known as the KRAS G12C mutation) and bind covalently to RAS G12C, targeting SII-P and preventing loading of GTP and engagement of effectors. A number of KRAS G12C mutation inhibitors are currently in Phase 1 clinical trials (*e.g.*, Amgen Inc.’s AMG-510 and Mirati Therapeutics, Inc.’s MRTX849), with early clinical data reporting evidence of activity in KRAS G12C mutation-positive cancers, particularly NSCLC. These drugs have generated enormous excitement, with the most advanced drug, AMG-510, showing an overall response rate (“ORR”) of 48% in 23 evaluable NSCLC patients with eight out of 11 responders remaining in response and on treatment. Similarly, MRTX849 has shown a 50% ORR in six patients with NSCLC in its initially presented Phase 1 data set.

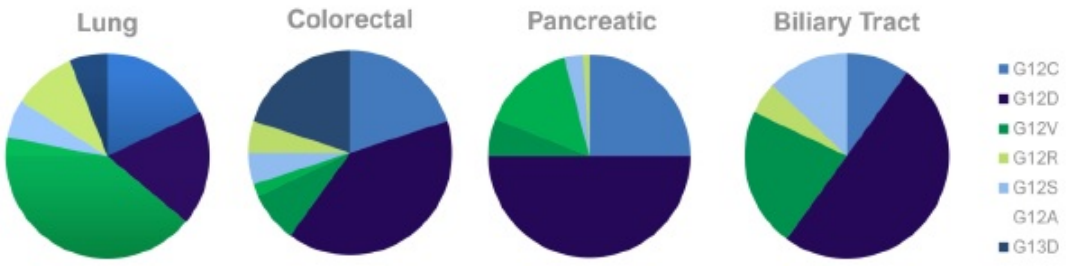
We believe the significance of these successes is field-altering, as for the first time there is evidence that inhibition of mutated RAS isoforms may be undertaken in the same manner as other successful small molecule targeted therapies had shown possible against other mutated oncogenes. In other words, RAS has become a clinically validated target. However, these current investigational drugs are mutation specific—with G12C representing approximately 9% of RAS mutations in cancer. As shown below, KRAS represents the most commonly mutated isoform of RAS, and there is a spectrum of activating mutations that have been observed with this isoform. This means that only approximately 11% of the KRAS mutations can be addressed with G12C inhibitors. A variety of activating mutations have also been observed with the HRAS and NRAS isoforms, which remain unaddressed. While these observations have proven that RAS-directed therapy using small molecule inhibitors is possible with clinical effect, results so far are confined to a small subset of patients carrying a particular mutation. That said, the market capitalization of the companies pursuing KRAS G12C inhibitors has grown by many billions of dollars during 2019.

Frequency of RAS Mutations by Tumor Type (cancers with >5% RAS mutation frequency)



Adapted from: Cox et al., Nat Rev Drug Discov, 2014

Frequency of Specific KRAS mutations in KRAS-Mutated Lung, Colorectal, Pancreatic and Biliary Tract Cancers



Adapted from: Vasan et al., Clinical cancer research, 2014

We believe that our pan-RAS program is poised to take advantage both of the fact that RAS inhibition has been shown to be clinically valid, and that initial successes have been confined to a fraction of tumors that carry RAS mutations. A broadly acting RAS inhibitor with the potential to treat RAS-driven cancers regardless of RAS isoform or mutation (*i.e.*, a pan-RAS inhibitor) would be clinically useful. It is also not yet well understood what resistance mechanisms to KRAS G12C mutation inhibitors will develop in the clinic. A pan-RAS inhibitor may be clinically preferable in KRAS G12C mutation-positive patients if resistance to KRAS G12C mutation inhibitors leads to mutations in other RAS isoforms or other KRAS mutations, and may also have utility in such patients who have been treated previously with a KRAS G12C mutation inhibitor. There is a clear need to continue to develop new and more effective direct inhibitors of RAS, preferably with broad activity against the multiple RAS isoforms and various mutations. Given the frequency of RAS mutations overall, a pan-RAS inhibitor would have potential to address a substantial proportion of cancer patients—significantly more than any other genetic target for which drugs have been developed to date (and, we estimate, approximately 11 times more patients than are addressable by the KRAS G12C mutation inhibitors). Therefore, our pan-RAS program is our highest priority.

Our Approach

Our lead RAS inhibitor molecules are novel indene derivatives of sulindac, a well-studied and clinically utilized anti-inflammatory agent with activity against cells carrying mutated RAS. Our RAS inhibitor molecules have been engineered to eliminate cyclooxygenase-2 ("COX-2") inhibitory activity, present in sulindac, to lessen the potential cardiovascular side effects observed with sulindac and other related drugs.

We believe our RAS inhibitor molecules have potential for RAS inhibition in a broad variety of clinical settings, because they exhibit the characteristics we believe are necessary in a pan-RAS inhibitor. Our RAS inhibitor molecules potently, selectively, and reversibly inhibit growth of tumor cells harboring mutant RAS, while having greater than 100-fold selectivity over cells with normal RAS activity. Inhibitory activity has been observed with low nanomolar potency (<10 nM) in KRAS-, HRAS-, and NRAS-driven models with a variety of mutations (e.g. KRAS G12C, G13D, G12V, G12S; HRAS G12D; and NRAS Q61K) across a variety of tumor types, which suggests that these molecules could have utility across the broad spectrum of RAS mutations and tumor types in which these mutations have been observed to drive cancer. This potent activity is observable in both monolayer cultures, and in 3-D spheroid cultures, which may have higher predictive value for anti-tumor activity. These compounds inhibit downstream signaling through RAF and PI3K pathways, which is consistent with their acting directly on RAS, as opposed to another pathway molecule. They initiate cell-cycle arrest and induce apoptosis, consistent with cell killing. Importantly, the inhibitors demonstrate blockade of GTP loading of RAS in the nucleotide-free state in cell-free biochemical assays, suggesting that their mechanism of action is through interference of GTP-mediated signaling. They have exhibited *in vivo* activity in RAS mutant tumor models. Finally, an emerging characteristic of RAS inhibition is the stimulation of anti-tumor immunity. This has been shown with AMG 510, a KRAS G12C inhibitor presently in the clinic, and it suggests that effective RAS inhibition stimulates several anti-tumor immune mechanisms. Our inhibitors have been shown to similarly stimulate anti-tumor T-cell-mediated immune mechanisms. These multiple lines of evidence are all consistent with the characteristics one would expect to observe with a drug that is killing cells by direct inhibition of RAS.

We believe these molecules have potential for RAS inhibition in a broad variety of clinical settings. Over the next 12-18 months our main goals are to understand the specific mechanism of action and physical basis of binding of the compounds to RAS, and to optimize the initially identified series of compounds to identify a lead development candidate.

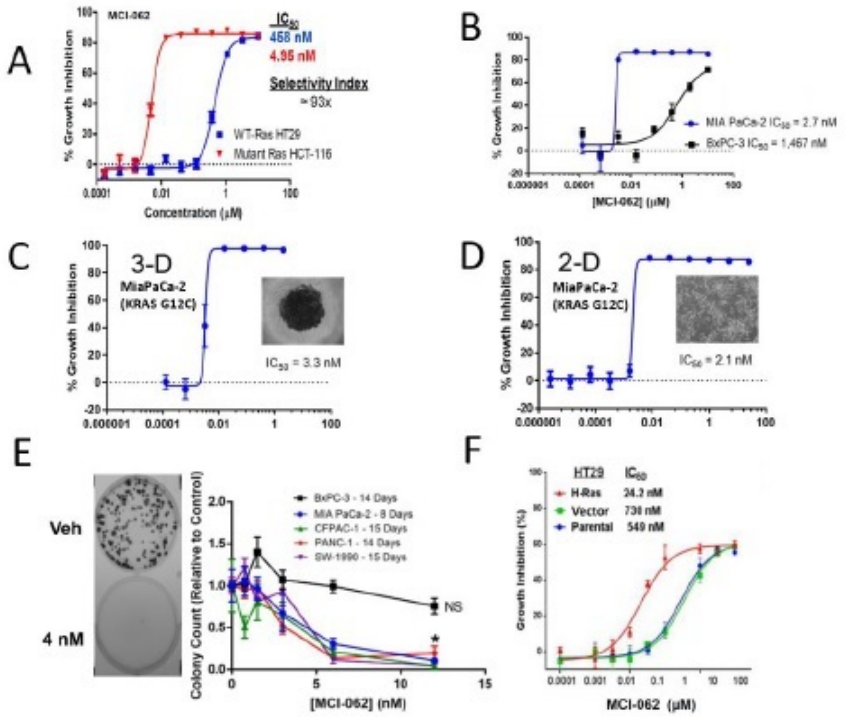
One of our lead compounds in the pan-RAS program, ANC 007 (also referred to as MCI-062), has been observed to have less than 10 nanomolar cellular potency in monolayer cultures of tumor cells harboring mutant RAS. Similar potency was observed in 3D spheroid cultures, which are cell cultures that are permitted to grow in all three dimensions and are considered by some to be more predictive of *in vivo* activity than monolayer culture. Cell lines with wild-type ("WT") RAS and concurrent upstream mutations (e.g. EGFR) that signal through RAS display similar inhibition to cell lines with mutated RAS. Cell lines with WT RAS in the absence of upstream activation are less sensitive (>100-fold selectivity), regardless of downstream activating mutations. Sensitivity to ANC 007 can be conferred by transduction of HT-29 cells (WT RAS) with mutant RAS. This means that mutated (or activated) RAS is required for the activity of the drug. These observations are consistent with the inhibition of RAS regardless of isoform, and regardless of the mutations tested. In addition, they suggest that the activation of RAS (by mutation or upstream signaling) is a key feature of selectivity. If this key finding of pan-RAS inhibition with this series of compound can be translated into a drug candidate exhibiting similar broad activity *in vivo*, we believe the clinical potential is substantial.

Potent and Selective Pan-RAS Inhibition with ANC 007

Mutation Status	IC_{50}, Cell-based Assay (nM)	Cell Line	Tumor Origin	Genotype
KRAS G12C	2.1	*Mia PaCa-2*	Pancreatic	Mutant RAS
KRAS G12D	2.4	*PANC-1*	Pancreatic	
KRAS G12D	6.3	*SW-1990*	Pancreatic	
KRAS G12S	6.8	*A549*	Lung	
KRAS G12V	5.8	*CFPAC-1*	Pancreatic	
KRAS G12V	6.5	*SW480*	Colon	
KRAS G13D	3.6	*MDA-MB-231*	Breast	
KRAS G13D	4.7	*HCT116*	Colon	
HRAS G12D	3.9	*Hs578*	Breast	
NRAS Q61K	2.1	*SK-MEL-2*	Melanoma	
NRAS Q61K	2.4	*H1299*	Lung	
WT RAS / mut. EGRF	3.9	*H1975*	Lung	RAS activated upstream
WT RAS / mut. PDGFR	5.8	*B16*	Melanoma	
WT RAS / mut. NF1	6.7	*SKOV3*	Ovarian	
WT RAS	350	*OV90*	Ovarian	WT RAS
WT RAS	9600	*H3322*	Lung	
WT RAS	19100	*NHAEC*	Normal Lung	
WT RAS	>25000	*SK-MEL-28*	Melanoma	
WT RAS / mut. RAF	512	*HT29*	Colon	RAS pathway activated downstream
WT RAS / mut. RAF	2500	*BXPC3*	Pancreatic	

Source: Keeton et al., AACR 2019; Mattox et al. AACR 2019; McConnell et al. AACR 2017; Data on File. ANC 007 has previously been referred to as MCI-062.

Potent and Selective RAS Inhibition of Monolayer and Spheroid Culture with ANC 007



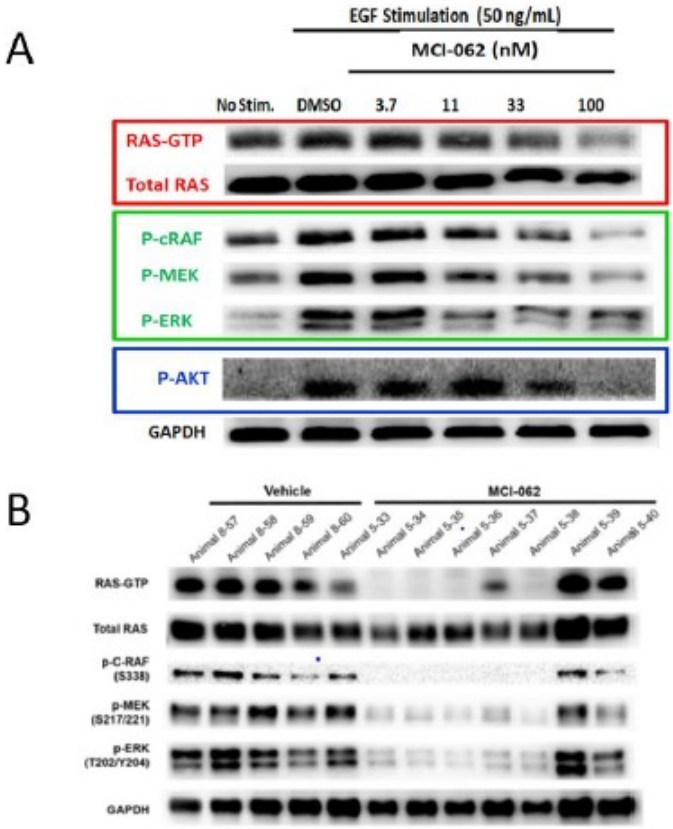
Panels:

- ***A, B, C, D:*** Growth inhibitory activity of ANC 007 (MCI-062) was tested using the CellTiter-Glo luminescence assay.
- ***E:*** Inhibition of colony formation was tested on a five different cell lines using ANC 007. BcPC-3 is a pancreatic cell line with non-mutated, or wild type, RAS. Other four cell lines carry RAS mutations.
- ***F:*** Replication incompetent retrovirus encoding HRAS-G12V mutant or empty vector was prepared by transfection of A293T cells with packaging and envelope plasmids. Crude supernatant collected and used to tranduce HT29 colon cancer cells. Stable pools of each were expanded and expression of HRAS was characterized by western blot.

Source: Keeton et al., AACR 2019; Mattox et al. AACR 2019; Data on File.

ANC 007 has been shown to inhibit signaling through RAF and PI3K pathways (*i.e.*, nodes in the signal transduction cascade that are downstream (distal) to RAS), which suggests that the node of inhibition is RAS itself, rather than one of the effectors further downstream. As shown below, treatment of MIA-PaCa-2 pancreatic cancer cells with KRAS G12C results in inhibition of signaling of the MAPK pathway as evidenced by inhibition of phosphorylation of CRAF, MEK, and ERK. AKT phosphorylation is also inhibited. The observation that both sides of the signaling pathways downstream from RAS (RAF/MEK/ERK and AKT) are inhibited suggests that the node of inhibition is RAS itself, rather than one of the effectors further downstream. MAPK signaling in KRAS G13D mutant HCT-116 colon cancer cells is inhibited *in vivo* as well.

Inhibition of Downstream Signaling Through RAF and PI3K Pathways with ANC 007



Panels:

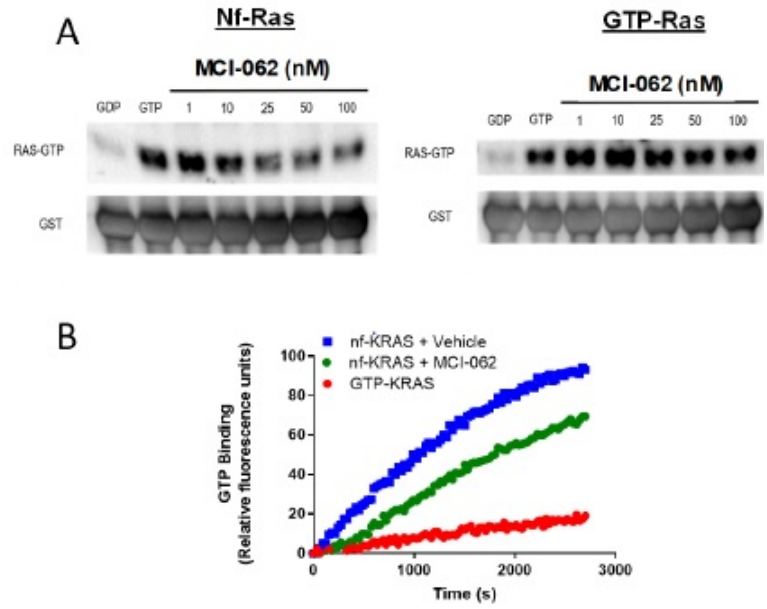
- ***A,*** ANC 007 (MCI-062) reduced RAS-GTP levels and inhibits activation of downstream RAS signaling in MIA-PaCa-2 pancreatic cancer cells Cells were treated with vehicle or ANC 007 for 24 hours in serum-free media and subsequently stimulated with 30 ng/mL EGF for 10 minutes. RAS- GTP levels after treatment were determined by the active RAS pull-down using GST-RAF1- RBD/glutathione agarose and detection by Western blotting. Detection of phospho-protein levels was performed by Western blot.

- ***B,*** ANC 007 inhibits activation of downstream RAS signaling and activates anti-tumor immunity in murine RAS mutant colon cancer model. Mice were implanted in the right flank with 10 million HCT- 116 tumor cells per mouse. ANC 007-treated mice received 5 mg/kg MCI-062 twice daily by peritumoral administration. Vehicle-treated mice received 5% DMSO/5% cremophor EL/90% water once daily by peritumoral administration. RAS-GTP levels in tumor lysates were determined by the active RAS pull-down and detection by Western blotting. Levels of MAPK proteins and immune markers were determined by Western blotting with the whole tumor lysate. Each lane corresponds to an individual animal.

Source: Keeton et al., AACR 2019; Mattox et al. AACR 2019.

To initially characterize the molecular mechanism of action of ANC 007, it has been tested in cell-free biochemical assays utilizing recombinant KRAS in order to evaluate the potential for direct binding of the drug to the RAS protein. Incubation of ANC 007 with nucleotide-free KRAS followed by addition of GTP led to a concentration dependent reduction of RAS-GTP levels in an RBD pull-down experiment. This effect was not observed when ANC 007 was incubated with GTP-loaded RAS. The RBD assay utilizes the Ras-binding domain (RBD) of the RAS effector kinase Raf1 which been shown to bind specifically to the GTP-bound form of RAS proteins, making it an ideal tool for affinity purification of GTP-Ras. This experiment suggests ANC 007 directly inhibits GTP binding to RAS when RAS is in the nucleotide-free state but not in the GTP-bound state. Similarly, in a guanine nucleotide exchange assay, which uses a fluorescently-labeled guanine nucleotide analogue (MANT-GTP) to evaluate nucleotide binding to RAS, addition of ANC 007 to nucleotide-free KRAS inhibits MANT-GTP binding. We believe the results of these cell-free experiments indicate that the mechanism of ANC 007 involves direct binding to RAS to exert its effect. Further work, including such structural biology methodologies as x-ray crystallography, are planned to more specifically elucidate the mechanism of action and binding contacts of these compounds.

Inhibition of GTP Binding to Recombinant KRAS in Cell-Free Biochemical Assays Under Nucleotide-Free (nf) Conditions with ANC 007



Panels:

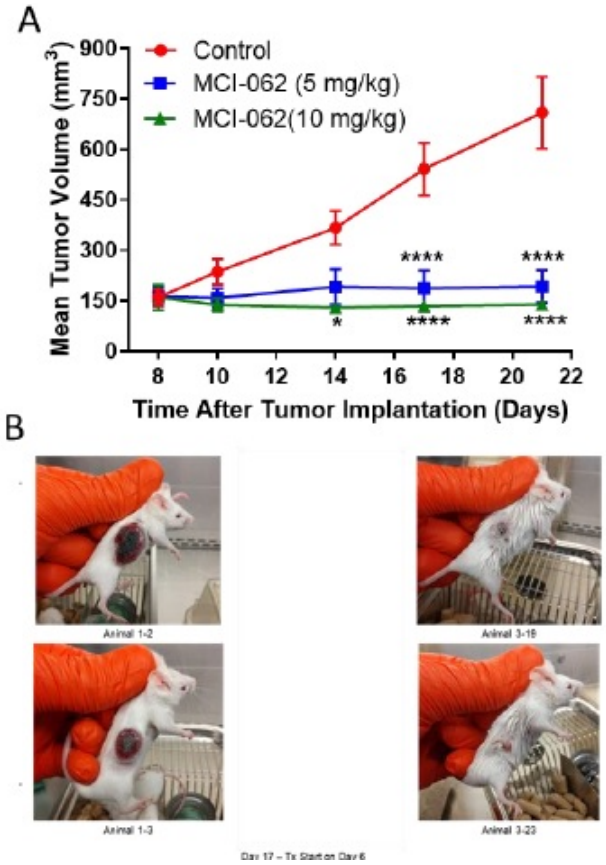
- ***A,*** ANC 007 (MCI-062) inhibits GTP binding to recombinant nucleotide-free RAS in RBD pull-down experiment. Nucleotide-free recombinant WT-KRAS was prepared by incubation with 20 mM EDTA on ice. ANC 007 or vehicle was incubated 1 h with nucleotide-free WT-KRAS, followed by addition of GTP and an additional 30 min incubation (left) or, ANC 007 was incubated with WT-KRAS after addition of GTP (GTP-bound, right). RAS-GTP levels after treatment were determined by the active RAS pull-down assay using GST-RAF1-RBD/glutathione agarose and detection by Western blotting.

- ***B,*** ANC 007 inhibits GTP binding to recombinant nucleotide-free RAS in guanine nucleotide exchange assay. Nucleotide-free recombinant WT-KRAS was prepared by incubation with 20 mM EDTA on ice. Nucleotide free KRAS was incubated with ANC 007 or vehicle for 1 h on ice, followed by addition of an excess of $MgCl_2$ with fluorogenic MANT-GTP. Recombinant KRAS not treated with EDTA (GTP-KRAS) was included as a control indicator of intrinsic turnover rate. The development of fluorescence reflecting MANT-GTP binding to KRAS was monitored over the course of a 45 min incubation.

Source: Mattox et al. AACR 2019; Data on File.

ANC 007 has exhibited potent anti-tumor activity in RAS-driven tumor models in mice, consistent with the cell based *in vitro* data. As shown below, ANC 007 inhibited tumor growth by intratumoral administration in KRAS mutant colon tumor xenograft models (HCT116 and CT26 cell lines).

In Vivo Antitumor Activity in RAS-driven Tumor Models with ANC 007



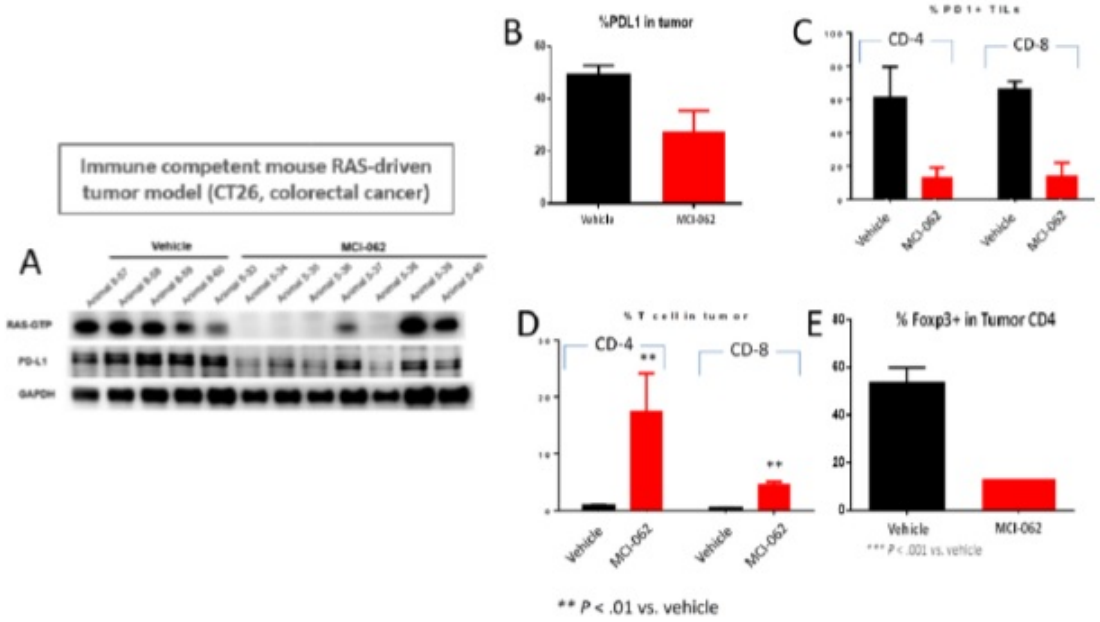
Panels:

- ***A:*** ANC 007 (MCI-062) inhibits growth of KRAS mutant HCT-116 tumor cells in a subcutaneous mouse xenograft model. Athymic nude mice were implanted in the right flank with 10 million tumor cells per mouse. Mice were treated once daily by intratumoral administration. Control mice received vehicle only (5% DMSO/5% cremophor EL/90% water) once daily by intratumoral administration. N=8 mice for vehicle group, n=7 mice for 5 mg/kg ANC 007 group, n=4 mice for 10 mg/kg ANC 007 group.

- ***B:*** Mice were implanted in the right flank with one million CT-26 tumor cells per mouse. ANC 007 treated mice received 5 mg/kg ANC 007 twice daily by peritumoral administration. Vehicle-treated mice received 5% DMSO/5% cremophor EL/90% water once daily by peritumoral administration. Shown on left is control (vehicle-treated) mice and on the right are mice treated with ANC 007.

As shown below, in an immune competent mouse RAS-mutant tumor model, ANC 007 suppressed tumor growth in association with decreased PD-L1 levels in tumors; decreased PD-1 in T-cells; increased proportion of CD4+ and CD8+ T-cells in tumors; and reduced Treg cells in tumors (as evidenced by Foxp3 expression). Similar effects on the tumor immune microenvironment have been observed with KRAS G12C inhibitors, including AMG-510, and this stimulation of anti-tumor immunity appears to be an emerging characteristic of RAS inhibition itself. These lines of evidence suggest that effective RAS inhibition stimulates several anti-tumor immune mechanisms., and ANC 007 has been shown to similarly stimulate these anti-tumor T-cell-mediated immune mechanisms.

Inhibition of Tumor Growth with ANC 007 Associated with Activation of Antitumor Immunity



Panels:

- ***A:*** ANC 007 (MCI-062) reduces PD-L1 expression in RAS driven tumor model. Mice were implanted in the right flank with one million CT26 tumor cells per mouse. ANC 007-treated mice received 5 or 10 mg/kg ANC 007 once daily by intratumoral administration. Vehicle-treated mice received 5% DMSO/5% cremophor EL/90% water once daily by intratumoral administration. RAS-GTP levels in tumor lysates were determined by the active RAS pull-down and detection by Western blotting. of immune markers was performed on whole tumor lysate.

- ***B, C, D, E:*** ANC 007 reduces PD-1, increases proportion of CD4+ and CD8+ T-cells, and reduces Tregs. Subcutaneous CT-26 murine tumors were excised from vehicle or ANC 007 treated mice, and digested for 1 h using the gentle-MACS dissociator and murine tumor digestion protease cocktail. Following digestion, single cell suspensions were recovered by passage through a cell strainer, and cell counts were normalized by quantitation using a hemacytometer. Fluorescently labelled antibodies used to quantitate the indicated cell populations by flow cytometry.

Preclinical Development

We initiated development of a series of compounds that exhibit pan-RAS inhibition as detailed in the experiments above. The lead compounds demonstrate low nM IC50 potency against all RAS isoforms and all mutants tested, in cell lines of several histologies, and in monolayers and spheroids; inhibit RAS signaling; induce cell cycle arrest and apoptosis; inhibit binding of GTP to nucleotide-free RAS; bind to the GTP catalytic domain, in computational structural studies; inhibit mutant RAS-driven tumor growth *in vivo*; and demonstrate *in vivo* activation of anti-tumor immunity that includes the down-regulation of PD-L1. Over the next 12-18 months we plan to (1) replicate and expand on the data generated previously by ADT, including further characterization of the biological activity of the compounds; (2) undertake structural biology investigations to understand the specific mechanism of action and physical basis of the compounds binding to RAS; and (3) optimize the initially identified series of compounds, including ANC 007, to identify a lead development candidate for further preclinical and then clinical development. The preclinical work will be primary performed by a contract research organization(s) (“CRO”), with oversight and strategic guidance by us.

We have internally initiated experiments with ANC 007 and have replicated key cell-based data, including monolayer and spheroid cell viability and colony forming assays, with results consistent with those generated by ADT for the molecule across multiple cell lines and RAS mutations. This work has independently confirmed similar potency and selectivity results with ANC 007 to those presented.

A key aspect of developing these compounds is to gain a detailed understanding of their mechanism of action and binding to RAS. To that end, we have embarked on a suite of biophysical and structural biology studies, including techniques such as nano differential scanning fluorimetry (nanoDSF), microscale thermophoresis (MST), protein nuclear magnetic resonance (NMR) and x-ray crystallography to understand specifically how these compounds bind to the RAS protein. This data will be crucial to understanding how this family of compounds exert their effect and learnings will be integrated into the medicinal chemistry strategy in order to develop an optimized product candidate. ANC 007 and related compounds require further optimization in order to identify a suitable clinical candidate. Evaluation of orally bioavailable candidates will include work up of ADME (absorption, distribution, metabolism, and excretion) profile, *in vivo* pharmacokinetic profile and efficacy, as well as initial assessment of *in vivo* toxicity. From the time of lead candidate nomination, we anticipate that it will take approximately 12 months to perform IND-enabling studies and submit an IND for First in Human studies, which we would anticipate to commence in 2022.

Clinical Development Plan and Regulatory Pathway

Clinical development will be initiated once a lead product candidate has been nominated, all necessary IND-enabling studies have been performed and an IND application has been successfully submitted to and accepted by the U.S. Food and Drug Administration ("FDA") and adequate financing has been secured. Initial Phase 1 clinical investigation will be performed in patients with advanced solid tumors harboring a RAS mutation, with the objective of identifying a recommended Phase 2 dose and to evaluate the safety and tolerability of the product candidate, as well as to evaluate preliminary anti-tumor activity. Given the initial clinical activity observed in lung cancer with the KRAS G12C inhibitors in the clinic, we anticipate that NSCLC may be an area of initial focus, as well as colorectal and pancreatic cancer (given the prevalence of RAS mutations in these cancers). However, we anticipate that this study would enroll patients with multiple tumor types as long as a RAS mutation is present.

The clinical development path of other targeted therapies in genetically defined tumors, such as those with EGFR, ALK, ROS1 and TRK aberrations, suggest that there exists the opportunity for accelerated clinical development of a RAS inhibitor as well, provided the investigational drug exhibits high response rate with clinically meaningful duration in a well-defined population with a significant unmet medical need. As in these prior examples, accelerated approval may be initially granted on the basis of a single well-executed, multi-center single arm, Phase 2 study (with the potential for different cohorts based on tumor type to support multiple indications in a single study). Given the clinical proof of concept observed in NSCLC with the G12C inhibitors, we anticipate prioritizing RAS mutant NSCLC patients previously treated with standard of care (*i.e.*, platinum-based chemotherapy/checkpoint inhibitors) as an initial pivotal cohort. Other potential pivotal cohorts include advanced CRC, after 5-FU/oxaliplatin/irinotecan, and advanced pancreatic adenocarcinoma, after 5-FU or gemcitabine based therapy. Given the clinical need and the size of the patient population we anticipate this study would proceed rapidly.

After approval in an initial indication, we would then pursue indication expansion with additional tumor types, earlier lines of therapy, and combination therapy (including with chemotherapy, other targeted therapies and checkpoint inhibitors, which have shown potential for synergy with RAS inhibition preclinically). Beyond initial pivotal cohort considerations, we will investigate RAS mutation in other appropriate tumor types such as bladder cancer and melanoma, and consider the potential for tumor agnostic indication, particularly in rare tumors and/or tumor types with infrequent RAS mutations, which is another area with potential for approval based on Phase 2 data. Patients who have failed G12C-specific inhibitor would also be a defined cohort to evaluate early on—given the hypothesis that resistance here may be mediated by other RAS isoforms or mutations.

A robust translational medicine effort is needed as clinical and biomarker data may point to differential activity based on activating mutation or specific RAS gene, if so development will need to take these considerations into account (patient selection).

An appropriately expansive clinical development plan will contemplate how to move into investigation of first line treatment once activity is observed in the refractory setting. Confirmatory studies for initial indication(s) can be randomized Phase 3 studies in earlier lines of therapy with standard of care comparators. This may likely involve investigation of combination therapy, and therefore we plan for early evaluation of combination safety and preliminary efficacy, based on tumor types showing activity in monotherapy evaluation to potentially inform confirmatory studies and other indication expansion, depending on tumor type/setting. Combinations may be with chemotherapy, checkpoint inhibitors and other rational combination partners based on emerging molecular mechanisms of resistance to RAS inhibition.

Beyond first line treatment in the advanced/metastatic setting, earlier stage disease/adjuvant setting is an exciting space to consider given the potential to significantly alter the course of disease. Moving targeted therapy into the adjuvant space has been challenging, but success has been seen with checkpoint inhibition and smart trial design (*e.g.*, durvalumab in Stage III NSCLC). These are longer trials compared to metastatic setting, but the relatively large RAS patient populations (*e.g.*, in NSCLC and colorectal cancer) make this attractive/feasible to consider. Finally, an additional area to consider, based on the preclinical data, is patients with RAS WT tumors with upstream activation who have failed targeted therapy/standard of care—such as Her2 mutant NSCLC and EGFR mutant NSCLC (*e.g.*, T790M/C797S 'triple mutant').

As mentioned above, in light of business circumstances and in order to conserve cash and preserve optionality while alternatives are being identified and assessed, we made a decision during July 2020 to undertake reductions in headcount and other cost saving measures. These included plans to temporarily reduce our internal and external research and development work on the Company's RAS Program until there is greater clarity regarding Anchiano's ability to fund the program. We continue to undertake actions for the promotion of the program and its assets and towards strengthening the protection of all related intellectual property.

PDE10/β-catenin Program

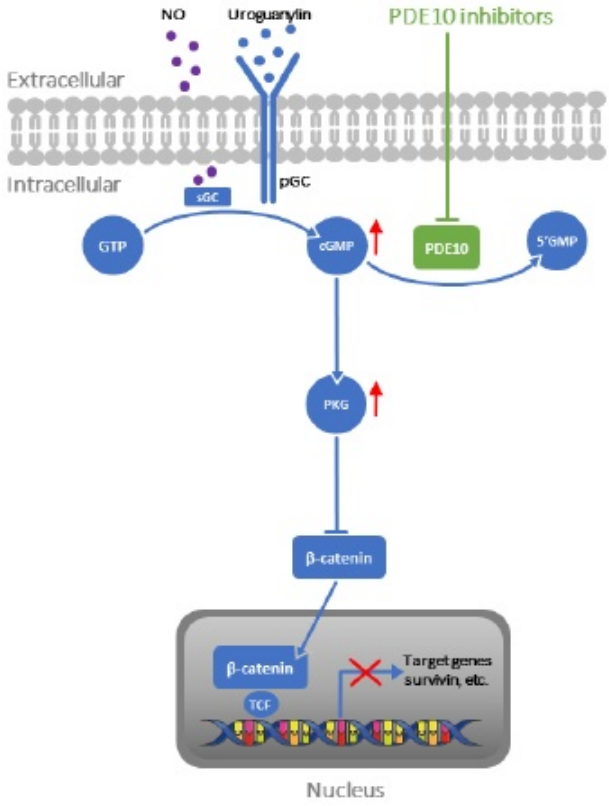
Background

Genetic alterations in components that make up the Wnt signaling pathway, which includes APC and β-catenin, are prevalent in a number of cancer types, occurring in approximately 90% of colorectal cancers. This translates into approximately 48,000 deaths annually due to colorectal cancer carrying Wnt/APC/β-catenin pathway mutations in the Unites States alone. Additionally, germline mutations of APC lead to the hereditary cancer syndrome, FAP, which affects approximately 16,000 additional patients in the United States annually.

Wnt signaling controls the level of intracellular activated β-catenin, a key effector of oncogenic signal transduction, and oncogenic alterations in Wnt, APC, or β-catenin all result in elevated and uncontrolled levels of β-catenin. Wnt signaling is initiated upon binding of secreted Wnt ligands to Frizzled receptors and low-density lipoprotein receptor-related protein ("LRP") co-receptors, which induces phosphorylation of Dishevelled ("Dvl"). Phosphorylated Dvl then associates with Axin, leading to dissociation of the β-catenin destruction complex (which includes APC and GSK3β). Free β-catenin then accumulates in the cytoplasm and translocates to the nucleus. Mutations which activate the Wnt pathway all culminate in the accumulation of high levels of oncogenic β-catenin in the cell nucleus. Therefore, we believe a successful intervention in this pathway requires lowering β-catenin levels or otherwise inhibiting it. β-catenin, a transcription factor, has been considered historically to be an "undruggable" target, lacking the deep binding pockets present in enzymes and receptors. As a result, drug screening efforts have primarily focused on other pathway components.

Recent studies have shown that PDE10 is overexpressed during early stages of tumorigenesis and is essential for tumor cell growth. PDE10 inhibition increases cyclic GMP levels in tumor cells to activate protein kinase G (PKG) signaling leading to the degradation of the oncogenic pool of β-catenin to suppress critical proteins essential for tumor cell proliferation and survival. For the foregoing reasons, we believe that targeting PDE10 provides a novel approach to selectively suppress β-catenin mediated transcriptional activity.

Wnt/APC/β-catenin and PDE10 pathways



Adapted from Li et al., Oncogene, 2014

Abbreviations:

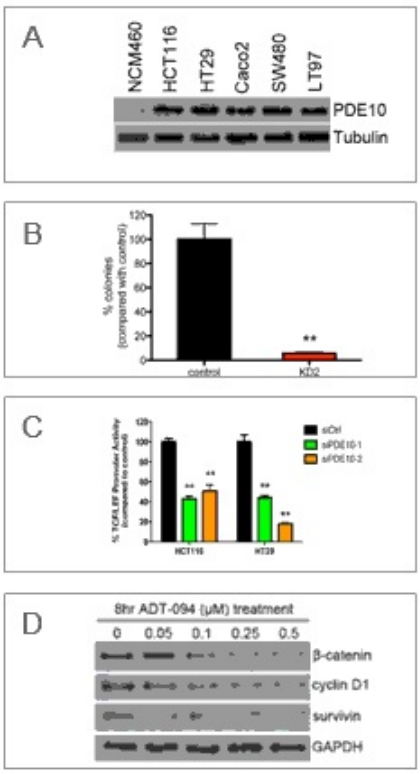
5'GMP =	*guanosine monophosphate*	*cGMP =*	*cyclic guanosine monophosphate*
GTP =	*guanosine triphosphate*	*NO =*	*nitric oxide*
PDE10 =	*phosphodiesterase type 10*	*pGC =*	*particulate guanylyl cyclase*
PKG =	*protein kinase G*	*sGC =*	*soluble guanylyl cyclase*
TCF =	*T-cell factor*		

Our Approach

Our PDE10/ β-catenin program has identified small molecule indene derivatives that selectively and potently inhibit PDE10 and suppress Wnt/APC/β-catenin signaling in preclinical models. PDE10 inhibition has been shown to down regulate β-catenin expression and inhibits polyp and tumor growth. It has potential for application in the treatment of cancer as well as spontaneous and familial polyposis syndromes. Our orally available small molecule PDE10 inhibitors have unique advantages over known PDE10 inhibitors with potential for development in FAP, colon, lung, liver, breast and other cancers.

Inhibition of PDE10 induces cGMP/PKG signaling to phosphorylate and induce degradation of β-catenin to suppress key proteins essential for tumor cell proliferation and survival. PDE10 knockdown ("KD") or inhibition with small molecules inhibits growth and colony formation of colon, lung, and breast tumor cells.

PDE10 overexpression in colon tumor cells; inhibition blocks colony formation and ß-catenin/Tcf transcription.



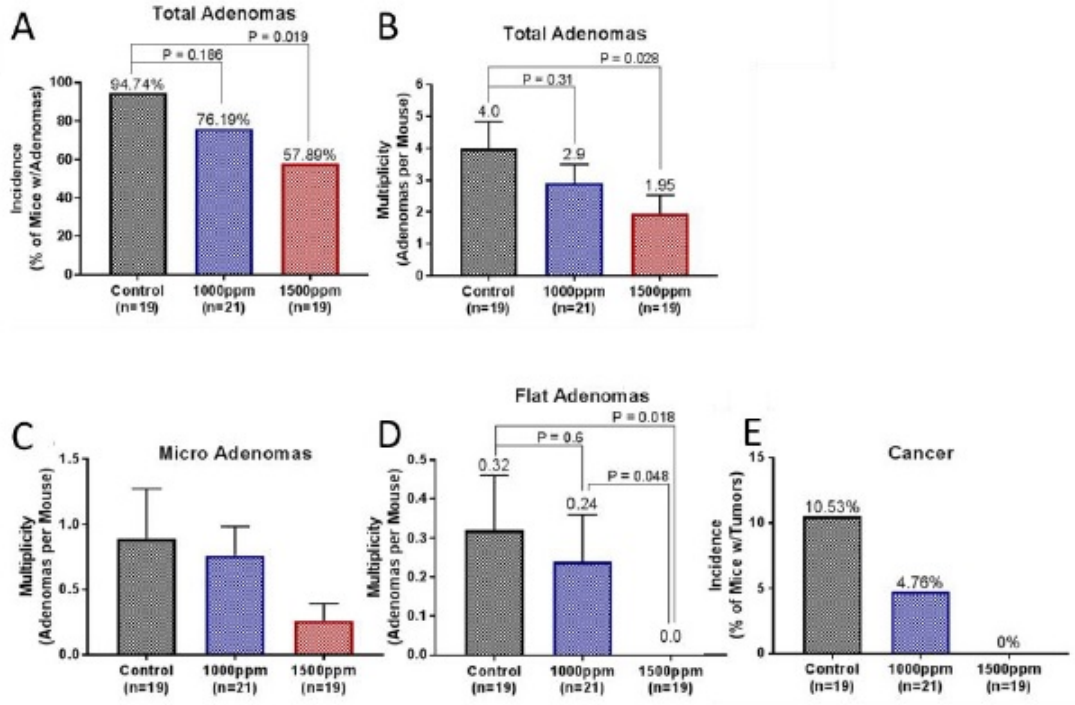
Panels:

- ***A:*** Differential PDE10 levels in normal colonocytes (NCM460) and colon tumor cells as measured by Western blot.
- ***B:*** PDE10 siRNA knockdown inhibits colony formation of HT29 colon tumor cells.
- ***C:*** PDE10 siRNA suppresses Tcf transcription of key regulatory genes (e.g., survivin, cyclin D, myc, etc.).
- ***D:*** Treatment of HT29 cells with PDE10 inhibitor ANC 094 (also referred to as ADT-094) leads to reduction of ß-catenin and products of Tcf transcription as measured by Western blot.

Source: Li et al., Oncogene, 2015; Data on File.

One representative compound in this program, ANC 061 (also referred to as MCI-030) inhibits PDE10 to activate cGMP/PKG signaling, resulting in the phosphorylation and degradation of the oncogenic pool of β-catenin to selectively inhibit the growth of colon tumor cells in vitro. Oral administration to mice with the Apc+/min-FCCC genotype (a mouse strain with the APC mutation that produces an augmented incidence of colorectal adenomas and small intestinal cancers, used as a model to study polyposis syndromes and colon cancer) significantly inhibited incidence and multiplicity of colon adenomas and carcinomas in a dose-dependent fashion. Further *in vivo* studies with ANC 061 are in progress at Fox Chase Cancer Center to confirm these findings. These studies are funded by NCI, and if proof of concept is established there is the potential to further develop this compound in FAP in collaboration with NCI through its PREVENT Cancer Preclinical Drug Development Program.

Inhibition of Colon Tumorigenesis in the Apc^{Min} Model



Panels:

- ***A,*** ANC 061 (MCI-030) induced a dose dependent decrease in adenoma incidence from 94.74% in control mice to 76.19% in mice treated with 1000 parts per million (ppm) ANC 061 and 57.80% of mice treated with 1500 ppm ANC 061.

- ***B,*** Adenoma multiplicity was also significantly reduced from 4.0 in the control group to 2.9 in mice treated with 1000 ppm ANC 061, and to 1.95 in mice treated with 1500 ppm ANC 061.

- ***C,*** A reduction in micro adenomas was also observed.

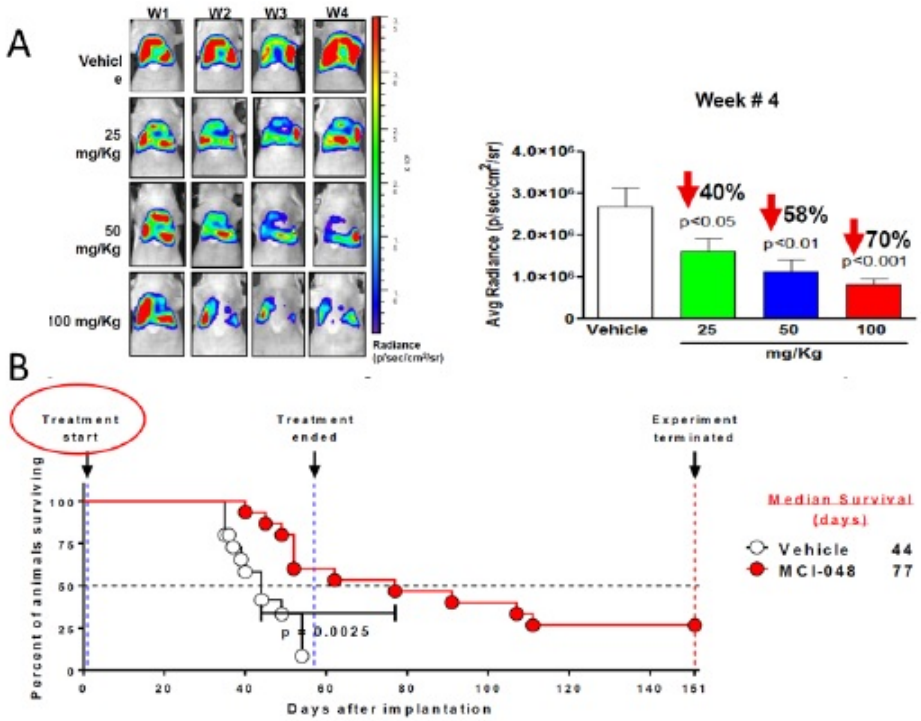
- ***D,*** Multiplicity of flat adenomas was abolished in mice receiving 1500 ppm and reduced in mice treated with 1000 ppm ANC 061 from 0.32 per mouse in the control group to 0.24, respectively.

- ***E,*** Incidence of mice with cancer was reduced from 10.53% in the vehicle group to 4.76% in mice treated with 1000 ppm ANC 061 and to 0% in mice treated with 1500 ppm ANC 061, n=19-21.

Source: Ward et al., AACR 2019.

Another compound in this program, ANC 030 (also referred to as MCI-048) administered orally inhibits tumor growth in an orthotopic lung cancer mouse model without apparent toxicity. ANC 030 significantly extends survival in the A549 mouse model from a median 44 to 77 days with 25% of mice surviving until the end of the experiment. It was also effective in multiple other mouse models of lung and breast cancer, including models of metastasis.

Inhibits Lung Tumorigenesis in A549 Lung Cancer Model



Panels:

- ***A,*** The A549 human lung adenocarcinoma cells with luciferase (Luc) tag were generated using lentiviral particles expressing luciferase gene driven by a CMV promoter and a stable A549Luc clone was selected. Female athymic nude mice were implanted with $1x10^6$ A549Luc cells intrathoracically. Mice were treated by oral gavage once a day with the vehicle (Maalox) or MCI-048 at doses of 25, 50, or 100 mg/kg (n = 7/group) starting five days before tumor cell implantation. After implantation, treatment continued for 4 additional weeks. Tumor growth was monitored weekly through the detection of the bioluminescence of the A549Luc cells using In Vivo Imaging System (IVIS, IVIS Spectrum, Caliper Life Sciences). Signal intensity was quantified as the average number of photons emitted from a mouse within the chest cavity (Living Image software, version 4.3.1.)

- ***B,*** Female athymic nude mice were implanted with $1x10^6$ cells per mouse of cultured A549 human lung adenocarcinoma cells into the intrathoracic space of the left lung on Day 0. Animals were randomly assigned to two treatment groups (n=15) on Day 1 and treated with either MCI-048 formulated in Maalox by oral gavage at a dose of 100 mg/kg once daily for 8 weeks or with Maalox using the same schedule starting on Day 1. All surviving mice were euthanized on Day 151.

Source: Zhu et al. AACR 2019

Preclinical Development

We initiated development of a series of compounds that exhibit potent PDE10 inhibition and induce degradation of β-catenin to suppress key proteins essential for tumor cell proliferation and survival. Initial plans for continued preclinical development will be funded with ADT using SBIR grants to ADT. While we are excited by the potential for this program, we have made the decision to initially prioritize advancement of our pan-RAS program. Once a product candidate has been nominated for IND-enabling studies in the pan-RAS program, we plan to allocate resources for development of the PDE10/ β-catenin program. We estimate approximately six months will be necessary from that time for lead optimization and product candidate nomination. From lead candidate nomination, we anticipate approximately 12 months to perform IND enabling studies and submit an IND for First in Human studies. Development of the program could potentially be accelerated with additional resources.

Clinical Development Plan and Regulatory Pathway

Clinical development will be initiated once a lead product candidate has been nominated, all necessary Investigational New Drug (IND) enabling studies have been performed and an IND application has been successfully submitted to and accepted by the USA. Initial Phase 1 clinical investigation in cancer will be performed in patients with advanced solid tumors, focusing on tumor types where the Wnt/APC/β-catenin pathway is implicated such as colorectal cancer, hepatocellular carcinoma, breast cancer and lung cancer, with the objective of identifying a recommended Phase 2 dose and to evaluate the safety and tolerability of the product candidate, as well as to evaluate preliminary anti-tumor activity. We anticipate that colorectal cancer may be an initial indication of focus in pivotal development, given the prominence of the Wnt/APC/β-catenin pathway in this disease. Subsequent development will be dependent on the signs of activity observed. If efficacy data allows (i.e. high response rate with meaningful duration of response in an indication of high unmet need), an accelerated approval path based on Phase 2 data may be considered. If not, a more traditional approach with a randomized Phase 3 program comparing to standard of care treatment will be required.

A separate development path in FAP may also be pursued. This would initiate with a Phase 1 dose escalation study in healthy volunteers (single dose) and FAP patients (multiple dose). A randomized Phase 3 program in patients with FAP is anticipated to be required for registration.

As mentioned above, in light of business circumstances, and in order to conserve cash and preserve optionality while alternatives are being identified and assessed, we made a decision during July 2020 to undertake reductions in headcount and other cost saving measures. These included plans to temporarily reduce our internal and external research and development work on the Company's PDE10/β-catenin Programs until there is greater clarity regarding Anchiano's ability to fund the program. We continue to undertake actions for the promotion of the program and its assets and towards strengthening the protection of all related intellectual property.

Collaborations and License Agreements

ADT

In September 2019, we entered into the Collaboration Agreement with ADT pursuant to which we agreed to use commercially reasonable efforts to conduct research and development activities with respect to the pan-RAS and PDE10/β-catenin programs under the oversight of a steering committee jointly established with ADT. ADT is a private company focused on discovering, developing and securing patent protection for novel molecules that inhibit activated RAS- or Wnt-mediated signaling pathways that drive the growth of many human cancers. ADT's technology currently comprises a broad, novel proprietary small-molecule class, encompassing at least two distinct mechanistic subclasses that share a common chemical core; one subclass targets RAS and the other subclass inhibits PDE10 to activate cGMP/PKG signaling and induce degradation of the oncogenic pool of β-catenin.

Under the terms of the Collaboration Agreement, we were granted an exclusive option to license the RAS and PDE10/β-catenin programs in exchange for a $3.0 million upfront payment to ADT and will fund certain research activities. At any time through obtaining an IND designation, we will have the option to exclusively license the compounds we develop worldwide and will be responsible for all aspects of preclinical and clinical development and global commercialization. If we exercise our option, we will pay ADT an option exercise fee and will be responsible for development and commercialization of any compounds or products containing any compounds under the pan-RAS and PDE10/ß-catenin programs. We will also incur additional payment obligations to ADT for any product candidates developed under the pan-RAS and PDE10/ß-catenin programs, including milestone payments based on certain events with respect to product development and regulatory achievements, and royalty payments based on net sales of any commercialized products. We are responsible for all aspects of development for the pan-RAS and PDE10/ß-catenin programs. We also have the option to sublicense the licenses granted to us by ADT.

In connection with the Collaboration Agreement, we also entered into a Consulting and Collaboration Research Support Agreement with ADT (the "Support Agreement"), whereby ADT provides support services for our research and development activities with respect to the pan-RAS and PDE10/ß-catenin programs, including providing key research and discovery personnel, in exchange for a fee.

ADT may terminate the Collaboration Agreement in the event of a material default in any of our material obligations under the Collaboration Agreement (following a cure period). In the event the Collaboration Agreement is terminated, all licenses and options granted to us will be terminated and we will not be able to develop the compounds under the pan-RAS and PDE10/ß-catenin programs or any products containing such compounds. The Collaboration Agreement also restricts assignment except to a successor of substantially all of the business to which the Collaboration Agreement relates, whether in a merger, sale of stock, sale of assets, reorganization or other transaction.

Yissum

On November 14, 2005, we entered into the License Agreement with Yissum, which was subsequently amended several times, most recently in November 2013. Yissum granted us an exclusive, worldwide license for the development, use, manufacture and commercialization of products arising out of patents owned by, and patent applications filed by Yissum in connection with the H19 and IGF2-P4 genes. Yissum retained right, title and interest in the products, technologies or other inventions arising out of our research and development of these patents and patent applications, except for intellectual property developed with funding from the Israel Innovation Authority ("IIA"), which will be owned by us and transferred to Yissum only upon our dissolution or termination of the License Agreement or upon a decision by the IIA that it no longer requires us to own the intellectual property developed with its funding. We have the right to grant sub-licenses to third parties in accordance with the terms set forth in the License Agreement.

In November 2019, we discontinued the pivotal Phase 2 Codex study, evaluating the gene therapy inodiftagene in patients with BCG-unresponsive NMIBC. After a thorough analysis of the data, we determined that there was a low probability of surpassing the pre-defined futility threshold at the planned interim analysis, which required 10 complete responses in 35 patients. At the time we discontinued the study, 16 patients were evaluable after the first disease assessment on treatment, of which three patients, or 19%, had experienced a complete response. The data also indicated a low probability of achieving an efficacy profile that in the company's estimation would be necessary to support regulatory approval. The safety data on the investigational product were consistent with those observed in prior trials.

In April 2020 we notified Yissum that as a result of our decision to discontinue clinical development of inodiftagene, we will cease payments to maintain intellectual property ("IP") we licensed from Yissum that supported the development and as related to the License Agreement. In August 2020 we agreed with Yissum on termination of the License Agreement, we destroyed or returned all IP documentation to Yissum, and Yissum and we mutually waived, released and discharged the other from all claims of any type.

Our Competitive Strengths

Our technologies are small molecule targeted therapies that are directed against two pathways that have been long understood to contribute fundamentally to the pathogenesis of human cancer, the RAS pathway and the Wnt/APC/β-catenin biochemical pathway. We are initially focusing on our pan-RAS program, and we are developing compounds that exhibit pan-RAS cytotoxicity.

We believe we can develop these compounds into product candidates, and that our competitive strengths put us in a unique position for success if we pursue the path towards further development after the review of strategic alternatives, as follows:

- ***Our product candidates are targeted therapies.*** We believe that the application of small molecule targeted therapy approaches to pan-RAS inhibition has a high likelihood of success. The development of small molecule targeted therapies against the products of mutated driver oncogenes is one of the most productive endeavors in the field of cancer therapy. Mutated driver oncogenes cause cancer cell proliferation, the first and most fundamental hallmark of cancer. The RAS genes are the most common example of such mutated driver oncogenes. These cancer genes have been identified by natural selection as being critical drivers of malignant proliferation and they are prime therapeutic targets. This potential for therapeutic exploitation has in turn been coupled with progress in physical methods and chemical engineering that allow the design of small molecules that directly inhibit the function of the key mutated driver genes. This approach has resulted in successful therapies for cancers whose genetic alterations include mutations in a variety of oncogenes. An important observation from this field is that, in general, preclinical data, both *in vitro* and *in vivo*, have been very strongly predictive for the development of these therapies. If the physical inhibition of the target molecule can be established and characterized by structural, chemical and biochemical methods and the target gene is a mutated positively acting driver gene, then preclinical activity correlates strongly with clinical activity. The RAS family of genes are driver oncogenes, the most commonly mutated oncogenes known. We believe that our existing preclinical data demonstrating and characterizing small molecule pan-RAS inhibition forms the foundation for development of these molecules into product candidates that can be used in clinical settings.

- ***Our molecules are first-in-class molecules.*** There are no small molecule targeted therapies that have successfully been shown to exhibit pan-RAS inhibitory activity, and whose mechanism of action involves direct inhibition of RAS. A variety of approaches to RAS inhibition have been tested, including interference with the intracellular localization and processing of RAS, inhibition of its binding to other signaling molecules, and other approaches. Current clinical–stage investigational drugs, such as AMG-510, have been shown to bind to and directly inhibit the KRAS G12C mutation, a subset of mutant RAS proteins. KRAS is one of 3 RAS family genes, and approximately 9% of RAS mutations are KRAS G12C mutations. To our knowledge, no other pan-RAS inhibitors like our molecules are currently being tested.

- ***Our preclinical data strongly support the activity of our molecules against cancer.*** The characteristics one would predict in molecules with preclinical pan-RAS inhibitory activity include: selectivity for activated RAS; nanomolar potency against cells harboring mutant RAS; consistency of biochemical data with RAS inhibition (as opposed to other pathway points of inhibition); evidence for binding RAS directly; *in vivo* anti-tumor activity; and immunological stimulation *in vivo* consistent with other clinical RAS inhibitors. Our small molecule inhibitors have been demonstrated to have these characteristics, and we believe we can develop our molecules into product candidates that will have potential for pan-RAS inhibition in a variety of clinical settings.

- ***Recent data have validated cancer treatment with a RAS inhibitor.*** Until recently, the unique biochemistry and biology of the RAS gene family had resisted efforts of cancer biologists to discover and develop drugs capable of inhibiting the activity of the mutated protein. However, recent developments have led to the discovery of small molecules capable of inhibiting a particular mutated form of RAS, known as KRAS G12C. Preliminary successes of drugs under development such as AMG-510 and MRTX849, are field-altering, as for the first time there is evidence that inhibition of mutated RAS isoforms may be undertaken in the same manner as other successful small molecule targeted therapies had shown possible against other mutated oncogenes. In other words, RAS is a clinically validated target susceptible to small-molecule targeted therapy approaches.

- ***Our development plan addresses substantial unmet needs.*** Despite the preliminary success demonstrated by AMG 510 and MRTX849, KRAS is only one of three mutated isoforms of the RAS gene family, comprising approximately 85% of RAS mutations, and only approximately 11% of KRAS mutations are of the G12C type. A number of tumor types have large proportions of mutations in other RAS isoforms. Melanoma exhibits mutations in RAS in approximately 30% of cases, almost all of which are in NRAS. Of the 55% of colorectal cancers that carry RAS mutations, 5% are NRAS. Approximately half of the mutations in multiple myeloma are in NRAS. The RAS mutations in thyroid cancer and acute myeloid leukemia are predominantly NRAS (approximately 5-15% (depending on sub-type) and 15% respectively) . Bladder and head and neck cancers carry largely HRAS mutations. This means that while recent observations have proven that RAS-directed therapy using small molecule inhibitors is possible with clinical effect, results so far are confined to a small subset of patients carrying a particular mutation. In a larger sense, even though preliminary success has been demonstrated by KRAS G12C mutation inhibitors, at this time there are no approved inhibitors of mutated RAS in cancers that carry these genetic lesions. We believe there is much potential for broader treatment of RAS-mutated tumors, for treatment of tumors that have become resistant after KRAS G12C mutation-inhibitor therapy, for earlier line treatment and for combination therapy, and we believe that we can develop our molecules into product candidates capable of potentially meeting these broader needs.

Intellectual Property

While our policy is to obtain patents by application, license or otherwise, to maintain trade secrets and to seek to operate without infringing on the intellectual property rights of third parties, technologies related to our business have been rapidly developing in recent years. Additionally, patent applications that we may file or license from third parties may not result in the issuance of patents, and our current or future issued patents may be challenged, invalidated or circumvented. Therefore, we cannot predict the extent of claims that may be allowed or enforced against our patents, nor be certain of the priority of inventions covered by pending third-party patent applications. If third parties prepare and file patent applications that also claim technology or therapeutics to which we have rights, we may have to engage in proceedings to determine priority of invention, which could result in substantial costs to us, even if the eventual outcome is favorable. Moreover, because of the extensive time required for clinical development and regulatory review of products we may develop, it is possible that the patent or patents on which we rely to protect such products could expire or be close to expiration by the commencement of commercialization, thereby reducing the value of such patent. Loss or invalidation of certain of our patents, or a finding of unenforceability or limited scope of certain of our intellectual property, could have a material adverse effect on us. See "*Risk Factors—Risks Related to Our Intellectual Property and Potential Litigation.*"

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, such agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors or others.

Pan-RAS and PDE10/β-catenin Program Patents

Pursuant to the Collaboration Agreement, we have been granted an exclusive option to license patent rights for our pan-RAS and PDE10/b-catenin programs. This patent portfolio includes three issued U.S. patents, 2 issued Japanese patents, and one issued patent in each of China, Australia, Europe and Hong Kong directed to RAS inhibitor compounds, prodrugs and methods of use. In addition to this we have two pending related U.S. patent applications directed to RAS and PDE10 inhibitor compounds and corresponding foreign pending counterpart patent applications, and one Patent Cooperation Treaty ("PCT") patent application directed to RAS inhibitor compounds. The issued patents, and pending U.S. patent applications, if issued, will expire in 2035. We expect any patents based on the PCT application, if we continue to pursue patent protection in the United States and elsewhere, if issued, to expire in 2039.

Additional Technologies

- BC-821 - Our licensed patent portfolio includes two issued U.S. patents directed to composition of matter and method of use, and related issued foreign patents and patent applications. We expect these patents and patent application, if issued, to expire between 2028 and 2029.

- Cancer-Specific TNF-α and DTA mutual expression vector - Our licensed patent portfolio includes one U.S. patent directed to nucleic acid vectors and related issued foreign patents. We expect these patents to expire in 2026.

- H19 targeted siRNA for cancer - Our licensed patent portfolio includes one issued U.S. patent directed to composition of matter, and related foreign patents. We expect these patents to expire in 2026.

- H19 targeted siRNA for rheumatoid arthritis - Our licensed patents include one issued U.S. patent directed to methods for treating rheumatoid arthritis, and related foreign patents. We expect these patents to expire in 2028.

Marketing, Sales and Distribution

Given our stage of development, we do not have any internal sales, marketing or distribution infrastructure or capabilities. In the event we receive regulatory approval for a future product candidate and secure adequate funding, we intend, where appropriate, to consider commercialization relationships. In addition, we may consider out-licensing some or all of our worldwide patent rights to more than one party to achieve the fullest development, marketing and distribution of any future product we develop.

Competition

Competition in the development of human cancer therapeutics, in particular targeted therapies, is intense and rapidly evolving. We face competition both in the United States and internationally from small and large private and publicly traded biotechnology and pharmaceutical companies, government agencies, universities and other research institutions. Many of our competitors have substantially greater resources and capabilities, in the form of financing, development, manufacturing, and commercialization, than we do. Our ability to create value for our shareholders depends on our ability to successfully develop product candidates that have differentiated benefits from competing drugs and biologics, that are either in development or commercially available. While we believe our approach, expertise, focus and intellectual property provide us with a competitive advantage, we are aware of several companies that inhibit the same molecular target, and in some cases in the same population, being pursued by us. We believe our primary competitors by program and target are as follows:

Pan-RAS Program: We are not aware of any competitors with development programs or molecules in clinical testing that target mutations across all three RAS family of genes (HRAS, KRAS, and NRAS). We are aware of several competitors with clinical and preclinical development programs that directly target one or more mutations in KRAS family of genes, including Mirati Therapeutics, Inc., Amgen, Inc., Boehringer Ingelheim AG, Merck & Co., Inc., and others. It is likely that other companies are also researching inhibitors in the HRAS and NRAS families of genes. We will continue to monitor scientific and patent publications for the emergence of other potential competitors.

PDE10/β-catenin Program: We are aware of several companies that have PDE10 inhibitor programs in preclinical or clinical development, including among others, H. Lundbeck A/S, Omeros Corporation, and Celon Pharma SA –mainly focused on CNS indications. Likewise, we are aware of several companies that have β-catenin inhibitor program in preclinical or clinical development, including among others, PRISM Pharma Co., Ltd, and Fog Pharmaceuticals, Inc. We will continue to monitor scientific and patent publications for the emergence of other potential competitors.

Government Regulation

We are subject to extensive regulation by the various national health regulatory authorities, such as the FDA, Health Canada and other national, state and provincial regulatory agencies.

U.S. Food and Drug Administration

The research, development, and marketing authorization of drugs and other pharmaceutical products in the United States is subject to the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), which empowers the FDA to require extensive non-clinical and clinical toxicity testing before a new drug or biologic is deemed safe and effective and receives marketing authorization. Following initial laboratory and animal testing that show that investigational use in humans is reasonably safe, a drug can be studied in clinical trials in humans under an IND in accordance with the regulations at 21 CFR 312.

In order to satisfy FDA data requirements, an extensive battery of preclinical experiments to assess the safety of such new drugs are conducted, followed by two or three phases of clinical trials before they are considered for widespread human use. Upon successful completion of a future clinical trial program, we may be in a position to manufacture and market our prospective pharmaceutical products. The marketing authorization of our products would be conditional upon obtaining the approval of health authorities in each country in which they would be marketed, including, but not limited to, the FDA and the EMA. FDA regulations govern the following activities that we may perform, or that have been performed on our behalf, to ensure that drugs that we develop are safe and effective for their intended uses:

- preclinical (animal) testing including toxicology studies;
- submission of an IND;
- human testing in clinical trials, Phases 1, 2 and 3;
- recordkeeping and retention;
- pre-marketing review through submission of a new drug application ("NDA");
- drug manufacturing, testing and labeling, which must comply with current good manufacturing practice ("cGMP") regulations;
- drug marketing, sales and distribution; and
- post-marketing study commitments (Phase 4), post-marketing pharmacovigilance surveillance, complaint handling, reporting of deaths or serious injuries, product sample retention, manufacturing deviation reporting and repair or recall of drugs.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- disqualification of clinical investigator and/or sponsor from current and future studies;
- clinical hold on clinical trials;
- operating restrictions, partial suspension or total shutdown of production;
- refusal to approve an NDA;
- post-marketing withdrawal of approval; and
- criminal prosecution.

The FDA's preclinical and IND requirements

The first step to obtaining FDA approval of a new drug involves development, purification and pre-clinical testing of a pharmaceutically active agent in laboratory animals. Once appropriate preclinical data have been generated to demonstrate that the drug is reasonably safe for initial testing in humans, an IND can be prepared and submitted to the FDA for review. In the IND review process, FDA physicians and scientists evaluate the proposed clinical trial protocol, chemistry and manufacturing controls, pharmacologic mechanisms of action of the drug and toxicological effects of the drug in animals and *in vitro*. Within 30 days of the IND submission, the drug review division of the FDA may contact the filer regarding potential concerns and, if necessary, implement a clinical hold until certain issues are resolved satisfactorily. If the FDA does not take any action, the filer may proceed with clinical trials on the 31st day.

Clinical trials

Clinical trials represent the pre-market testing ground for unapproved drugs, generally taking several years to complete. Before testing can begin, an institutional review board ("IRB") must have been reviewed and approved for the use of human subjects in the clinical trial. During clinical trials, an investigational compound is administered to humans and evaluated for its safety and effectiveness in treating, preventing or diagnosing a specific disease or condition. The clinical trials generally consist of Phase 1, Phase 2, and Phase 3 testing. During clinical trials, the FDA and IRBs closely monitor the studies and may suspend or terminate trials at any time for a number of reasons, such as finding that patients are being exposed to an unacceptable health risk. The results of clinical trials are critical factors in the approval or disapproval of a new drug.

Submission and review of an NDA

An NDA requesting approval to market the drug for one or more indications may be submitted to the FDA once sufficient data has been gathered through preclinical and clinical testing. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the drug's chemistry, manufacturing, controls and proposed labeling, among other things. In most cases, the submission of an NDA is subject to a substantial application fee.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the NDA submission is accepted for filing, the FDA begins an in-depth substantive review. NDAs receive either standard or priority review. The FDA has a goal of ten months from the date of filing to review and act on a standard NDA for a new molecular entity. A drug representing a significant improvement over existing therapy in the treatment, prevention or diagnosis of a disease may receive priority review.

The FDA has various specific programs, including Fast Track, Breakthrough Therapy, Accelerated Approval and Priority Review, each of which is intended to expedite the process for reviewing drugs, and in certain cases involving Accelerated Review, permit approval of a drug on the basis of a surrogate endpoint. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Fast Track designation facilitates the development and expedites the review of drugs to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Although this designation does not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug.

The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the drug is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the drug within required specifications. In addition, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with good clinical practice requirements.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases, subpopulations, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require us to conduct Phase 4 testing, which involves clinical trials designed to further assess a drug's safety and/or effectiveness after NDA approval and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized.

Pervasive and continuing regulation in the United States

After a drug is approved for marketing and enters the marketplace, numerous regulatory requirements continue to apply. These include, but are not limited to:

- The FDA's cGMP regulations require manufacturers, including third-party manufacturers, to follow stringent requirements for the methods, facilities and controls used in manufacturing, processing, testing and packing of a drug product;
- Labeling regulations and the FDA prohibitions against the promotion of drug for unapproved uses (known as off-label uses), as well as requirements to provide adequate information on both risks and benefits during promotion of the drug;
- Approval of product modifications or use of the drug for an indication other than approved in the NDA;
- Adverse drug experience regulations, which require companies to report information on rare, latent or long-term drug effects not identified during pre-market testing;
- Post-market testing and surveillance requirements, including Phase 4 trials, when necessary, to protect the public health or to provide additional safety and effectiveness data for the drug; and
- The FDA's recall authority, whereby it can ask, or under certain conditions order, drug manufacturers to recall from the market a product that is in violation of governing laws and regulations.

After a drug receives approval, any modification in conditions of use, active ingredient(s), route of administration, dosage form, strength or bioavailability, will require a new clearance or approval, for which it may be possible to submit a supplemental NDA, referring to preclinical and certain clinical studies presented in the drug's original NDA, accompanied by additional clinical data necessary to demonstrate the safety and effectiveness of the product with the proposed changes. Additional clinical studies may be required for proposed changes.

Fraud and abuse laws in the United States

A variety of U.S. federal and state laws apply to the sale, marketing and promotion of drugs that are paid for, directly or indirectly, by U.S. federal or state healthcare programs such as Medicare and Medicaid. The restrictions imposed by these laws are in addition to those imposed by the FDA, the U.S. Federal Trade Commission and corresponding state agencies. Some of these laws significantly restrict or prohibit certain types of sales, marketing and promotional activities by drug manufacturers. Violation of these laws may result in significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties and exclusion or debarment from United States federal and state healthcare and other programs. Many private health insurance companies also prohibit payment to entities that have been sanctioned, excluded or debarred by U.S. federal agencies.

Anti-kickback statutes in the United States

The U.S. federal anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending of a good or service, for which payment may be made in whole or in part under a United States federal healthcare program such as the Medicare and Medicaid programs. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, the furnishing of supplies or equipment, payments of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that, if any one purpose of an arrangement involving remuneration is to induce referrals or otherwise generate business involving goods or services reimbursed in whole or in part under federal healthcare programs, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other U.S. federal healthcare programs. In addition, some kickback allegations have been claimed to violate the U.S. False Claims Act (as discussed below).

The federal anti-kickback statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the statute is broad and may technically prohibit many innocuous or beneficial arrangements, the Office of Inspector General of the Department of Health and Human Services ("OIG") has issued a series of regulations, known as "safe harbors." These safe harbors set forth provisions which, if met in form and substance, will assure healthcare providers and other parties that they will not be prosecuted under the federal anti-kickback statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy an applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG or the United States Department of Justice.

Many states have adopted laws similar to the U.S. federal anti-kickback statute. Some of these state prohibitions are broader than the U.S. federal statute, and apply to the referral of patients and recommendations for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs. Government officials have focused certain enforcement efforts on marketing of healthcare items and services, among other activities, and have brought cases against individuals or entities with sales personnel who allegedly offered unlawful inducements to potential or existing physician customers in an attempt to procure their business.

U.S. False Claims Act

The U.S. False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment by a federal healthcare program or knowingly making, or causing to be made, a false statement or record in order to have a false claim paid or avoiding, decreasing or concealing an obligation to pay money to the federal government. The federal government's interpretation of the scope of the law has in recent years grown increasingly broad. Most states also have statutes or regulations similar to the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment. Several drug manufacturers have been prosecuted under the false claims laws for allegedly providing free drugs to physician customers with the expectation that the physician customers would bill federal programs for the product. In addition, several recent cases against drug manufacturers have alleged that the manufacturers improperly promoted their products for "off-label" use, outside of the scope of the FDA-approved labeling.

U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA)

HIPAA created a new federal healthcare fraud statute that prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government-sponsored programs. Among other things, HIPAA also imposes new criminal penalties for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services, along with theft or embezzlement in connection with a healthcare benefits program and willful obstruction of a criminal investigation involving a federal healthcare offense. Further, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information on its behalf and their subcontractors that use, disclose, access, or otherwise process individually identifiable health information.

U.S. Affordable Care Act Section 6002 (the Sunshine Act)

Enacted in 2010 under the Affordable Care Act of 2010, Public Law No. 111-148 (the "ACA"), the Physician Payments Sunshine Act is a national disclosure program that promotes transparency by publishing data on the financial relationships between the healthcare industry (applicable manufacturers) and healthcare providers (physicians and teaching hospitals) on a publicly accessible website. The Sunshine Act requires that certain manufacturers of drugs, devices, biologicals, or medical supplies report payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals as well as certain ownership or investment interests held by physicians or their immediate family members to the Centers for Medicare & Medicaid Services (CMS). Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives. A violation of this act may result in fines and/or civil liabilities. Any payment or transfer of value that is currently prohibited under the anti-kickback statute, the U.S. False Claims Act, or other health care fraud and abuse laws may still be subject to fines, sanctions, or lawsuit.

Non-U.S. regulation

Marketing authorization requests outside of the United States are subject to regulatory approval of the respective authorities in the country in which we would like to market. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved prior to its marketing application approval. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices might not be approved for such product. In the European Union, authorization can be obtained through one of the following pathways: (i) the "centralized" procedure, described in greater detail below, with applications made directly to the EMA leading to the grant of a European marketing authorization by the European Commission, (ii) the "decentralized procedure," whereby companies may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country, or do not fall within the mandatory scope of the centralized procedure, (iii) the "mutual recognition" procedure, in which applications are made to one or more member states, leading to national marketing authorizations mutually recognized by other member states, or (iv) a "national authorization" application made to a single EU member state. Based on the nature of our products, the marketing authorization will be through the centralized procedure.

The EMA is responsible for the centralized procedure, which results in a single marketing authorization that is valid across the European Union. Applications through the centralized procedure are submitted directly to the EMA. The procedure consists of three milestones:

(i) Evaluation by a scientific committee for up to seven months, at the end of which the committee adopts an opinion on whether the drug should be approved for marketing. During this period, the EMA may send questions to the company, at which time the aforementioned review clock stops until answers are provided.

(ii) Formal decision by the EMA's Committee for Medicinal Products for Human Use, which is transmitted to the European Commission, which issues a formal decision on the authorization of the product.

(iii) Marketing authorization: Once a European Community marketing authorization has been granted, the marketing-authorization holder can begin to make the medicine available to patients and healthcare professionals in all EU countries.

Even after a company receives marketing authorization, EU law regulates the distribution, classification for supply, labeling and packaging, and advertising of medicinal products for human use. The European Union also regulates the manufacture of medicinal products, requiring cGMP, set forth in the EU Guidelines to Good Manufacturing Practice — Medicinal Products for Human and Veterinary Use.

EU pharmacovigilance directives and regulations require a company to establish post-market surveillance systems that include individual adverse reaction case reports, periodic safety update reports, and company-sponsored post-authorization safety studies. If a medicinal product's overall risk and benefit profile is found to have changed significantly for any reason, it may be required to be varied, withdrawn, or have its use suspended.

Patent term restoration and extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") which permits a patent restoration of up to five years for patent term lost during product development and FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The PTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Pharmaceutical coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may seek to obtain regulatory approval. In the United States and other markets, sales of any future product for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our prospective products, in addition to the costs required to obtain the FDA approvals. Additionally, a future product may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In March 2010, a significant healthcare reform was signed into law in the United States. The healthcare reform law substantially changes the way healthcare will be financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The healthcare reform law contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which has impacted existing government healthcare programs and resulted in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Additionally, the healthcare reform law:

- Increased the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- Required collection of rebates for drugs paid by Medicaid managed care organizations; and
- Imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

There have been executive, judicial and Congressional challenges to certain aspects of the healthcare reform law. The U.S. Supreme Court is currently reviewing the constitutionality of the healthcare reform law, although it is unknown when a decision will be made. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the healthcare reform law and our business.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. We expect additional healthcare reform initiatives to be adopted in the future, particularly in light of the new presidential administration. We also expect these initiatives to increase pressure on drug pricing. Further, it is possible that additional governmental action is taken in response to the evolving effects of the COVID-19 pandemic.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after agreeing on a reimbursement price. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to set their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Environmental, Health and Safety Matters

We, our agents and our service providers, including our manufacturers, may be subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal of hazardous, radioactive and biological materials and wastes and the cleanup of contaminated sites. We believe that our business, operations and facilities, including, to our knowledge, those of our agents and service providers, are being operated in compliance in all material respects with applicable environmental and health and safety laws and regulations. All information with respect to any chemical substance is filed and stored as a Material Safety Data Sheet, as required by applicable environmental regulations. Based on information currently available to us, we do not expect environmental costs and contingencies to have a material adverse effect on us. However, significant expenditures could be required in the future if we, our agents or our service providers are required to comply with new or more stringent environmental or health and safety laws, regulations or requirements.

Employees

As of December 31, 2020, we had 3 employees based in Jerusalem, Israel and our Cambridge, Massachusetts office. The following table sets forth the total number of full-time employees as of the periods indicated by function and geography:

	As of December 31,	
	2020	**2019**
Function:		
Administrative	3	8
Research and development	0	8
Total	3	16
Geography:		
Israel	2	9
Cambridge, Massachusetts, USA	1	7
Total	**3**	**16**

Local labor laws govern the length of the workday and workweek, minimum wages for employees, procedures for hiring and dismissing employees, determination of severance pay, annual leave, sick days, advance notice of termination, Social Security payments or regional equivalents, and other conditions of employment and include equal opportunity and anti-discrimination laws. None of our employees is party to any collective bargaining agreements. We generally provide our employees with benefits and working conditions beyond the required minimums. We have a good relationship with our employees, and have never experienced any employment-related work stoppages.

Available Information

The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are available to the public through this website at http://www.sec.gov.

We maintain a corporate website at www.anchiano.com. Our reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, including our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to those reports, are accessible through our website, free of charge, as soon as reasonably practicable after these reports are filed electronically with, or otherwise furnished to, the SEC. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider information on our website to be part of this Annual Report on Form 10-K.

Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risk Factors Summary

Risks Related to the Proposed Merger with Chemomab

- If the proposed merger with Chemomab is not consummated, Anchiano could suffer materially and Anchiano's share price could decline.
- If the Merger is not completed, Anchiano's board of directors may decide to pursue a dissolution and liquidation of Anchiano. In such an event, the amount of cash available for distribution to our shareholders, if any, will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.
- Our shareholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.
- Should the Merger be consummated, the combined company may not pursue the advancement of Anchiano's existing developmental programs.

Risks Related to Our Business

- The current pandemic of COVID-19 and the future outbreak of other highly infectious or contagious diseases could seriously affect our business.
- We will require substantial additional funds to complete our research and development activities, and, if additional funds are not available, we may need to significantly scale back or cease our business.
- There is substantial doubt as to whether we can continue as a going concern.
- We depend completely on the success of our two preclinical programs and, if we are not able to advance these successfully through the preclinical and clinical development process, our business prospects will be materially and adversely affected.

Risks Related to our Preclinical Development

- Our preclinical developmental programs are at an early stage. As a result, we are unable to predict if, or when, we will successfully develop or commercialize any product under either program.
- If the preclinical and clinical studies that we are required to conduct to gain regulatory approval are delayed or unsuccessful, we may not be able to market any product that we develop in the future.
- If toxicities or serious adverse or undesirable side effects are identified during preclinical or clinical development, we may need to abandon or limit such development.

Risks Related to our Dependence on Third Parties

- We are substantially dependent on our Collaboration Agreement with ADT. If we fail to comply with our obligations under the Collaboration Agreement into which we entered with ADT, we could lose development and commercialization rights that are critical to the continuation of our business if the Merger is not consummated.
- We expect to rely significantly on preclinical contract research organizations and clinical research organizations to assist us with the development of the Compounds and any product that we develop in the future.
- If we, or if our service providers or any third-party manufacturers, fail to comply with regulatory requirements, we or they could be subject to enforcement actions, which could adversely affect our ability to market and sell a product we develop in the future.

Risks Related to our Operations

- If we are unable to re-hire and retain qualified employees, our ability to implement our business plan may be adversely affected.
- Product liability claims or lawsuits could cause us to incur substantial liabilities.
- Significant disruptions of our information technology systems, or those of our third-party vendors, or security breaches could adversely affect our business operations and/or result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information, including, among other things, trade secrets or other intellectual property, proprietary business information and personal information, and could result in financial, legal, business, and reputational harm to us.

Risks Related to Government Regulation

- Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.
- Coverage and adequate reimbursement may not be available for any future product candidates, which could make it difficult for us to sell profitably, if approved.

Risks Related to Our Intellectual Property

- We may be required in the future to license patent rights from third-party owners in order to develop a product. If we cannot obtain such licenses, or if such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.
- If we are unable to obtain and enforce patent protection for our inventions, our ability to develop and commercialize any product that we develop in the future will be harmed.
- Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

Risks Related to the ADSs

- The ADS price could continue to be highly volatile and you may not be able to resell your ADSs at or above the price you paid for them.
- A limited number of shareholders will have the ability to influence the outcome of director elections and other matters requiring shareholder approval.
- Because we no longer qualify as a foreign private issuer, we are required to comply fully with the reporting requirements of the Exchange Act applicable to U.S. domestic issuers and, as a result, are have incurred and will continue to incur significant legal, accounting and other expenses that we would not incur as a foreign private issuer.
- You may be subject to limitations on transfer of your ADSs.

Risks Related to the Proposed Merger with Chemomab (the "Merger")

If the proposed merger with Chemomab is not consummated, Anchiano could suffer materially and Anchiano's share price could decline.

The consummation of the proposed Merger with Chemomab is subject to a number of closing conditions, including the approval by our shareholders, approval by Nasdaq of our initial listing application of our ordinary shares represented by American Depositary Shares in connection with the Merger, and other customary closing conditions. In addition, at the closing date of the Merger, the net cash held by Anchiano, as described in the Merger Agreement, shall be positive or zero, or, if it is negative, the deficit in such net cash at the closing date of the Merger shall be no greater than $300,000. We are targeting a closing of the transaction in March-April 2021.

If the proposed Merger is not consummated, we may be subject to a number of material risks, and our share price could be adversely affected, as follows:

- We have incurred and expect to continue to incur significant expenses related to the proposed Merger with Chemomab, even if the Merger is not consummated.

- The Merger Agreement contains covenants restricting our solicitation of competing acquisition proposals and the conduct of our business between the date of signing the Merger Agreement and the closing of the Merger. As a result, significant business decisions and transactions before the closing of the Merger require the consent of Chemomab. Accordingly, we may be unable to pursue business opportunities that would otherwise be in our best interest as a standalone company. We have invested significant time and resources in the transaction process and if the Merger Agreement is terminated we will have a limited ability to continue our current operations without obtaining additional financing.

- Our collaborators and other business partners and investors in general may view the failure to consummate the Merger as a poor reflection on our business or prospects.

- Some of our collaborators and other business partners may seek to change or terminate their relationships with us as a result of the proposed Merger or the failure thereof.

- As a result of the Merger, current and prospective employees could experience uncertainty about their future roles within the combined company. This uncertainty may adversely affect our ability to retain our key employees, who may seek other employment opportunities.

- Our management team may be distracted from day to day operations as a result of the proposed Merger.

- Nasdaq could determine to delist our ADSs which could have an adverse effect on the value of our ADSs and any future ability to raise capital.

In addition, if the Merger Agreement is terminated and our board of directors determines to seek another business combination, it may not be able to find a third party willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the Merger. In such circumstances, our board of directors may elect to, among other things, divest all or a portion of our business, or take the steps necessary to liquidate all of our business and assets, and in either such case, the consideration that we receive may be less attractive than the consideration to be received by us pursuant to the Merger Agreement and related financing.

If the Merger is not completed, Anchiano's board of directors may decide to pursue a dissolution and liquidation of Anchiano. In such an event, the amount of cash available for distribution to our shareholders, if any, will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the Merger will be completed. If the Merger is not completed, our board of directors may decide to pursue a dissolution and liquidation of Anchiano. In such an event, the amount of cash available for distribution to our shareholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our shareholders were to approve, a dissolution and liquidation, we would be required under Israeli law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our shareholders. As a result of this requirement, a portion of our remaining cash assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of Anchiano ADSs could lose all or a significant portion of their investment in the event of Anchiano's liquidation, dissolution or winding up.

Some Anchiano officers and directors have interests in the Merger that may influence them to support or approve the Merger.

Some of our officers and directors participate in arrangements that provide them with interests in the Merger that are different from our shareholders, including, among others, the continued service as an officer or director of the combined company, continued indemnification and the potential ability to sell an increased number of shares of the combined company in accordance with Rule 144 under the Securities Act of 1933, as amended. These interests, among others, may influence our officers and directors to support or approve the Merger.

The Merger may be completed even though material adverse changes may result from the announcement of the Merger, industry-wide changes and other causes.

In general, either party can refuse to complete the Merger if there is a material adverse change affecting the other party following December 14, 2020, the date of the Merger Agreement. However, some types of changes do not permit either party to refuse to complete the Merger, even if such changes would have a material adverse effect on Anchiano, to the extent they resulted from the following (unless, in some cases, they have a disproportionate effect on Anchiano or Chemomab, as the case may be):

- changes or conditions generally affecting the industries or markets in which Anchiano and Chemomab operate, and changes in the industries in which Anchiano and Chemomab operate regardless of geographic region (including legal and regulatory changes);
- acts of war, armed hostilities or terrorism;
- changes in financial, banking or securities markets;
- any change in, or any compliance with or action taken for the purpose of complying with, any federal, state, national, foreign, material local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any governmental body (including under the authority of Nasdaq or the Financial Industry Regulatory Authority), or changes in any interpretations thereof;
- any change in U.S. generally accepted accounting principles or interpretations thereof;
- the announcement of the Merger Agreement or the pendency of the Merger;
- the taking of any action required to be taken by the Merger Agreement;
- pandemics (including the COVID-19 pandemic), including any worsening thereof, man-made disasters, natural disasters, acts of God or other force majeure event; and
- changes in U.S. or non-U.S. general economic or political conditions, or in the financial, credit or securities markets in general, including any shutdown of any governmental authority.

If adverse changes occur but Anchiano and Chemomab must still complete the Merger, the combined company's share price may suffer.

The market price of the combined company's shares may decline as a result of the Merger.

The market price of the combined company's shares may decline as a result of the Merger for a number of reasons, including if:

- the combined company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts;
- the effect of the Merger on the combined company's business and prospects is not consistent with the expectations of financial or industry analysts; or
- investors react negatively to the effect on the combined company's business and prospects from the Merger.

Our shareholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

If the combined company is unable to realize the strategic and financial benefits currently anticipated from the Merger, our shareholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. Significant management attention and resources will be required to integrate the two companies. Delays in this process could adversely affect the combined company's business, financial results, financial condition and share price following the Merger. Even if the combined company were able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration and that these benefits will be achieved within a reasonable period of time.

During the pendency of the Merger, we will be subject to contractual limitations set forth in the Merger Agreement that restrict our ability to enter into business combination transactions with another party.

Covenants in the Merger Agreement impede our ability to make acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the Merger. As a result, if the Merger is not completed, we may be at a disadvantage to our competitors. In addition, while the Merger Agreement is in effect and subject to limited exceptions, we are prohibited from soliciting, initiating, encouraging or taking actions designed to facilitate any inquiries or the making of any proposal or offer that could lead to entering into certain extraordinary transactions with any third party, such as a sale of assets, an acquisition of such party's securities, a tender offer for such party's securities, a merger or other business combination outside the ordinary course of business. Any such transactions could be favorable to our shareholders.

Because the lack of a public market for Chemomab's ordinary shares makes it difficult to evaluate the fairness of the Merger, Chemomab's shareholders may receive consideration in the Merger that is greater than the fair market value of Chemomab's ordinary shares.

The outstanding share capital of Chemomab is privately held and is not traded in any public market. The lack of a public market makes it difficult to determine the fair market value of Chemomab's ordinary shares. Since the number of Anchiano ADSs to be issued to Chemomab's shareholders was determined based on negotiations between the parties, it is possible that the value of the our ADSs to be issued in connection with the Merger will be greater than the fair market value of Chemomab's ordinary shares.

The combined company will incur significant transaction costs as a result of the Merger, including investment banking, legal and accounting fees. In addition, the combined company will incur significant consolidation and integration expenses which cannot be accurately estimated at this time. Actual transaction costs may substantially exceed estimates and may have an adverse effect on the combined company's financial condition and operating results.

Should the Merger be consummated, Chemomab's principal shareholders, and certain executive officers and directors, will own a significant percentage of Anchiano shares and will be able to exert significant control over matters submitted to the shareholders for approval.

Under the terms of the Merger Agreement, on a pro-forma basis and after closing of the Merger but prior to the closing of the planned financing to occur as a condition to the completion of the Merger of at least $30 million , the Chemomab securityholders immediately before the Merger are expected to own approximately 90% of the aggregate number of ordinary shares of Anchiano (on a fully diluted basis) and the securityholders of Anchiano immediately before the Merger are expected to own approximately 10% of the aggregate number of ordinary shares of Anchiano (on a fully diluted basis), subject to certain assumptions and to the net cash adjustment mechanism set forth in the Merger Agreement.

After the Merger with Anchiano, certain of Chemomab's officers and directors, and shareholders who held more than 5% of the Chemomab ordinary shares, will beneficially own a significant percentage of Anchiano securities. This significant concentration of share ownership may adversely affect the trading price for Anchiano securities because investors often perceive disadvantages in owning shares in companies with controlling shareholders. These shareholders, if they acted together, could significantly influence all matters requiring approval by the shareholders following the Merger, including the election of directors and the approval of mergers or other business combination transactions. The interests of these shareholders may not always coincide with the interests of other shareholders.

Certain shareholders could attempt to influence changes within Anchiano that could adversely affect Anchiano's operations, financial condition and the value of Anchiano's ordinary shares.

Anchiano's shareholders may from time to time seek to acquire a controlling stake in Anchiano, engage in proxy solicitations, advance shareholder proposals or otherwise attempt to effect changes. Campaigns by shareholders to effect changes at publicly-traded companies are sometimes led by investors seeking to increase short-term shareholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases or sales of assets or the entire company. Responding to proxy contests and other actions by activist shareholders can be costly and time-consuming and could disrupt Anchiano's operations and divert the attention of the Anchiano board of directors and senior management from the pursuit of the proposed transaction. These actions could adversely affect Anchiano's operations, financial condition, Anchiano's ability to consummate the Merger and the value of Anchiano ordinary shares.

Should the Merger be consummated, the combined company may not pursue the advancement of Anchiano's existing developmental programs.

In September 2019, we entered into an option to license agreement with ADT Pharmaceuticals, LLC pursuant to which the parties agreed to conduct research and development activities of novel small-molecule inhibitors (RAS and PDE10/β-catenin). As part of the arrangement, we are 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 us. 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.

Following the effective time of the Merger, Chemomab (as successor in interest to Anchiano) will have sole authority over whether and how to pursue the continued development of the RAS compounds pursuant to the ADT License Agreement (if at all), and there is no guarantee that Chemomab will pursue the continued development. Anchiano and Chemomab (as successor in interest to Anchiano following the Merger) may decide to assign the license agreement or terminate the agreement at any time in its entirety or on a compound-by-compound basis after providing 90 days written notice to ADT.

Anchiano and Chemomab have become involved in securities litigation in connection with the Merger and may become involved in additional securities litigation or shareholder derivative litigation in connection with the Merger, which has and may continue to divert the attention of Anchiano and Chemomab management and harm the combined company's business, and insurance coverage may not be sufficient to cover all related costs and damages.

Securities litigation or shareholder derivative litigation frequently follows the announcement of certain significant business transactions, such as the sale of a business division or announcement of a business combination transaction. As disclosed in Note 10 of Notes to Consolidated Financial Statements, Anchiano and Chemomab have been named as defendants in securities litigation in connection with the Merger and may become involved in additional securities litigation or shareholder derivative litigation in connection with the Merger, and the combined company may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect the business of Anchiano, Chemomab and the combined company.

Should the Merger be consummated, following which Chemomab's business is expected to constitute a significant portion of the business of the combined company, additional significant risks may apply to the combined business as detailed in the proxy statement/prospectus previously filed on February 12, 2021, and incorporated by reference herein (File No. 333-252070), and will include "Risks Related to Chemomab's Business, Research and Development and the Biopharmaceutical Industry," "Risks Related to Chemomab's Intellectual Property Rights," "Risks Related to Chemomab's Regulatory Approvals," "Risks Related to Commercialization of Chemomab's Product Candidates," "Risks Related to Chemomab's Incorporation and Location in Israel," or "Risks Related to the Combined Company" occur, those events could cause the potential benefits of the Merger not to be realized.

Risks Related to our Business

The current pandemic of COVID-19 and the future outbreak of other highly infectious or contagious diseases could seriously affect our business.

Broad-based business or economic disruptions could adversely affect our planned research and development activities and ability to raise additional funds. For example, to date, the COVID-19 pandemic has caused significant disruptions to the Israeli, United States and global economy and has contributed to significant volatility and negative pressure in financial markets. The global impact of the outbreak is continually evolving and, as additional cases of the virus are identified, many countries, including Israel and the United States, have reacted by instituting quarantines, restrictions on travel and mandatory closures of businesses. Most countries, including where we or the third parties with whom we engage operate, have also reacted by instituting quarantines, restrictions on travel, "shelter in place" rules, and restrictions on types of business that may continue to operate.

The extent to which COVID-19 may impact our activities and operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the severity of COVID-19, or the effectiveness of actions to contain and treat COVID-19. The continued spread of COVID-19 globally could adversely impact our activities and operations in Israel and the United States, including our ability to raise additional funds, identify third parties we engage, or seek to engage for preclinical and clinical development activities, and identify and engage with third parties within the framework of other business and strategic initiatives. These could all delay progress, increase our operating expenses, and have a material adverse effect on our financial results.

We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operation and financial condition.

We recently changed our business strategy, are now a preclinical development company, and may encounter difficulties in managing this transition, which could significantly disrupt our business.

On November 15, 2019, we announced the discontinuation of our Phase 2 Codex study evaluating the gene therapy inodiftagene vixteplasmid in patients with bladder cancer. After analysis of the data, we determined that there is a low probability of surpassing the predefined futility threshold at the planned interim analysis, which required 10 complete responses in 35 patients. The data also indicated a low probability of achieving an efficacy profile that, in our estimation, would be necessary to support regulatory approval. As a result, we changed our business strategy in November 2019 to devote our full resources to our small molecule pan-RAS inhibitor and PDE10/β-catenin inhibitor programs that we acquired in September 2019. To manage this change, we undertook a workforce reduction in order to accommodate our new business strategy. In particular, as previously announced, we closed our office and laboratories located in Israel due to the discontinuation of our Phase 2 Codex study. Following the closure of the Israeli facilities, our sole office was located in Cambridge, Massachusetts. Our lease for this office in Cambridge, Massachusetts terminated on February 28, 2021. We are allowed, however, to continue using this address to receive mail. Due to our limited resources, we may not be able to effectively manage this change in our business strategy. If our current management team is unable to effectively manage this transition, our expenses may increase more than expected and we may not be able to implement our business strategy. In addition, as discussed above, our strategy may be subject to review.

We will require substantial additional funds to complete our research and development activities, and, if additional funds are not available, we may need to significantly scale back or cease our business.

We have generated substantial accumulated losses since inception. We have not generated any revenues to date and do not expect to generate any revenue in the near future. As a result, we expect to continue to experience negative cash flow for the foreseeable future. We can offer no assurance that we will ever operate profitably or that we will generate positive cash flow in the future. A significant portion of our research and development activities has been financed by the issuance of equity securities (including in our initial public offering in February 2019). There is no certainty that we will be able to obtain additional sources of funding for our research and development activities (see the risk factor entitled "Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our technologies or assets"). A lack of adequate funding may cause a cessation of all or part of our research and development activities and business.

We will require substantial funds to discover, develop, protect and conduct research and development for our prospective products, including pre-clinical studies and clinical trials, and to manufacture and market any such product that may be approved for commercial sale. As of December 31, 2020, we held approximately $5.4 million in cash and cash equivalents. Our current available funds are not sufficient for all of these activities and we expect our current available funds to be adequate to satisfy our capital and operating needs through to the completion of the contemplated merger. Our financing needs may also increase substantially because of the results of our research and development, preclinical studies and clinical trials and costs arising from additional regulatory approvals. We may not succeed in raising additional funds in a timely manner. The timing of our need for additional funds will depend on a number of factors, which are difficult to predict or may be outside of our control, including:

- the resources, time and costs required to initiate and complete our research and development and to initiate and complete preclinical studies and clinical trials and to obtain regulatory approvals for any products that we develop in the future;
- progress in our research and development programs;
- the timing and amount of milestone, royalty and other payments; and
- costs necessary to protect any intellectual property rights.

If our estimates and predictions relating to any of these factors are incorrect, we may need to modify our business plan. Additional funds may not be available to us when needed on acceptable terms, or at all. If we are unable to raise funds on acceptable terms, we may not be able to execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements. This may seriously harm our business, financial condition and results of operations. If we are not able to continue operations, investors may suffer a complete loss of their investments in our securities.

We are now an early-stage preclinical biotechnology company and may never be able to successfully develop a marketable product. We have only recently acquired two preclinical programs, and there is no assurance that our future operations will generate any revenue. If we cannot develop a marketable product or generate sufficient revenues, we may be required to suspend or cease operations.

We are now an early-stage preclinical biotechnology company that recently acquired an option to develop, manufacture and commercialize two developmental programs targeting oncogenic pathways that are focused on small molecule inhibitors RAS and PDE10/ß-catenin (the "Compounds") pursuant to a collaboration and license agreement we entered into with ADT on September 20, 2019 (the "Collaboration Agreement"). Our operations prior to that date were not relevant to the development of the Compounds. Our operations relating to our two current preclinical programs have been limited to business planning, performing research, analyzing preclinical data and preparing to advance identified molecules through additional preclinical studies. The Compounds identified by us in connection with both our Pan-RAS and PDE10/ß-catenin programs are in the concept, research and preclinical stages. As a result, we cannot be certain that our research and development efforts will be successful or, if successful, that any products that are developed from the Compounds will ever be approved by the U.S. FDA. Typically, it takes 10 to 12 years to develop one new medicine from the time it is discovered to when it is available for treating patients, and longer timeframes are not uncommon. Even if approved, any products that are developed from the Compounds may not generate sufficient commercial revenues for us to continue operating. Our operating history should not be considered when evaluating our performance as it relates to our abandoned bladder cancer product candidate. As a result, we are subject to all of the business risks associated with a new enterprise, including, but not limited to, risks of unforeseen capital requirements, failure of business strategy either in research, preclinical testing or in clinical trials, failure to establish business relationships, and competitive disadvantages against other companies. If we fail to become profitable, we may be forced to suspend or cease our operations.

We do not have a history of commercial sales and do not anticipate earning operating income over the coming years, and our failure to receive marketing approval for a product that we develop in the future would negatively impact our ability to continue our business operations.

Our predecessor entity, BioCancell Therapeutics Inc. ("BTI"), was formed on July 26, 2004, and since then we have been a development-stage company. We have never received marketing approval for any product candidate and, as a result, have not recorded any sales. We expect that we will operate at a loss over the coming years, as we do not expect to generate any revenue from operations in the near term. We may not be able to develop, or receive marketing approval for, any product from our current preclinical research and development efforts. In addition, even if we obtain all necessary approvals to market a product, there is no certainty that there will be sufficient demand to justify the production and marketing of any such product.

There is substantial doubt as to whether we can continue as a going concern.

Our consolidated financial statements as of December 31, 2020 contain an explanatory paragraph that states that our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. Our financial statements do not include any measurement or presentation adjustment for assets or liabilities that might result if we would be unable to continue as a going concern. We have incurred operating losses since inception, have not generated any revenues and have not achieved profitable operations. Our net loss, accumulated during the development stage through December 31, 2020, totaled approximately $117 million, and we expect to continue to incur substantial losses in future periods while we continue our research and development activities.

We depend completely on the success of our two preclinical programs and, if we are not able to advance these successfully through the preclinical and clinical development process, our business prospects will be materially and adversely affected.

We have no products that are in active clinical development or approved for commercial sale. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the research and development of small molecule inhibitors (pan-RAS and PDE10/β-catenin programs). Our business depends completely on the successful preclinical and clinical development of products derived from the Compounds. We cannot be certain that any such product candidate will be developed or receive regulatory approval given that the Compounds remain in early preclinical stages of development.

Our ability to develop, obtain regulatory approval for, and ultimately commercialize, a product derived from the Compounds effectively will depend on many factors, including the following:

- successful completion of preclinical studies and clinical trials, which will depend substantially upon the satisfactory performance of third-party contractors;
- successful achievement of the objectives of planned preclinical studies and clinical trials, including the demonstration of a favorable risk-benefit outcome;
- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States;
- establishing efficient and effective commercial manufacturing, supply and distribution arrangements;
- establishing sufficient market share and promoting acceptance of the product by patients, the medical community and third-party payors;

- successfully executing an effective pricing and reimbursement strategy;
- maintaining a continued acceptable safety and adverse event profile following regulatory approval; and
- qualifying for, identifying, registering, maintaining, enforcing and defending intellectual property rights and claims.

The Compounds will require additional non-clinical and clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can be in a position to generate any revenue from product sales. We are not permitted to market or promote any product derived from the Compounds before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval. If we are unable to develop or receive marketing approval in a timely manner or at all, we could experience significant delays or an inability to commercialize products derived from the Compounds, which would materially and adversely affect our business, financial condition and results of operations.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our technologies or assets.

Until such time, if ever, as we can generate sufficient revenues, we expect to finance our cash needs through equity offerings, debt financings or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We will require substantial funding to fund our developmental efforts, our operating expenses and other activities. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, certain price protection rights may be triggered and the terms of the newly issued securities may include liquidation or other preferences that adversely affect your rights. Investors in the June 2018 fundraising are entitled to certain price protection rights with respect to their ordinary shares and warrants in the event of a future share issue by us where the price per share is less than the price per share reflected in our initial public offering, which triggered these rights. Additionally, debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or both of our preclinical development programs, which would adversely impact our potential revenues, results of operations and financial condition.

We may allocate our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may later prove to be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must limit our licensing, research, and development programs to specific drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. In addition, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing, or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

The pharmaceutical and biotechnology market is highly competitive. If we are unable to compete effectively with existing products, new treatment methods and new technologies, we may be unable to commercialize any products that we may develop in the future.

The biotechnology market is highly competitive, is subject to rapid technological change and is significantly affected by existing rival drugs and medical procedures, new product introductions and the market activities of other participants. Pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations may pursue the research and development of technologies, drugs or other therapeutic products for the treatment of some or all of the diseases that we are target. We also may face competition from products that have already been approved and accepted by the medical community for the treatment of these same indications. We are aware of a number of companies developing small molecule drugs for the treatment of cancer. Our competitors may develop products more rapidly or more effectively than us. Many of our competitors have:

- much greater experience, financial, technical and human resources than we have at every stage of the discovery, development, manufacture and commercialization process;
- more extensive experience in preclinical studies, conducting clinical trials, obtaining and maintaining regulatory approvals and manufacturing and marketing products;
- products that have been approved or are in late stages of development;
- established distribution networks;
- collaborative arrangements with leading companies and research institutions; and
- entrenched and established relationships with healthcare providers and payors.

In addition, many of these companies, in contrast to us, are well-capitalized. As a result of any of the foregoing factors, our competitors may develop or commercialize products, including small molecule inhibitors, with significant advantages over any product that we may develop in the future. If our competitors are more successful in commercializing their products than us, their success could adversely affect our competitive position and harm our business prospects.

Even if we receive regulatory approval to market a product that we develop in the future, the market may not be receptive to the product upon its commercial introduction.

We may have difficulties convincing the medical community and third-party payors to accept and use any product that we are able to develop in the future even following our receipt of regulatory approval for commercialization. Key participants in pharmaceutical marketplaces, such as physicians, third-party payors and consumers, may not accept a product that we develop. Even if such a product is accepted by these participants, the medical community may not consider effectiveness and safety alone as a sufficient basis for prescribing such as product in lieu of other alternative treatment methods and medications that are available.

Risks Related to our Preclinical Development

Our preclinical developmental programs are at an early stage. As a result, we are unable to predict if, or when, we will successfully develop or commercialize any product under either program.

We currently have no products beyond preclinical studies and our internal product development programs are at an early stage of preclinical development. Any product that we develop in the future will require significant investment in both preclinical studies and later clinical trials. We cannot be certain that preclinical and clinical development of any product derived from our current product development programs will be successful or that we will obtain regulatory approval or be able to successfully commercialize any product and generate revenue. Success in preclinical studies does not ensure that clinical trials will be successful, and the clinical trial process may fail to demonstrate that a product that we develop is safe and effective for its proposed use. Any such failure could cause us to abandon further development of one or more products and may delay development of other potential products. Any delay in, or termination of, our preclinical studies or clinical trials will delay and possibly preclude the filing of a new drug application with the FDA or comparable regulatory authorities and, ultimately, our ability to generate any product revenue.

Any product that we develop in the future will be required to undergo a time-consuming, costly and burdensome pre-market approval process, and we may be unable to obtain regulatory approval for such product.

Any product that we develop in the future will be subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical studies, clinical trials and extensive regulatory approval processes are required to be successfully completed in the United States and in many foreign jurisdictions, such as the European Union and Japan, before a new product may be offered and sold in any of these countries or regions. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays.

Preclinical studies and clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because any product that we develop in the future will be based on new technologies, we expect that it will require extensive research and development and necessitate substantial manufacturing and processing costs. In addition, costs to treat potential side effects that may result from a product we develop may be significant. Accordingly, our preclinical and clinical trial costs could be significantly higher than for more conventional therapeutic technologies or drug products.

In the United States, the products that we intend to develop and market are regulated by the FDA under its drug development and review process. The time required to obtain FDA and other approvals for any product that we develop in the future is inherently unpredictable. Before such products can be marketed, we must obtain clearance from the FDA first through submission of an IND, then through successful completion of human testing under three phases of clinical trials and finally through submission of an NDA. Even after successful completion of clinical testing, there is a risk that the FDA may request further information from us, disagree with our findings or otherwise undertake a lengthy review of our NDA submission.

There can be no assurance that the FDA will grant a license for any NDA that we may submit. It is possible that none of the products that we develop in the future will obtain the appropriate regulatory approvals necessary for us to commence the offer and sale of such products. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from a particular prospective product.

If we decide to market any drug that we develop in jurisdictions in addition to the United States, we may incur the same costs or more in satisfying foreign regulatory requirements governing the conduct of preclinical and clinical trials, manufacturing and marketing and commercialization of any product that we develop in the future. Approval by the FDA by itself does not assure approval by regulatory authorities outside the United States. Each of these foreign regulatory approval processes includes all of the risks associated with the FDA approval process, as well as risks attributable to having to satisfy local regulations within each of these foreign jurisdictions. Our inability to obtain regulatory approval outside the United States may adversely compromise our business prospects.

If the preclinical and clinical studies that we are required to conduct to gain regulatory approval are delayed or unsuccessful, we may not be able to market any product that we develop in the future.

We may experience delays in any phase of the preclinical or clinical development of a product, including during its research and development. The completion of any of these studies may be delayed or halted for numerous reasons, including, but not limited to, the following:

- the FDA, IRBs, the European Union regulatory authorities (the European Medicines Agency (“EMA”) and national authorities), or other regulatory authorities do not approve a clinical study protocol or place a clinical study on hold;
- patients do not enroll in a clinical study or results from patients are not received at the expected rate;
- patients discontinue participation in a clinical study prior to the scheduled endpoint at a higher than expected rate;
- patients experience adverse events from a product we develop;

- patients die during a clinical study for a variety of reasons that may or may not be related to the product that is the subject of the study;
- third-party clinical investigators do not perform the studies in accordance with the anticipated schedule or consistent with the study protocol and good clinical practices or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- third-party clinical investigators engage in activities that, even if not directly associated with our studies, result in their debarment, loss of licensure, or other legal or regulatory sanction;
- regulatory inspections of manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend the preclinical or clinical studies;
- changes in governmental regulations or administrative actions;
- the interim results of the preclinical or clinical study, if any, are inconclusive or negative; and
- the study design, although approved and completed, is inadequate to demonstrate effectiveness and safety.

We have limited experience in conducting and managing preclinical studies and any product that we develop in the future may not have favorable results in later clinical trials or receive regulatory approvals.

We have limited experience in conducting and managing the preclinical studies and clinical trials necessary to obtain regulatory approvals for a product. We may rely on third parties for preclinical and clinical development activities and our reliance on third parties will reduce our control over these activities. Accordingly, third-party contractors may not complete activities on schedule, or may not conduct preclinical studies and clinical trials in accordance with regulatory requirements or our trial design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them, which may delay the affected trial.

Clinical failure can occur at any stage of preclinical or clinical development. Preclinical studies and clinical trials may produce negative or inconclusive results, and our collaborators or we may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in pre-clinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in preclinical studies and clinical trials, even after seeing promising results in earlier trials or studies.

We may experience difficulties in identifying and recruiting suitable patients for clinical studies, which may significantly compromise our ability to develop a product in the future.

We may experience difficulties in identifying and recruiting suitable patients for clinical studies because of the high demand for such patients' involvement in current and future studies and trials for potential drugs or because the supply of suitable patients may be low because of strict inclusion criteria requirements. The realization of any of the foregoing risks may significantly compromise our ability to develop a future product, which would adversely impact our potential revenues, results of operations and financial condition.

If toxicities or serious adverse or undesirable side effects are identified during preclinical or clinical development, we may need to abandon or limit such development.

We do not have a product candidate in clinical development and, as a result, the risk we are unable to successfully develop a future product is high. A product's preclinical toxicology profile might not support moving the product into clinical studies, and even then, it is impossible to predict when, or if, any future product that we develop will prove effective or safe in humans or will receive regulatory approval. If any such product is associated with undesirable side effects or has characteristics that are unexpected, we may need to abandon its development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

The commercial value of any clinical study that we may commence and conduct in the future will significantly depend upon our choice of medical indication and our selection of a patient population for our clinical study of an indication, and our inability to commence clinical testing or our choice of clinical strategy may significantly compromise our business prospects.

If we successfully complete a clinical study, the commercial value of any such study will depend significantly upon our choice of indication and our selection of a patient population for that indication. We may incorrectly assess the market opportunities of an indication or may incorrectly estimate or fail to appreciate fully the scientific and technological difficulties associated with treating an indication. Furthermore, the quality and robustness of the results and data of any clinical study that we may conduct in the future will depend upon our selection of a patient population for clinical testing. Our inability to commence clinical testing or our choice of clinical strategy may significantly compromise our business prospects.

Risks Related to our Dependence on Third Parties

We are substantially dependent on our Collaboration Agreement with ADT. If we fail to comply with our obligations under the Collaboration Agreement into which we entered with ADT, we could lose development and commercialization rights that are critical to the continuation of our business if the Merger is not consummated.

On September 20, 2019, we entered into the Collaboration Agreement with ADT in which we agreed to use commercially reasonable efforts to conduct research and development activities with respect to the Compounds under the oversight of a jointly established steering committee. As part of the arrangement, we are primarily responsible for the research, development, manufacturing and regulatory activities relating to the Compounds. In consideration for the rights granted under the Collaboration Agreement, we agreed to make milestone payments to ADT with respect to the development and commercialization of any products containing the Compounds. ADT also granted us an exclusive option to research, develop, manufacture and commercialize Compounds relating to patents owned by ADT and any products containing such Compounds worldwide in exchange for an additional fee. We agreed to pay ADT royalties ranging in the low- to mid-single digit percentage on sales of any products containing the Compounds. ADT may terminate the Collaboration Agreement in the event of our material default in any of our material obligations under the Collaboration Agreement (following a cure period). In the event the Collaboration Agreement is terminated, all licenses and options granted to us will be terminated and we will not be able to develop the Compounds or any products containing the Compounds. The Collaboration Agreement also restricts assignment except to a successor of substantially all of the business to which the Collaboration Agreement relates, whether in a merger, sale of stock, sale of assets, reorganization or other transaction. If the Merger is not consummated, the loss of such rights would materially adversely affect our business, financial condition, operating results and prospects. To the extent the strategic review results in a determination to monetize the pan-RAS program, we may be limited in our ability to do so.

The failure of ADT to effectively perform its obligations under the Collaboration Agreement could materially and adversely affect us.

Pursuant to the terms and conditions set forth in the Collaboration Agreement, ADT contractually agreed to collaborate with us in order to conduct research and development activities of the Compounds under the oversight of a joint steering committee that we established with ADT. As part of the arrangement, ADT is required to assist us with research activities relating to the Compounds as necessary. In connection with the Collaboration Agreement, ADT also granted us an exclusive option to research, develop, manufacture and commercialize Compounds relating to patents owned by ADT and any products containing such Compounds worldwide. Our right to research, develop, manufacturer and commercialize the Compounds is exclusively based upon the rights provided to us by ADT as part of the Collaboration Agreement. If ADT or a successor company fails or refuses to perform its obligations under, or comply with the terms and conditions set forth in, the Collaboration Agreement for any reason, we may not be able to research, develop, manufacture and/or commercialize the Compounds or any products containing the Compounds, which would materially adversely affect our business, financial condition, operating results and prospects.

We are dependent on ADT for certain support services related to our research and development activities with respect to the Compounds and any failure or delay by ADT to provide such services could harm our business.

In connection with the Collaboration Agreement, we also entered into a Consulting and Collaboration Research Support Agreement with ADT (the "Support Agreement"), whereby ADT provides support services for our research and development activities with respect to the Compounds, including providing key research and discovery personnel. We are dependent upon ADT's continued performance under this Support Agreement. To the extent ADT is unable to, or determines not to, perform these support services, we may not be able to undertake the research and development activities to develop the Compounds on our own or find other collaborators on acceptable terms. This could impact our ability to develop the Compounds and materially adversely impact our business, financial condition, operating results and prospects.

We expect to rely significantly on preclinical contract research organizations and clinical research organizations to assist us with the development of the Compounds and any product that we develop in the future.

Our reliance on clinical research organizations may result in delays in completing, or a failure to complete, non-clinical testing or clinical trials if they fail to perform under our agreements with them. In the course of product development, we expect to engage clinical manufacturing organizations to manufacture drug material for us to be used in non-clinical and clinical testing and contract research organizations to conduct and manage non-clinical and clinical studies. As a result, many important aspects of our preclinical research activities and clinical testing will be out of our direct control. If any of these organizations we may engage in the future fail to perform their obligations under our agreements with them or fail to perform non-clinical testing and/or clinical trials in a satisfactory manner, we may face delays in completing such testing or trials. Furthermore, any loss or delay in obtaining contracts with such entities may also delay the completion of our preclinical studies, clinical trials, regulatory filings and the potential market approval of our potential drug compounds.

We may seek to enter into further collaborations in the future, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Any collaboration or license agreements that we may enter into in the future may impose various development, commercialization, funding, royalty, diligence, sublicensing, insurance and other obligations on us. Our obligations under any of these license agreements could include, without limitation:

- royalty payments;
- annual maintenance fees;
- providing progress reports;
- maintaining insurance coverage;
- paying fees related to prosecution, maintenance and enforcement of patent rights;
- minimum annual payments; and
- undertaking diligent efforts to develop and introduce therapeutic products into the commercial market as soon as practicable.

If we were to breach any of our material obligations as described above, the counterparties to any such agreements may have the right to terminate the agreement and any licenses contemplated thereby, which could result in our inability to develop, manufacture and sell products that are covered by the licensed technology or a competitor gaining access to the licensed technology.

If we, or if our service providers or any third-party manufacturers, fail to comply with regulatory requirements, we or they could be subject to enforcement actions, which could adversely affect our ability to market and sell a product we develop in the future.

If we, or if our service providers or any third-party manufacturers, fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could adversely affect our ability to successfully develop, market and sell a product we develop in the future and could harm our reputation. These enforcement actions may include:

- restrictions on, or prohibitions against, marketing;
- restrictions on importation;
- suspension of review or refusal to approve new or pending applications;
- suspension or withdrawal of product approvals;
- product seizures;
- injunctions; and
- civil and criminal penalties and fines.

Risks Related to our Operations

If we are unable to re-hire and retain qualified employees, our ability to implement our business plan may be adversely affected.

The loss of the service of key employees during the strategic review process that we went through during 2020 would likely delay our achievement of product development and our other business objectives should the proposed merger not complete.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Difficulty in hiring employees to fill key roles could slow or prevent our ability to develop and commercialize our products. Our financial condition and the announcement of our process of exploring strategic opportunities may result in difficulties retaining and attracting qualified employees.

In addition, we would expect to work extensively with consultants and advisors, including scientific and clinical advisors, who provide advice and/or services in various business and development functions, including preclinical and clinical development, operations and strategy, regulatory matters, legal, and finance, to assist us in formulating our research and development and commercialization strategy. The potential success of our drug development programs depends, in part, on collaborations with certain of these consultants and advisors. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. We do not know if we will be able to build and maintain such relationships or that such consultants and advisors will not enter into other arrangements with competitors, any of which could have a detrimental impact on our development objectives and our business.

Under applicable employment laws, we may not be able to enforce covenants not to compete.

Our employment agreements generally include covenants not to compete. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work. For example, Israeli courts have required employers seeking to enforce covenants not to compete to demonstrate that the competitive activities of a former employee will harm one of a limited number of material interests of the employer, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such an interest will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our competitiveness may be diminished.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our potential competitors. Some of these employees may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Our business may be affected by litigation and government investigations.

We may from time to time receive inquiries and subpoenas and other types of information requests from government authorities and others and we may become subject to claims and other actions related to our business activities. While the ultimate outcome of investigations, inquiries, information requests and legal proceedings is difficult to predict, defense of litigation claims can be expensive, time-consuming and distracting, and adverse resolutions or settlements of those matters may result in, among other things, modification of our business practices, costs and significant payments, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Product liability claims or lawsuits could cause us to incur substantial liabilities.

We will face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials. If we cannot successfully defend ourselves against claims that our products caused injuries, we could incur substantial liabilities. Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. Insurance coverage may be increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We are exposed to a risk of substantial loss due to claims that may be filed against us in the future because our insurance policies may not fully cover the risk of loss associated with our operations.

We are exposed to the risk of having claims seeking monetary damages being filed against us for loss or harm suffered by participants of our preclinical and clinical studies or for loss or harm suffered by users of any drug that may receive approval for commercialization in the future. In either event, the FDA or the regulatory authorities of other countries or regions may commence investigations of the safety and effectiveness of any such trial or commercialized drug, the manufacturing processes and facilities or marketing programs utilized in respect of any such trial or drug, and may result in mandatory or voluntary recalls of any commercialized drug or other significant enforcement action such as limiting the indications for which any such drug may be used, or suspension or withdrawal of approval for any such drug. Investigations by the FDA or any other regulatory authority in other countries or regions also could delay or prevent the completion of any of our other clinical development programs. In the event that we are required to pay damages for any such claim, we may be forced to seek bankruptcy or to liquidate because our asset and revenue base may be insufficient to satisfy the payment of damages and any insurance that we have obtained or may obtain for product, preclinical study or clinical trial liability may not provide sufficient coverage against potential liabilities. Our insurance policy for the discontinued inodiftagene compound provides coverage in the amount of up to $10 million in the aggregate.

Significant disruptions of information technology systems or security breaches could adversely affect our operations.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, among other things, trade secrets or other intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors that may or could have access to our confidential information. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized groups and individuals with a wide range of motives and expertise. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors, and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability, and threated the confidentiality, integrity, and availability of information.

Significant disruptions of our information technology systems, or those of our third-party vendors, or security breaches could adversely affect our business operations and/or result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information, including, among other things, trade secrets or other intellectual property, proprietary business information and personal information, and could result in financial, legal, business, and reputational harm to us.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations to third parties, or any data security incidents or other security breaches that result in the unauthorized access, release or transfer of sensitive information, including personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties asserting that we have breached our privacy, confidentiality, data security, or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition, or results of operations. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of preclinical or clinical data from completed or ongoing or planned preclinical studies or clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of a product could be delayed.

Risks Related to Government Regulation

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, and third-party payors play a primary role in the recommendation of any product for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal healthcare anti-kickback statute, as mentioned above, prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

- the federal False Claims Act imposes civil penalties, including civil whistleblower actions, against individuals or entities for knowingly presenting, or causing to be presented, claims for payment to the federal government that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal transparency requirements under applicable healthcare laws will require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines and exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Coverage and adequate reimbursement may not be available for any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which coverage and reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One third-party payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage, and adequate reimbursement, for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each third-party payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a third-party payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any future product candidates that we may develop.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any product candidate that we may develop.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and to accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Risks Related to Our Intellectual Property

We may be required in the future to license patent rights from third-party owners in order to develop a product. If we cannot obtain such licenses, or if such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.

We currently license patents from ADT in conducting our research and development activities pursuant to the Collaboration Agreement. We may be required to obtain additional licenses in the future if we believe it is necessary or useful for our business and our research and development efforts to use third-party intellectual property or if our efforts would infringe upon the intellectual property rights of third parties. Our business prospects depend in part on the ability of ADT and any future licensor, to obtain, maintain and enforce patent protection for our licensed intellectual property. Our licensors may terminate our license, may not successfully prosecute or may fail to maintain their patent applications that we have licensed, may determine not to pursue litigation against other persons that are infringing these patents or may pursue such litigation less aggressively than we would. Without protection for the intellectual property that we have licensed and that we may license in the future, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive position and harm our business prospects.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information.

We currently rely, and intend to rely in the future, on trade secrets, know-how and technology that are not protected by patents to maintain our competitive position. In order to protect our proprietary technology and processes, we also rely in part on confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information, and in such cases we could not assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive position and harm our business prospects.

If we are unable to obtain and enforce patent protection for our inventions, our ability to develop and commercialize any product that we develop in the future will be harmed.

Our success depends, to a considerable extent, on our ability to protect proprietary methods and technologies that we develop under the patent and other intellectual property laws of the United States and other countries, so that we may prevent others from unlawfully using our inventions and proprietary information. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the U.S. Patent and Trademark Office (the "PTO") and its foreign counterparts use to grant patents are not always applied predictably or uniformly and may change. There also is no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Even if our rights are not directly challenged, disputes among third parties could lead to the weakening or invalidation of our intellectual property rights. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed with respect to any patents issued to us or to others. Additionally, the mere issuance of a patent does not guarantee that it is valid or enforceable against third parties.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

A third party may sue us for infringing its patent rights or may claim that we have improperly obtained or used its confidential or proprietary information. Likewise, we may need to resort to litigation to enforce a patent issued or licensed to us or to determine the scope and validity of third-party proprietary rights. In addition, during an infringement proceeding, a court may decide that the patent rights we are asserting are invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, our licensors may have rights to file and prosecute such claims and we are reliant on them. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be significant, and the litigation would divert our management's efforts. From a financial perspective, there is a risk that we would not be able to sustain the costs of any such litigation and would be forced to seek bankruptcy or to liquidate because of our limited asset and revenue base.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

We may be subject to claims that former employees, collaborators or other third parties have an interest in, or right to compensation, with respect to our current patent and patent applications, future patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing a product for us. Litigation may be necessary to defend against these and other claims challenging inventorship or claiming the right to compensation. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or the right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We generally enter into assignment-of-invention agreements with our employees pursuant to which such individuals assign to us all rights to any inventions created in the scope of their employment or engagement with us. Although our employees have agreed to assign to us service invention rights and have specifically waived their right to receive any special remuneration for such assignment beyond their regular salary and benefits, we may face claims demanding remuneration in consideration for assigned inventions.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are similar to a product we develop, but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- We may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to the ADSs

The ADS price could continue to be highly volatile and you may not be able to resell your ADSs at or above the price you paid for them.

The trading price of the ADSs has been highly volatile, and is likely to continue to be highly volatile as we undertake the strategic review process, and such volatility may continue or become more severe if and when a transaction or business arrangement is announced or we announce that we are no longer exploring strategic opportunities. From our initial public offering on February 12, 2019 to December 31, 2020, the ADS price has ranged from $0.54 to $11.50 per ADS. The following factors, among others, could have a significant impact on the market price of the ADSs:

- actual or anticipated fluctuations in our results of operations;
- changes in operational strategy;
- variance in our financial performance from the expectations of market analysts;
- announcements by us or our competitors of significant business developments, changes in strategic relationships, acquisitions or development plans;
- announcements by us regarding the clinical development, commercialization and market acceptance of a therapeutic candidate;
- our involvement in litigation;
- our sale of ADSs, ordinary shares or other securities in the future;
- changes in personnel;
- the trading volume of the ADSs, particularly as a microcap company with a few significant shareholders;
- changes in the estimation of the future size and growth rate of our markets;
- market conditions in our industry; and
- general economic and market conditions.

The ADSs may have a low trading volume for a number of reasons, including that a substantial portion of the ADSs are held by a few significant shareholders, limiting our public float. As a result, holders of our ADSs may encounter difficulty selling their ADSs or obtaining a suitable price at which to sell such ADSs.

In addition, the stock markets have experienced extreme price and volume fluctuations, and securities of small cap and microcap companies are particularly volatile. Broad market and industry factors may materially harm the market price of the ADSs, regardless of our operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted against that company. If we were involved in any similar litigation, we could incur substantial costs and our management's attention and resources could be diverted.

A limited number of shareholders will have the ability to influence the outcome of director elections and other matters requiring shareholder approval.

According to a Schedule 13D filed on December 14, 2020, Clal Biotechnology Industries Ltd., or CBI, is the beneficial owner of approximately 25.1% of our outstanding shares and Access Industries Holdings LLC, or AIH, Access Industries Management, LLC, or AIM, Access Industries, LLC, or LLC, and Len Blavatnik beneficially own approximately 42.7% of Anchiano's outstanding shares (which includes the shares beneficially owned by CBI). In addition, according to a Schedule 13G filed on January 2, 2020, the Shavit Capital Funds collectively beneficially own approximately 21.7% of Anchiano's outstanding shares.

As a result of their significant holdings in our shares, Access, CBI and the Shavit Capital Funds have the ability to exert substantial influence over matters requiring approval by our shareholders, including electing directors and approving mergers, acquisitions or other business combination or corporate restructuring transactions. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could deprive our shareholders of an opportunity to receive a premium for their shares as part of a sale of our Company and might reduce our share price.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade the ADSs, the price of the ADSs could decline.

The trading market for the ADSs relies in part on the research and reports that equity research analysts publish about us and our business. The price of the ADSs could decline if one or more securities analysts downgrade the ADSs or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. The analysts at many brokerage firms do not currently monitor the trading activity or otherwise provide coverage of lower priced stocks, such as the ADSs. As a result, many investment funds are reluctant to invest in lower priced stocks. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile, subject even to large daily price swings, due in part to the failure to elicit meaningful stock analyst coverage and downgrades of the company's stock by analysts.

Because we no longer qualify as a foreign private issuer, we are required to comply fully with the reporting requirements of the Exchange Act applicable to U.S. domestic issuers and, as a result, have incurred and will continue to incur significant legal, accounting and other expenses that we would not incur as a foreign private issuer.

Beginning on January 1, 2020, we have been required to comply fully with the reporting requirements of the Exchange Act applicable to U.S. domestic issuers because we no longer qualify as a foreign private issuer. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer are expected to be significantly higher. We are now required to file periodic reports, proxy materials and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer.We have also been required to modify certain of our corporate governance policies and committee charters to comply with accepted governance practices and requirements associated with U.S. domestic listed issuers. In addition, we lost our ability to rely upon exemptions from certain Nasdaq corporate governance requirements that are available to foreign private issuers.

As a result of becoming a public company, our management is required to devote substantial additional time to new compliance initiatives as well as to compliance with ongoing public reporting requirements.

As a public company in the United States, we incur significant additional accounting, legal and other expenses that we did not incur before our initial public offering. We incur costs associated with corporate governance requirements of the SEC and Nasdaq, as well as requirements under Section 404 and other provisions of the Sarbanes-Oxley Act. These rules and regulations increase our legal and financial compliance costs, introduce new costs such as investor relations, stock exchange listing fees and shareholder reporting, and make some activities more time consuming and costly. The implementation and testing of such processes and systems require us to hire outside consultants and incur other significant costs. Any future changes in the laws and regulations affecting public companies in the United States, including Section 404 and other provisions of the Sarbanes-Oxley Act, and the rules and regulations adopted by the SEC and Nasdaq, for so long as they apply to us, will result in increased costs to us as we respond to such changes. These laws, rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, if any, or as executive officers.

We do not intend to pay dividends in the foreseeable future.

We do not anticipate paying any cash dividends on the ADSs. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our ordinary shares will be the investors' sole source of gain for the next several years. In addition, Israeli law limits our ability to declare and pay dividends, and may subject us to certain Israeli taxes.

You may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive dividends or other distributions on our ordinary shares and you may not receive any value for them, if it is illegal or impractical to make them available to you.

The depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act, but that are not properly registered or distributed under an applicable exemption from registration. In addition, conversion into U.S. dollars from foreign currency that was part of a dividend made in respect of deposited ordinary shares may require the approval or license of, or a filing with, any government or agency thereof, which may be unobtainable. In these cases, the depositary may determine not to distribute such property and hold it as "deposited securities" or may seek to affect a substitute dividend or distribution, including net cash proceeds from the sale of the dividends that the depositary deems an equitable and practicable substitute. We have no obligation under U.S. securities laws to register any ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. In addition, the depositary may deduct from such dividends or distributions its fees and may withhold an amount on account of taxes or other governmental charges to the extent the depositary believes it is required to make such withholding. This means that you may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the ADSs.

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could augur less favorable results to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that holders and beneficial owners of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement or the ADSs, including claims under federal securities laws, against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court. However, we believe that a jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the deposit agreement, by a court of the State of New York or a federal court, which have non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement and the ADSs. In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one that is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute), none of which we believe are applicable in the case of the deposit agreement or the ADSs. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any provision of the federal securities laws. If you or any other holder or beneficial owner of ADSs brings a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may augur different results than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

Holders of ADSs must act through the depositary to exercise their rights as our shareholders.

Holders of the ADSs do not have the same rights as our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement for the ADSs. Under Israeli law and our articles of association, the minimum notice period required to convene a shareholders' meeting is no less than 35 or 14 calendar days, depending on the proposals on the agenda for the shareholders meeting. When a shareholder meeting is convened, holders of the ADSs may not receive sufficient notice of a shareholders' meeting to permit them to withdraw their ordinary shares to allow them to cast their vote with respect to any specific matter. In addition, the depositary and its agents may not be able to send voting instructions to holders of the ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to holders of the ADSs in a timely manner, but we cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their ADSs. Furthermore, the depositary and its agents are not responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of the ADSs may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they requested. In addition, in the capacity as a holder of ADSs, they will not be able to call a shareholders' meeting.

You may be subject to limitations on transfer of your ADSs.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deem it advisable to do so because of any requirement of law or of any government or governmental body, under any provision of the deposit agreement, or for any other reason in accordance with the terms of the deposit agreement.

Our U.S. shareholders may suffer adverse tax consequences if we are characterized as a passive foreign investment company, or PFIC.

Generally, if for any taxable year, 75% or more of our gross income is passive income, or at least 50% of our assets are held for the production of, or produce, passive income, we would be characterized as a PFIC for U.S. federal income tax purposes. We believe that we were a PFIC in 2017, 2018 and 2019 and, based on estimates of our gross income and gross assets and the nature of our business, we believe that we will be classified as a PFIC for the taxable year ending December 31, 2020. Because PFIC status is based on our income, assets and activities for the entire taxable year, it is not possible to determine with certainty whether we will be characterized as a PFIC for the 2020 taxable year until after the close of the year. Moreover, we must determine our PFIC status annually based on tests that are factual in nature, and our status in future years will depend on our income, assets and activities in those years. In any taxable year in which we are characterized as a PFIC for U.S. federal income tax purposes, a U.S. holder that owns ADSs could face adverse U.S. federal income tax consequences, including having gains realized on the sale of the ADSs classified as ordinary income, rather than as capital gain, the loss of the preferential rate applicable to dividends received on the ADSs by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of ADS sales. Certain elections exist that may alleviate some adverse consequences of PFIC status and would result in an alternative treatment (such as mark-to-market treatment) of the ADSs. If we are a PFIC in any year, U.S. holders may be subject to additional Internal Revenue Service ("IRS") filing requirements, including the filing of IRS Form 8621, as a result of directly or indirectly owning stock of a PFIC.

We may be treated as a U.S. corporation for U.S. federal income tax purposes.

For U.S. federal income tax purposes, a corporation generally is considered tax resident in the place of its incorporation. We are incorporated under the laws of the State of Israel and, therefore, we should be a non-U.S. corporation under this general rule. However, Section 7874 of the Internal Revenue Code of 1986, as amended (the "Code"), contains rules that may result in a foreign corporation being treated as a U.S. corporation for U.S. federal income tax purposes. The application of these rules is complex and there is little guidance regarding certain aspects of their application.

Under Section 7874 of the Code, a corporation created or organized outside the United States will be treated as a U.S. corporation for U.S. federal tax purposes when (i) the foreign corporation directly or indirectly acquires substantially all of the properties held directly or indirectly by a U.S. corporation, (ii) the former shareholders of the acquired U.S. corporation hold at least 80% of the vote or value of the shares of the foreign acquiring corporation by reason of holding stock in the U.S. acquired corporation, and (iii) the foreign corporation's "expanded affiliated group" does not have "substantial business activities" in the foreign corporation's country of incorporation relative to its expanded affiliated group's worldwide activities. For this purpose, "expanded affiliated group" generally means the foreign corporation and all subsidiaries in which the foreign corporation, directly or indirectly, owns more than 50% of the stock by vote and value, and "substantial business activities" generally means at least 25% of employees (by number and compensation), assets and gross income of our expanded affiliated group are based, located and derived, respectively, in the country of incorporation.

We were incorporated on September 22, 2011 under the laws of the State of Israel for the purpose of a reincorporation merger ("Reincorporation"), which merged BTI with and into a wholly-owned subsidiary of BioCancell Ltd. We do not believe that we should be treated as a U.S. corporation as a result of the Reincorporation under Section 7874 of the Code because we believe that we have substantial business activities in Israel. However, the IRS may disagree with our conclusion on this point. In addition, there could be legislative proposals to expand the scope of U.S. corporate tax residence and there could be changes to Section 7874 of the Code or the Treasury Regulations promulgated thereunder that could result in us being treated as a U.S. corporation.

If it were determined that we should be treated as a U.S. corporation for U.S. federal income tax purposes, we could be liable for substantial additional U.S. federal income tax on our taxable income since the Reincorporation. In addition, payments of dividends to non-U.S. holders may be subject to U.S. withholding tax.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, results of operation or financial condition. In addition, current and potential shareholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of the ADSs.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. We are required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which requires annual management assessments of the effectiveness of our internal controls over financial reporting. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404. Disclosing deficiencies or weaknesses in our internal controls, failing to remediate these deficiencies or weaknesses in a timely fashion or failing to achieve and maintain an effective internal control environment may cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of the ADSs. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed.

As an "emerging growth company" under the Jumpstart Our Business Startups Act, we are permitted to, and intend to continue to, rely on exemptions from certain disclosure requirements, which could make the ADSs less attractive to investors.

For as long as we are deemed an emerging growth company, we are permitted to and intend to take advantage of specified reduced reporting and other regulatory requirements that are generally unavailable to other public companies, including:

- an exemption from the auditor attestation requirement in the assessment of our internal controls over financial reporting required by Section 404 of the Sarbanes-Oxley Act; and

- an exemption from compliance with any new requirements adopted by the Public Company Accounting Oversight Board (the "PCAOB") requiring mandatory audit firm rotation or a supplement to the auditor's report in which the auditor would be required to provide additional information about our audit and our financial statements.

We will be an emerging growth company until the earliest of (i) the last day of the fiscal year during which we had total annual gross revenues of $1.07 billion or more, (ii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt, (iii) December 31, 2024 or (iv) the date on which we are deemed a "large accelerated issuer" as defined in Regulation S-K of the Securities Act.

We cannot predict if investors will find the ADSs less attractive because we may rely on these exemptions. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and the market price of the ADSs may be more volatile.

We could now be treated as a smaller reporting company given that as of January 1, 2020 we are reporting as a U.S. domestic issuer.

We may take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could make the ADSs less attractive to investors.

We have a public float of less than $250 million and therefore qualify as a smaller reporting company under the rules of the SEC. As a smaller reporting company we are able to take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in its SEC filings. Decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find the ADSs less attractive if we rely on these exemptions. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and our share price may be more volatile. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status would end once we have a public float greater than $250 million. In that event, we could still be a smaller reporting company if our annual revenues were below $100 million and we have a public float of less than $700 million.

The ADSs may be delisted from Nasdaq if we fail to comply with continued listing standards.

If we fail to meet any of the continued listing standards of Nasdaq, the ADSs could be delisted from The Nasdaq Capital Market. These continued listing standards include specifically enumerated criteria, such as:

- a $1.00 minimum closing bid price;
- shareholders' equity of $2.5 million;
- 500,000 shares of publicly-held shares with a market value of at least $1 million;
- 300 round-lot shareholders; and
- compliance with Nasdaq's corporate governance requirements, as well as additional or more stringent criteria that may be applied in the exercise of Nasdaq's discretionary authority.

There can be no assurance that we will be able to maintain compliance and remain in compliance in the future. In particular, our share price may continue to decline for a number of reasons, including many that are beyond our control. See "—The ADS price could continue to be highly volatile and you may not be able to resell your ADSs at or above the price you paid for them."

If we fail to comply with Nasdaq's continued listing standards, we may be delisted and the ADSs will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board or OTCQX market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of the ADSs could depress our share price, substantially limit liquidity of the ADSs and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Further, delisting of the ADSs would likely result in the ADSs becoming a "penny stock" under the Exchange Act.

Recent changes to the composition of our board of directors and senior management may disrupt our business plans.

Four of our directors have recently resigned from our board of directors and our CEO and CFO were replaced. It is possible that these changes in the board's composition and any future changes to the composition of our senior management team may disrupt our business and may create uncertainty among investors, employees and our collaboration partner concerning our future direction and performance. Any such disruption or uncertainty could have a material adverse impact on our results of operations and financial condition and the market price of the ADSs.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

In January 2020, our board of directors approved our management's recommendation to close our Israeli office and laboratories. Following the closure of our Israeli facilities in May 2020, our sole remaining office was located in Cambridge, Massachusetts. Our lease for this office in Cambridge, Massachusetts terminated on February 28, 2021. We are allowed, however, to continue using this address to receive mail. We do not currently own or lease any real property.

Item 3. Legal Proceedings

From time to time, we may be party to litigation or other legal proceedings that we consider to be a part of the ordinary course of our business. We are not currently involved in any legal proceedings that could reasonably be expected to have a material adverse effect on our business, prospects, financial condition or results of operations.

Since our publication of the proposed merger with Chemomab five separate complaints have been filed by putative stockholders of the Company challenging the proposed merger. In general, the complaints each allege that the Registration Statement on Form S-4 that we filed with the SEC on January 13, 2021, omitted or misrepresented material information regarding the merger. The complaints seek, among other things, injunctive relief, damages, and an award of plaintiff's costs, including attorneys' fees and expenses. It is still too early to assess and determine the possible / probable outcome of these complaints. See note 10B for additional detail.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's ADSs, Related Stockholder Matters and Issuer Purchases of Equity Securities

The ADSs, representing our ordinary shares, have been trading on Nasdaq under the symbol "ANCN" since February 12, 2019. Prior to that date, there was no public trading market for the ADSs. Our ordinary shares were traded on the Tel Aviv Stock Exchange ("TASE") until June 2019, under the symbol "ANCN".

As of February 18, 2020, there were seven holders of record of our ordinary shares.

Item 6. Selected Financial Data

Not applicable.

Item 7. 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 Annual Report on Form 10-K. 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 this Annual Report on Form 10-K 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.

On September 13, 2019, we entered into a Collaboration and License Agreement (the "License Agreement") with ADT Pharmaceuticals, LLV ("ADT"), pursuant to which we acquired the rights to two small molecule developmental programs targeting oncogenic pathways, focused on pan-mutant RAS inhibitors (our "pan-RAS-inhibitor program") and inhibitors of PDE10 and the β-catenin pathway, respectively. Under the License Agreement, we are primarily responsible for the research, development, manufacturing, regulatory and commercial activities with respect to the compounds conveyed and contemplated thereunder. Our operations are focused on the successful development, regulatory approval and commercialization of products derived from such compounds.

For further information regarding our business and operations, see "Item 1. Business."

Our corporate structure consists of a parent company, Anchiano Therapeutics Ltd. (formerly BioCancell Ltd.), incorporated in Israel, which wholly owns a subsidiary, Anchiano Therapeutics Israel Ltd. (formerly BioCanCell Therapeutics Israel Ltd.), incorporated in Israel, which itself wholly owns a subsidiary, Anchiano Therapeutics, Inc. (formerly BioCanCell USA, Inc.), incorporated in Delaware. We currently maintain offices in Cambridge, MA.

License Agreements

In September 2019, we publicly announced that we had entered into the License Agreement with ADT. Pursuant to the terms and conditions set forth in the License Agreement, we 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 are 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 License 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 License Agreement, we paid ADT a $3 million upfront fee in 2019, and agreed to pay to ADT (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 License Agreement at any time in its entirety or on a compound-by-compound basis after providing 90 days written notice to ADT. Since there is no alternative future use for the upfront fee, we accounted for it as a research and development expense.

In April 2020, we notified Yissum Technology Transfer Company of the Hebrew University Ltd. ("Yissum") that as a result of our previous decision to discontinue clinical development of inodiftagene, we will cease payments to maintain intellectual property ("IP") we licensed from Yissum under the licensing and development agreement between the parties. In August 2020 we agreed with Yissum on termination of the licensing and development agreement, we destroyed or returned all IP documentation to Yissum and we and Yissum mutually waived, released and discharged each other from all claims of any type.

Recent Events

On July 2, 2020, our Chief Executive Officer Dr. Frank Haluska sent a letter to the Chairman of our board of directors outlining Dr. Haluska's belief that events had occurred that were sufficient to trigger his ability to resign for "Good Reason" under his employment agreement. Our board of directors informed Dr. Haluska that it disagreed with the letter's assertions regarding "Good Reason" and treated the letter as a constructive resignation effective as of July 2, 2020. On July 12, 2020, Dr. Frank Haluska tendered his written resignation from our board of directors, effective immediately. Dr. Haluska referenced the matters articulated in his letter of July 2, 2020, and the Company's response and actions following receipt of the letter as the basis for his resignation from the Board. It is our position, based on our legal counsel, that the CEO resigned without Good Reason, is not entitled to severance, and we will contest any and all claims for severance. Prior to the appointment of Mr. Neil Cohen as CEO in October 2020 (see below) our board of directors handled all matters related to CEO duties.

In light of business circumstances, and in order to conserve cash and preserve optionality while alternatives are being identified and assessed, we made a decision during July 2020 to undertake reductions in headcount and other cost saving measures. These included plans to temporarily reduce its internal and external research and development work on the Company's pan-RAS-inhibitor program until there is greater clarity regarding Anchiano's ability to fund the program. We continue to undertake actions for the promotion of the program and its assets and towards strengthening the protection of all related intellectual property.

We also engaged Oppenheimer & Co. to act as our financial advisor to review strategic alternatives focused on maximizing shareholder value. This has resulted in the contemplated merger with Chemomab

On October 20, 2020, we appointed Mr. Neil Cohen as Chief Executive Officer of Anchiano. Mr. Cohen continues to serve as a member of our board of directors. The Company also appointed Andrew Fine to serve as our Chief Financial Officer. Mr. Fine previously served as our Interim Chief Financial Officer pursuant to a subcontracting agreement.

On December 14, 2020 we entered into an Agreement and Plan of Merger with Chemomab, an Israeli limited company and a clinical-stage biotech company focusing on the discovery and development of innovative therapeutics for fibrosis-related diseases with high unmet need, which included the proposed Merger of CMB Acquisition Ltd., a wholly owned subsidiary of ours, with Chemomab as the surviving company, subject to shareholder approval.

At the effective time of the Merger, we anticipate that each share of Chemomab common stock outstanding immediately prior to the effective time of the Merger will be converted into the right to receive approximately 1,028.99 shares of Anchiano common stock, subject to adjustment to account for a reverse split of Anchiano common stock at a reverse split ratio to be determined by Anchiano's board of directors, subject to shareholder approval, and to be implemented prior to the consummation of the Merger.

Immediately following the merger, and prior to any private investment as part of the merger, the former Chemomab security holders will own approximately 90% of the aggregate number of shares of Anchiano common stock and the security holders of Anchiano as of immediately prior to the Merger will own approximately 10% of the aggregate number of shares of Anchiano common stock on a fully diluted basis.

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, despite our strategic decision during 2020 to temporarily reduce development of the Company's RAS program and to institute various cost savings measures to preserve liquid resources. 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 do not believe that it is possible at this time to accurately project total expenses required for us to reach commercialization of our product candidates. 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. Should our strategic merger initiatives not come to fruition we expect our research and development expenses to increase over the next several years as our clinical programs progress and as we seek to initiate clinical trials of additional product candidates. 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;
- expenses incurred in operating our laboratories and small-scale equipment;
- 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 Expenses, Net

Finance expenses, 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 6c in "Item 8. Financial Statements and Supplementary Data" below), offset by interest income.

Restructuring Expenses

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 and employee severance and associated termination costs related to the reduction of our 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 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.

Income Taxes

We have yet to generate taxable income in Israel. We have historically incurred operating losses resulting in carry forward tax losses totaling approximately $117 million as of December 31, 2020. We anticipate that we will continue to generate tax losses for the foreseeable future and that we will be able to carry forward these tax losses indefinitely to future taxable years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses. We have provided a full valuation allowance with respect to the deferred tax assets related to these carry forward losses.

Results of Operations

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

	Year ended December 31,	
	2020	**2019**
Operating Expenses:		
Research and development	$ 3,783	$ 13,303
General and administrative	7,180	6,245
Restructuring expense	749	3,350
Total operating expenses	11,712	22,898
Finance (income) expense,net	(103)	4,226
Net loss and comprehensive loss	$ 11,609	$ 27,124
Loss per share basic and diluted	$ 0.31	$ 0.79
Weighted average number of shares outstanding used in computation of basic and diluted loss per share in thousands	37,099	34,446

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.

Year ended December 31, 2020 Compared to the Year Ended December 31, 2019

Research and development expenses

Research and development expenses decreased by approximately $9.5 million, 72%, to approximately $3.8 million for the year ended December 31, 2020 compared to approximately $13.3 million for the year ended December 31, 2019. The decrease resulted primarily from the restructuring decisions made in July 2020 and the related decision to temporarily reduce our research activities on the RAS programs and sever our research and development employees while continuing to undertake all necessary actions for the maintenance of the program, its assets and all related intellectual property and licenses..

General and administrative expenses

General and administrative expenses increased by approximately $1.0 million, or 16%, to approximately $7.2 million for the year ended December 31, 2020 compared to approximately $6.2 million for the year ended December 31, 2019. The increase was primarily due to increases in professional fees, insurance and manpower expenses, offset by a decrease in share-based payment.

Restructuring expenses

Restructuring expenses decreased by approximately $2.6 million, or 78%, to approximately $0.7 million for the year ended December 31, 2020 compared to approximately $3.4 million for the year ended December 31, 2019

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 manufactures 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 Israeli employees.

In July 2020, we made the strategic decision to temporarily reduce development of our RAS program and to institute various cost savings measures to preserve liquid resources. At the same time, we continued to actively pursue the maintenance of our Licensing Agreement with ADT and protection of our intellectual property assets. The cost saving activities included contract termination with outsourced contractors working on clinical activities and to whom we are required to make certain payments to terminate the contracts.

Financing expense, net

Financing expense, net decreased by approximately $4.3 million, or 102%, to reflect financing income of approximately $0.1 million for the year ended December 31, 2020 compared to a financing expense of approximately $4.2 million for the year ended December 31, 2019. Financing income for the year ended December 31, 2020 was primarily interest income, foreign currency exchange rate gains. The financing costs in 2019 were primarily due to 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.

Income tax

Income tax remained at $0 million for the year ended December 31, 2020 as for the year ended December 31, 2019. Prior to 2019 our U.S. subsidiary provided us with general and clinical trial management services. For these services, our US subsidiary was compensated on a cost-plus basis, and recorded income taxes accordingly. In 2019, following our acquisition of the programs from ADT, our U.S. subsidiary ceased to provide us with general clinical trial management services and expenses related to the ADT programs are not part of the cost-plus compensation and accordingly our US subsidiary does not have taxable income for the current year.

Cash Flows

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

	Year ended December 31,		Increase/(decrease)	
	2020	**2019**	**$**	**%**
	(in thousands)			
Net cash used in operating activities	$ (12,712)	$ (16,458)	$ (3,746)	-23%
Net cash provided by (used in) investing activities	102	(95)	(197)	-207%
Net cash provided by financing activities	297	26,621	(26,324)	-99%
Net increase (decrease) in cash, cash equivalents and restricted cash	**$ (12,313)**	**$ 10,068**	**$ (22,381)**	**-222%**

Operating activities

Net cash used in operating activities decreased by approximately $3.7 million, to approximately $12.7 million for the year ended December 31, 2020 compared to approximately $16.5 million for the year ended December 31, 2019. This decrease is primarily due to the decrease in clinical trial expenses, manufacturing expenses, manpower expenses and as offset by restructuring expenses.

Investing activities

Net cash used in investing activities decreased by approximately $0.2 million, to reflect approximately $0.1 million of net cash provided by investing activities for the year ended December 31, 2020 compared to $0.1 million of net cash used in investing activities for the year ended December 31, 2019. This decrease was primarily due to the sale of laboratory equipment from our now closed facility in Israel, partially offset by purchases of fixed assets.

Financing activities

Net cash provided by financing activities decreased by approximately $26.3 million, to approximately $0.3 million for the year ended December 31, 2020 compared to $26.6 million for the year ended December 31, 2019. The net cash provided by financing activities for the year ended December 31, 2020 reflects an adjustment of share issuance expenses that were expensed in 2019 in relation to our initial public offering in the first quarter of 2019. We had no other financing activities in 2020.

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 years ended December 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 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.

Financial Derivatives

We evaluate all financial instruments issued in connection with its equity offerings when determining the proper accounting treatment for such instruments in our financial statements. We consider a number of generally accepted accounting principles under U.S. GAAP to determine such treatment and evaluates the features of the instrument to determine the appropriate accounting treatment. We utilize the Probability Weighted Expected Return Method (PWERM), Option Pricing Model (OM) or other appropriate methods to determine the fair value of its derivative financial instruments such as the warrant liability. For financial instruments indexed to and potentially settled in our shares that are determined to be classified as liabilities on the consolidated balance sheet, changes in fair value are recorded as a gain or loss in our consolidated statement of operations with the corresponding amount recorded as an adjustment to the liability on its consolidated balance sheet.

Accrued Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts 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 cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees payable to clinical research organizations and investigative sites in connection with clinical trials, vendors in connection with preclinical development activities, vendors related to product manufacturing, development, and distribution of clinical materials; and professional service fees for consulting and related services.

We base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to our contract arrangements. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows and expense recognition. 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 service fees, we estimate the time period over which services will be performed 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 prepaid accordingly. 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 our reporting changes in estimates in any particular period.

Recently-Issued Accounting Pronouncements

Certain recently-issued accounting pronouncements are discussed in Note 2, Summary of Significant Accounting Policies, to the consolidated financial statements included in "Item 8. Financial Statements and Supplementary Data" of this Annual Report.

Liquidity and Capital Resources

Following several fundraising rounds in prior years, in June 2018, we completed a $22.9 million fundraising round from investors in the United States and Israel, as well as existing shareholders, led by Shavit Capital Funds. In consideration for the investment, we issued 5,960,787 ordinary shares (constituting approximately 38% of our issued and outstanding share capital after completion of the transaction) at a price per share of approximately $3.842, as well as 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 and may be exercised on a cashless basis. In addition, we granted the investors price protection rights (to shares and warrants) in the event of a future share issuance where 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).

In February 2019, we raised $30.5 million in our Nasdaq initial public offering, allocating 2,652,174 ADSs, each representing five ordinary shares. In accordance with price protection rights granted in 2018 and activated in the offering, we allocated 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).

As shown in the accompanying consolidated financial statements, we have incurred losses and cash flow deficits from operations since inception, resulting in an accumulated deficit at December 31, 2020 of approximately $117 million. We have financed operations to date primarily through public and private placements of equity securities. We anticipate that we will continue to incur net losses for the foreseeable future. We believe that our existing cash and cash equivalents will only be sufficient to fund our projected cash needs until the completion of the contemplated merger with Chemomab during the first half of 2021. Accordingly, these factors, among others, raise substantial doubt about our ability to continue as a going concern. To meet future capital needs, and should the contemplated merger with Chemomab not be completed, we 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 us. Our failure to obtain sufficient funds on commercially acceptable terms when needed would have a material adverse effect on our 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 our expenses could vary materially and adversely as a result of a number of factors. We have based our estimates on assumptions that may prove to be wrong, and our expenses could prove to be significantly higher than we currently anticipate.

Current Outlook

We estimate that our current cash resources will allow us to complete the contemplated merger with Chemomab during the first half of 2021, meaning that should the merger not be completed further fundraising will be required in order to identify and pursue alternative strategic partnerships or complete the research and development of our product candidates. Should the contemplated merger not be completed we would expect to satisfy our future cash needs through capital raising from the public, private investors and institutional investors, such as through the public offering of ordinary shares that we completed in February 2019. We may also engage with a partner in order to share the costs associated with the development and manufacturing of our product candidates or seek to enter an out-licensing agreement.

Developing drugs, conducting preclinical and clinical trials, obtaining commercial manufacturing capabilities and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. We will require significant additional financing in the future to fund our operations, including if and when we progress into clinical trials of our product candidates, obtain regulatory approval for one or more of our product candidates, obtain commercial manufacturing capabilities and commercialize one or more of our product candidates. Our future capital requirements will depend on many factors, including, but not limited to:

- the progress and costs of our preclinical and clinical trials and other research and development activities;
- the scope, prioritization and number of our preclinical and clinical trials and other research and development programs;
- the amount of revenues and contributions we receive under future licensing, collaboration, development and commercialization arrangements with respect to our product candidates;
- the costs of development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval for one or more of our product candidates;
- our ability, or that of our collaborators, to achieve development milestones, marketing approval and other events or developments under potential future licensing agreements;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of contracting with third parties to provide sales and marketing capabilities for us or establishing such capabilities ourselves;
- the costs of acquiring or undertaking development and commercialization efforts for any future products, product candidates or technology;
- the magnitude of our general and administrative expenses; and
- any additional costs that we may incur under future in- and out-licensing arrangements relating to one or more of our product candidates.

Until we can generate significant recurring revenues, and should the contemplated merger not be completed, we would expect to satisfy our future cash needs through capital raising or by out-licensing and/or co-developing applications of one or more of our product candidates. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of or eliminate research or development plans for, or commercialization efforts with respect to, one or more of our product candidates and make necessary change to our operations to reduce the level of our expenditures in line with available resources.

We are a development-stage company and it is not possible for us to predict with any degree of accuracy the outcome of our research and development efforts. As such, it is not possible for us to predict with any degree of accuracy any significant trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on our net loss, liquidity or capital resources, or that would cause financial information to not necessarily be indicative of future operating results or financial condition. However, to the extent possible, certain trends, uncertainties, demands, commitments and events are described in this item.

Item 8. Financial Statements and Supplementary Data

See the Index to Consolidated Financial Statements on Page F-1 attached hereto.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Management's Annual Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting at December 31, 2020. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework (2013). Based on that assessment under those criteria, management has determined that, as of December 31, 2020, our internal control over financial reporting was effective.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Our directors and executive officers, their ages and positions as of the date of this Annual Report are as follows:

Name	Age	Position
Neil Cohen	57	Chief Executive Officer and Director
Andrew Fine	50	Chief Financial Officer
Stan Polovets[(1)(2)(3)]	57	Chairman
Ruth Alon[(1)(2)(3)]	69	Director
Isaac Kohlberg[(1)(2)(3)]	69	Director

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Governance Committee

A brief biography of each person who serves as an executive officer and/or director of our Company is set forth below:

Neil Cohen has served as a member of Anchiano's board of directors since April 2020 and as Anchiano's interim Chief Executive Officer since October 2020. Mr. Cohen has served as the Chairman and Chief Executive Officer of Castel Partners Ltd. since January 2012. In 1994, he co-founded Israel Seed Partners, a leading venture capital firm, and managed the firm until 2019. Mr. Cohen has invested in and served on the boards of directors of many private technology companies, including a large number which were acquired or completed successful initial public offerings, including Compugen (Nasdaq: CGEN), Shopping.com (Nasdaq: SHOP, acquired by EBAY), Broadlight (acquired by Broadcom, Nasdaq: AVGO) and Cyota (acquired by RSA). He is a venture partner at SKY, an Israeli middle-market private equity firm, Hetz Ventures Management Ltd., an early-stage Israeli venture capital fund, and Shavit Capital. Mr. Cohen was previously the Business Editor of The Jerusalem Post and began his career in the private equity group at N M Rothschild & Sons Limited in London. Mr. Cohen received a B.A. and M.A. in Oriental Studies, with first class honors, from Oxford University.

Stan Polovets has served as chairman of Anchiano's board of directors since April 2020. Mr. Polovets is a graduate of Stanford Graduate School of Business, he also currently serves as a member of the Board of Overseers of New York University (NYU) Tandon School of Engineering, NYU President's Global Council, and the Council on Foreign Relations. Mr. Polovets previously served as CEO of AAR, a private equity firm with a global energy portfolio valued in excess of $25 billion, and as Sr. Vice President at TNK-BP, one of the world's largest oil companies. Mr. Polovets also held management, advisory, M&A and various financial positions at ExxonMobil, KPMG, TNK-BP and EY. Prior to joining Anchiano's board, Mr. Polovets served as Lead Non-Executive Director of Clal Industries, Lead Independent Director of L1 Energy, Lead Independent Director at Taavura, member of the Board of Overseers at Stanford University's Hoover Institution, Chairman for Eastern Europe at Edelman, and director at oil companies Slavneft and TNK-BP. He is a co-founder and chairman of The Genesis Prize Foundation, a prominent international philanthropic group.

Andrew Fine has served as our Chief Financial Officer since October 2020 having previously served as our interim Chief Financial Officer since July 2020. Mr. Fine has over 20 years of experience in executive financial and operational roles and is currently Co-Managing Director at Line Consulting Ltd. Mr. Fine previously held roles as Chief Financial Officer at Seeking Alpha, ScaleMP and Freightos, leading finance and operations for the companies' global activities. Mr. Fine holds a BA and an MBA from the Hebrew University of Jerusalem.

Ruth Alon has served as a director since September 2017. Ms. Alon is the founder and Chief Executive Officer of Medstrada Israel, a venture capital fund focusing on food and nutrition technologies. Between 1997 and 2016, Ms. Alon served as a general partner of Pitango Venture Capital. Prior to her tenure at Pitango, Ms. Alon held senior positions with Montgomery Securities from 1981 to 1987, Genesis Securities, LLC from 1993 to 1996, and Kidder Peabody & Co. from 1987 to 1993, as well as managing her own medical device independent consulting business in San Francisco from 1995 to 1996. Ms. Alon was the founder and chairperson of Israel Life Science Industry, a not-for-profit organization then representing the mutual goals of approximately 700 Israeli life science companies. She is also the co-founder of IATI, Israel Advanced Technology Industries, an umbrella organization for all high-tech and life sciences companies in Israel. She has a B.A. in economics from The Hebrew University of Jerusalem, Israel and an M.B.A. from Boston University.

Isaac Kohlberg has served as a director since February 2017. He is the Senior Associate Provost and Chief Technology Development Officer at Harvard University. Previously, he was Chief Executive Officer of the Tel Aviv University Economic Corporation and Chief Executive Officer of RAMOT at Tel Aviv University, a technology transfer company. He served as Vice President at New York University Medical Center and Vice Provost of New York University. He also served as the Managing Director of Yeda R&D Company of the Weizmann Institute of Science. Mr. Kohlberg serves on the board of directors of CBI and Elicio Therapeutics, a privately-held biotechnology company of which CBI is a substantial shareholder. Mr. Kohlberg received a diploma in French cultural and historical studies from the University of Strasbourg, an M.B.A. from INSEAD and an LL.B. from Tel Aviv University.

Committees of the Board of Directors

Our board of directors has established the following committees. Each committee operates in accordance with a written charter that sets forth the committee's structure, operations, membership requirements, responsibilities and authority to engage advisors.

Audit Committee

Under the Companies Law, the Exchange Act and Nasdaq rules, we are required to establish an Audit Committee.

The responsibilities of an Audit Committee under the Companies Law include identifying and addressing flaws in the business management of the company, reviewing and approving related party transactions, establishing whistleblower procedures, overseeing the company's internal audit system and the performance of its internal auditor, and assessing the scope of the work and recommending the fees of the company's independent accounting firm. In addition, the Audit Committee is required to determine whether certain related party actions and transactions are "material" or "extraordinary" for the purpose of the requisite approval procedures under the Companies Law and to establish procedures for considering proposed transactions with a controlling shareholder.

In accordance with U.S. law and Nasdaq requirements, our Audit Committee is also responsible for the appointment, compensation and oversight of the work of our independent auditors and for assisting our board of directors in monitoring our financial statements, the effectiveness of our internal controls and our compliance with legal and regulatory requirements.

Under the Companies Law and related regulations, the Audit Committee must consist of at least three directors who meet certain independence criteria. Under the Nasdaq rules, we are required to maintain an Audit Committee consisting of at least three independent directors, all of whom are financially literate and one of whom has accounting or related financial management expertise. Each of the members of the Audit Committee is required to be "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act.

Our Audit Committee currently consists of Ms. Ruth Alon, Mr. Stan Polovets and Mr. Isaac Kohlberg. All of the members are independent as defined in the Companies Law, SEC rules and Nasdaq listing requirements. Our board of directors has determined that all members of our Audit Committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq rules. Our board of directors has determined that Ms. Ruth Alon is an Audit Committee financial expert as defined by the SEC rules and has the requisite financial experience as defined by the Nasdaq rules.

Compensation Committee

Under both the Companies Law and Nasdaq rules, we are required to establish a Compensation Committee.

The responsibilities of a Compensation Committee under the Companies Law include recommending to the board of directors, for ultimate shareholder approval by a special majority, a policy governing the compensation of directors and officers based on specified criteria, reviewing modifications to and implementing such compensation policy from time to time, and approving the actual compensation terms of directors and officers prior to approval by the board of directors.

In accordance with U.S. law and Nasdaq requirements, our Compensation Committee is also responsible for the appointment, compensation and oversight of the work of any compensation consultant, independent legal counsel and other advisors retained by the Compensation Committee.

The Companies Law and related regulations require the appointment of a Compensation Committee that complies with the requirements of Nasdaq. Under Nasdaq rules, we are required to maintain a Compensation Committee consisting of at least two independent directors; each of the members of the Compensation Committee is required to be independent under Nasdaq rules relating to Compensation Committee members, which are different from the general test for independence of board and committee members. Our Compensation Committee currently consists of Ms. Ruth Alon, Mr. Stan Polovets and Mr. Isaac Kohlberg. All of the members are independent as defined in the Companies Law and the Nasdaq listing requirements.

Corporate Governance and Nominating Committee

We have established a Corporate Governance and Nominating Committee, responsible for making recommendations to the board of directors regarding candidates for directorships and the size and composition of the board. In addition, the committee is responsible for overseeing our corporate governance guidelines and reporting and making recommendations to the board concerning corporate governance matters. Under the Companies Law, nominations for director may also, under certain circumstances, be made by shareholders in accordance with the conditions prescribed by applicable law and our articles of association. Our Corporate Governance and Nominating Committee currently consists of Ms. Ruth Alon, Mr. Stan Polovets and Mr. Isaac Kohlberg. All of the members are independent as defined in the Nasdaq listing requirements.

Internal Auditor

Under the Companies Law, the board of directors is required to appoint an internal auditor recommended by the Audit Committee. The role of the internal auditor is to examine, among other things, whether the company's actions comply with applicable law and proper business procedures. The internal auditor may not be an interested party, a director or an officer of the company, or a relative of any of the foregoing, nor may the internal auditor be our independent accountant or a representative thereof. Mr. Joseph Ginossar, CPA, who is the chief executive officer of Fahn Kanne Control Management Ltd. (the Business Risk Services division of Grant Thornton Israel), currently serves as our internal auditor.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and holders of more than 10% of our ordinary shares to file with the SEC reports regarding their ownership and changes in ownership of our equity securities. We believe that all Section 16 filings requirements were met by our officers and directors during 2020.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that includes provisions ranging from restrictions on gifts to conflicts of interest. All of our employees and directors are bound by this Code of Business Conduct and Ethics. Violations of our Code of Business Conduct and Ethics may be reported to the Audit Committee. The Code of Business Conduct and Ethics includes provisions applicable to all of our employees, including senior financial officers and members of our Board of Directors and is posted on our website. We intend to post amendments to or waivers from any such Code of Business Conduct and Ethics.

Item 11. Executive Compensation

Aggregate Compensation of Directors and Officers

The aggregate compensation we paid to our executive officers and directors for the year ended December 31, 2020 was approximately $2.7 million. This amount includes amounts paid, set aside or accrued to provide pension, severance, retirement or similar benefits or expenses, but does not include share-based compensation expenses, or business travel, professional and business association dues and expenses reimbursed to office holders, and other benefits commonly reimbursed or paid by companies in our industry. As of December 31, 2020, options to purchase 220,353 ordinary shares granted to our officers and directors were outstanding under our share option plan at a weighted average exercise price of $0.6 per share.

Individual Compensation of Officers

The table and summary below outlines the compensation granted to our five most highly compensated officers with respect to the year ended December 31, 2020. For purposes of the table and the summary below, "compensation" includes base salary, bonuses, equity-based compensation, retirement or termination payments, benefits and perquisites such as car, phone and social benefits and any undertaking to provide such compensation.

Name and Principal Position	Salary[1] (USD in thousands)	Bonus[2] (USD in thousands)	Equity-Based Compensation[3] (USD in thousands)	Total (USD in thousands)
Mr. Jonathan Burgin				
Ex.Chief Financial and Operating Officer	$ 457	$ -	$ 73	$ 530
Dr. Frank G. Haluska				
Ex.Chief Executive Officer	$ 303	$ -	$ 83	$ 385
Dr. David Kerstein				
Ex.Chief Medical Officer	$ 426	$ -	$ (107)	$ 319
Dr. Ron Knickerbocker				
Ex.Senior Vice President of Clinical Development and Data Sciences	$ 354	$ -	$ (53)	$ 301
Mr. Sean Daly				
Ex.Vice President of Clinical Operations	$ 295	$ -	$ (26)	$ 269

(1) Salary includes gross salary plus payment by us of social benefits on behalf of the officer. Such benefits may include, to the extent applicable, payments, contributions and/or allocations for risk insurance (e.g., life, or work disability insurance), payments for social security, vacation, medical insurance and benefits, and other benefits and perquisites consistent with our policies.

(2) Represents bonuses granted with respect to 2020.

(3) Represents the equity-based compensation expenses recorded in our consolidated financial statements for the year ended December 31, 2020, based on the options' fair value on the grant date, calculated in accordance with applicable accounting guidance for equity-based compensation. For a discussion of the assumptions used in reaching this valuation, see Note 2L to our annual consolidated financial statements included in this Annual Report on Form 10-K.

Outstanding Equity Awards

The table below outlines the unexercised options; stock that has not vested; and equity incentive plan awards for each executive officer outstanding as of December 31, 2020.

	Option award			
Name	Number of securities underlying unesercised options (#) exercisable	Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date
Neil Cohen	-	55,000	0.17	14-Jul-30
	3,533	-	76.60	24-Sep-21
	4,504	-	7.29	8-May-24
Burgin Jonathan	6,000	-	3.76	26-Apr-25
	87,500	12,500	2.83	8-Sep-27
	98,875	127,125	1.03	30-Jun-29
	562,782	-	2.60	27-Dec-26
Haluska Frank	164,942	-	2.90	25-Sep-27
	909,203	-	3.67	30-Jun-28

Director Compensation

The table below outlines the unexercised options; stock that has not vested; and equity incentive plan awards for each executive officer outstanding as of December 31, 2020.

Name	Feed earned or paid in cash ($)	Stock awards ($)	Option awards ($)	Non-equity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation ($)	Total ($)	Outstanding options as of December 31, 2020
Veru Dennison	19,375	-	3,975	-	-	-	23,350	-
Howard Lawrance	10,625	-	3,975	-	-	-	14,600	-
Hardy Reginald	10,938	-	3,975	-	-	-	14,913	-
Ofer Gonen	8,750	-	0	-	-	-	8,750	-
Polovets Stan	71,250	-	1,933	-	-	-	73,183	55,000
Neil Cohen	32,408	-	1,933	-	-	-	34,341	55,000
Alon Ruth	53,050	-	10,289	-	-	-	63,340	55,353
Kohlberg Isaac	40,427	-	10,289	-	-	-	50,717	55,000

Employment Agreements

The material employment terms for Dr. Haluska, our former Chief Executive Officer, are as follows: (1) an annual salary of $480,000 ($400,000 until April 30, 2019, when it was amended by a general meeting of our shareholders); (2) an annual bonus, subject to achievement of objectives set by the board of directors, in the target amount of $200,000; (3) payment of nine months' of salary upon termination (or resignation for a good reason event), a partial annual bonus (pro rata) and partial vesting acceleration of option warrants (and in the case of termination or voluntary resignation with regard to changes in control of the company, a full annual bonus and full vesting acceleration of option warrants); and (4) all employee benefit plans, programs and arrangements, and all fringe benefits and perquisites that are made available to our senior executives, including health insurance coverage in accordance with the terms of our health insurance plan. In total, we have allocated Dr. Haluska options to purchase 2,059,016 ordinary shares in connection with his employment agreement. Of these, options to purchase 562,782, 164,942 and 909,203 ordinary shares vest in four annual tranches from the date of his employment (May 2016) with respective exercise prices of $2.60, $2.90 and $3.67, and options to purchase 422,090 ordinary shares vest in 16 quarterly tranches from the date of approval by our Board with an exercise price of $1.03.

The material employment terms for Neil Cohen, our interim Chief Executive Officer, as of October 20, 2020 consist of a monthly salary of $12,000. Prior to Mr. Cohen's employment, and in his capacity as a Director, we allocated Mr. Cohen options to purchase 55,000 ordinary shares. These options vest over a period of 3 years, with 33.33% vesting after 12 months from the date of approval by our Board and thereafter vest in 8 quarterly tranches.

Our other employees are employed under the terms prescribed in their respective employment contracts. The employees are entitled to the social benefits prescribed by law and as otherwise provided in their agreements. These agreements each contain provisions standard for a company in our industry regarding non-competition, confidentiality of information and assignment of inventions. We also provide certain of our employees with a company car, which is leased from a leasing company. These contracts provide for notice periods of varying duration for termination of the agreement by us or by the relevant employee, during which time the employee will continue to receive base salary and benefits.

Equity Incentive Plans

2011 Share Option Plan

On December 19, 2011, our board of directors adopted a share option plan (the "2011 Plan"), to allocate options to purchase our ordinary shares to our directors, officers, employees and consultants, and those of our affiliated companies (as such term is defined under the 2011 Plan), or the Grantees. The 2011 Plan is administered by our board of directors or a committee that was designated by our board of directors for such purpose, or the Administrator.

Under the 2011 Plan, we may grant options to purchase ordinary shares ("Options"), under four tracks: (i) Approved 102 capital gains Options through a trustee, which was approved by the Israeli Tax Authority in accordance with Section 102(a) of the Israeli Income Tax Ordinance ("ITO"), and granted under the tax track set forth in Section 102(b)(2) of the ITO, or the Approved 102 Capital Gains Options. The holding period under this tax track is 24 months from the date of allocation of Options to the trustee or such period as may be determined in any amendment of Section 102 of the ITO, or any applicable tax ruling or guidelines; (ii) Approved 102 Earned Income Options through a trustee, granted under the tax track set forth is Section 102(b)(1) of the ITO, or the Approved 102 Earned Income Options. The holding period under this tax track is 12 months from the date of allocation of Options to the trustee or such period as may be determined in any amendment of Section 102 of the ITO; (iii) Unapproved 102 Options (the Options will not be allocated through a trustee and will not be subject to a holding period), or the Unapproved 102 Options; and (iv) 3(i) Options (the Options will not be subject to a holding period). These Options shall be subject to taxation pursuant to Section 3(i) of the ITO, or Section 3(i).

Options pursuant to the first three tax tracks (under Section 102 of the ITO) can be granted to our employees and directors and the grant of Options under Section 3(i) can be granted to our consultants and controlling shareholders (a controlling shareholder is defined under the Section 102 of the ITO is a person who holds, directly or indirectly, alone or together with a "relative," (i) the right to at least 10% of the company's issued capital or 10% of the voting power; (ii) the right to hold at least 10% of the company's issued capital or 10% of the voting power, or the right to purchase such rights; (iii) the right to receive at least 10% of the company's profits; or (iv) the right to appoint a company's director). Grantees who are not Israeli residents may be granted options that are subject to the applicable tax laws in their respective jurisdictions.

We determine, in our sole discretion, under which of the first three tax tracks above the Options are granted and we notify the Grantee in a grant letter, as to the elected tax track. As mentioned above, consultants and controlling shareholders can only be granted Section 3(i) Options.

The number of ordinary shares authorized to be issued under the 2011 Plan will be proportionately adjusted for any increase or decrease in the number of ordinary shares issued as a result of a distribution of bonus shares, change in our capitalization (split, combination, reclassification of the shares or other capital change), or issuance of rights to purchase ordinary shares or payment of a dividend. We will not allocate fractions of ordinary shares and the number of ordinary shares shall be rounded up to the closest number of ordinary shares.

In the event of a (i) merger or consolidation in which we (in this context, specifically Anchiano Therapeutics Ltd.) is not the surviving entity or pursuant to which the other company becomes Anchiano Therapeutics Ltd.'s parent company or that pursuant to which Anchiano Therapeutics Ltd. is the surviving company but another entity holds 50% or more of Anchiano Therapeutics Ltd. voting rights, (ii) an acquisition of all or substantially all of our ordinary shares, (iii) the sale of all or substantially all Company assets, or (iv) any other event with a similar impact, the Company may exchange all of its outstanding Options granted under the 2011 Plan that remain unexercised prior to any such transaction for options to purchase shares of the successor corporation (or those of an affiliated company) following the consummation of such transaction.

Unless otherwise determined by the Administrator, the exercise price of an Option granted under the 2011 Plan will be the average of the market price of the Company's ordinary shares during the 22 business days prior to the date on which our board of directors authorized the grant of Options; provided, however, that such exercise price cannot be lower than the market price at the close of the trading day at which it was granted by our board of directors. The exercise price will be specified in the grant letter every Grantee received from us in which the Grantee notifies of the decision to grant him/her Options under the 2011 Plan.

Unless otherwise determined by the Administrator, the Options granted under the Plan will become vested and may be exercised in 16 equal portions of 6.25% of the total number of Options, at the end of each quarter following the day the Options were granted. Unless otherwise determined by our board of directors, the Options may be exercised for ten years following the date of grant, unless terminated earlier, and as long as the Grantee is employed by the Company (or by an affiliated company), or provides service to the Company (or an affiliated company).

The Administrator may, in its absolute discretion, accelerate the time at which Options granted under the 2011 Plan or any portion of which will vest.

Unless otherwise determined by the Administrator, in the event that the Grantee's employment was terminated, not for Cause (as defined in the 2011 Plan), the Grantee may exercise that portion of the Options that had vested as of the date of such termination until the end of the specified term in the grant letter or the 2011 Plan. The portion of the Options that had not vested at such date, will be forfeited and can be re-granted according to the terms of the 2011 Plan.

2017 Equity-Based Incentive Plan

On February 22, 2017, our board of directors adopted our 2017 Equity-Based Incentive Plan (the "2017 Plan"), to allocate a variety of share-based awards to our directors, officers, employees, consultants, advisors and service providers, and those of our affiliates (companies that control us, are controlled by us or are under common control with us), or the Participants. The 2017 Plan is currently administered by our board of directors, and may be administered by a committee designated by our board of directors for such purpose, or the Administrator.

Under the 2017 Plan, we may grant options to purchase ordinary shares or ADSs, restricted shares or ADSs, restricted share units and other awards based on our ordinary shares, all of which are referred to as Awards. We may grant Awards under the same four tracks as described above with respect to the 2011 Plan, subject to the same conditions as apply for the 2011 Plan. In addition, we may grant incentive stock options and nonqualified stock options to Participants who are residents of the United States, and we may grant awards to Participants who are residents of other countries that comply with the laws of those jurisdictions.

The number of ordinary shares authorized to be issued under the 2017 Plan will be proportionately adjusted for any increase or decrease in the number of ordinary shares issued as a result of a distribution of bonus shares, change in our capitalization (split, combination, reclassification of the shares or other capital change), issuance of rights to purchase ordinary shares or payment of a dividend. We will not allocate fractions of ordinary shares and the number of ordinary shares shall be rounded down to the closest number of ordinary shares.

In the event of a (i) merger, consolidation, amalgamation or the like with or into another corporation, (ii) an acquisition (including an exchange) of all or substantially all of our ordinary shares, (iii) the sale of all or substantially all of our assets, or (iv) any other event determined by the Administrator to have a similar impact, then – unless otherwise determined by our board of directors in its sole and absolute discretion – any Award then outstanding will be assumed or an equivalent Award shall be substituted by the successor corporation, under substantially the same terms as the Award.

The exercise price of an option granted under the 2017 Plan will, in general, be no less than the fair market value of the Company's ordinary shares on the date of grant, subject to any minimum exercise price prescribed by law. The Administrator determines the vesting provisions for each Award and may, in its sole discretion, accelerate the time at which options granted under the 2017 Plan will vest. Unless otherwise determined by the Administrator, options may be exercised for ten years (five years in the case of an incentive stock option granted to a 10% shareholder), and as long as the Participant is employed by the Company (or by an affiliated company) or provides services to the Company (or an affiliated company). If a Participant's employment is terminated, other than for cause, the Participant may generally exercise vested options for a limited period following termination.

In accordance with the terms of the 2017 Plan, on January 1 of each calendar year during the term of the 2017 Plan, the number of shares available for issuance under the 2017 Plan shall be increased by 4% of the total number of company shares outstanding on December 31 of the immediately preceding calendar year, or such lesser number as shall be determined by the administrator of the plan, subject to adjustments required for recapitalization events.

As of February 18, 2020, our board of directors has approved the issuance, under our incentive plans, of options to purchase 3,737,849 ordinary shares currently outstanding at an average exercise price of $2.51 per share.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth information, as of February 18, 2020, regarding beneficial ownership of our ordinary shares (including ordinary shares represented by ADSs):

- each person who is known by us to own beneficially more than 5% of our ordinary shares;
- each director;
- each executive officer; and
- all of our directors and executive officers collectively.

Beneficial ownership is determined in accordance with the rules of the SEC. Under these rules, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. For purposes of the table below, we deem ordinary shares issuable pursuant to options or warrants that are currently exercisable or exercisable within 60 days of the date of this Annual Report on Form 10-K, if any, to be outstanding and to be beneficially owned by the person holding the options or warrants for the purposes of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise noted, the address of each director and current and former executive officer of Anchiano is One Kendall Square, Building 1400E, Suite 14-105, Cambridge, Massachusetts 02139.

NAME OF BENEFICIAL OWNER	Total Beneficial Ownership	Percentage of Ordinary Shares Beneficially Owned*
5% and Greater Shareholders		
Clal Biotechnology Industries Ltd.(1)	9,307,662	25.09%
Shavit Capital Funds(2)	8,868,546	21.67%
Access Industries Holdings LLC(3)	15,829,397	42.67%
Edgewater Partner Holdings Ltd. (4)	1,923,075	5.18%
Directors and Executive Officers		
Neil Cohen	62,110	*
Andrew Fine	—	*
Ruth Alon(5)	32,399	*
Isaac Kohlberg(6)	32,090	*
Stanislav Polovets	—	*
All current executive officers and directors as a group (5 persons)	126,599	*

* Percentage ownership based on 37,099,352 ordinary shares outstanding as of the date of this Annual Report on Form 10-K.

(1) The beneficial ownership is based in part on the latest available filing made with the SEC on Schedule 13D on December 14, 2020 and consists of 6,911,166 ordinary shares and warrants to purchase 2,396,496 ordinary shares. To the best of our knowledge, Clal Industries Ltd. owns 47% of the outstanding shares of, and controls CBI (TASE: CBI). The remaining 53% of CBI's outstanding shares are publicly-held and listed on the TASE. Clal Industries Ltd. is wholly owned by Access AI Ltd., which is owned by AI Diversified Holdings S.à r.l., which is owned by AI Diversified Parent S.à r.l., which is owned by AI Diversified Holdings Limited, or AIDH Limited. AI SMS owns a majority of the equity of AIDH Limited. AIH owns a majority of the equity of AI SMS, and LLC holds a majority of the outstanding voting interests in AIH. AIM controls LLC and AIH, and Len Blavatnik controls AIM. The address of each of Clal Industries Ltd. and CBI is Triangle Tower, 3 Azrieli Center, Tel Aviv 67023, Israel and the address of each of foregoing other than Clal Industries Ltd. and CBI is 40 West 57th Street, 28th Floor, New York, NY 10019.

(2) The beneficial ownership is based on the latest available filing made with the SEC on Schedule 13G January 2, 2020 and consists of 5,034,150 ordinary shares and warrants to purchase 3,834,395 ordinary shares. Gabriel Capital Management Ltd. ("GCM") is the management company to Shavit Capital Fund III (US), L.P. ("Shavit III"), which holds 3,056,305 of the aforementioned ordinary shares and warrants to purchase 2,314,286 ordinary shares, and certain other affiliated funds (collectively with Shavit III, the "Shavit Funds"). Gabriel Leibler is the sole shareholder of the sole shareholder of GCM. Decisions regarding the voting and disposition of securities held by the Shavit Funds are subject to approval by certain internal investment committees comprising three or more individuals, of which Mr. Leibler is a member. As of December 31, 2019, other Shavit Funds held in the aggregate 1,977,845 ordinary shares and warrants to purchase 1,520,110 ordinary shares. GCM may be deemed to beneficially own such securities held by the Shavit Funds. To the best of our knowledge, the general partner of Shavit III and Shavit Capital Fund 3 (Israel), L.P. is Shavit Capital Fund 3 GP, L.P., which is managed by Shavit Capital Management 3 (GP) Ltd. in its capacity as the general partner. The general partner of Shavit Capital Fund IV (US), L.P. and Shavit Capital Fund 4 (Israel), L.P. is Shavit Capital Fund 4 GP, L.P., which is managed by Shavit Capital Management 4 (GP) Ltd. in its capacity as the general partner. The controlling shareholder of Shavit Capital Management 3 (GP) Ltd. and Shavit Capital Management 4 (GP) Ltd. is a company, the controlling shareholder of which is Mr. Leibler. Neil Cohen holds a 3.45% interest in Shavit Capital Fund 3 (Israel), L.P. and a 1.67% interest in Shavit Capital Fund 4 (Israel), L.P. The address of each of the foregoing other than Mr. Leibler and Mr. Cohen is Jerusalem Technology Park, Building 1B, Box 70, Malha, Jerusalem, 96951 Israel. The address of Mr. Leibler is 4a Gidon Street, Jerusalem 9350604 Israel.

(3) The beneficial ownership is based on the latest available filing made with the SEC on Schedule 13D on December 14, 2020 and consists of (i) the ordinary shares, ADSs and warrants owned directly by CBI and (ii) 6,521,735 ordinary shares represented by 1,304,347 ADSs owned directly by AIH. For more information on AIH and CBI, see footnote (1) above.

(4) Consists entirely of ordinary shares. Edgewater Partner Holdings Ltd. is beneficially owned by Mr. Youqiang Yu, and as such, Mr. Yu may be deemed to beneficially own the ordinary shares beneficially owned by Edgewater Partner Holdings Ltd. The shareholder's business address is c/o Edgewater Partner Holdings Ltd., Novasage Chambers, Level 2, CCCS Building, Beach Road, Apia, Samoa.

(5) Represents 32,399 shares of Anchiano's issuable upon the exercise of options.

(6) Represents 32,090 shares of Anchiano's issuable upon the exercise of options.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Certain Relationships and Related Transactions

We have entered into employment agreements with each of our executive officers. Compensation arrangements for our executive officers and directors are described in the sections entitled "Item 11. Executive Compensation" and "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

Our Articles of Association permit us to insure each of our directors and officers to the fullest extent permitted by the Companies Law. We have obtained Directors and Officers insurance for our executive officers and directors.

All related party transactions are reviewed and approved by the Audit Committee, as required by the Audit Committee Charter.

Family Relationships

There are no family relationships among directors or executive officers of our Company.

Corporate Governance and Independent Directors

In compliance with the listing requirements of Nasdaq, we have a comprehensive plan of corporate governance for the purpose of defining responsibilities, setting high standards of professional and personal conduct and assuring compliance with such responsibilities and standards. We currently regularly monitor developments in the area of corporate governance to ensure we are in compliance with the standards and regulations required by Nasdaq.

Our board of directors consists of four directors, of whom three (Ms. Ruth Alon, Mr. Isaac Kohlberg and Mr. Stan Polovets) qualify as independent directors under the corporate governance standards of the Nasdaq rules and the independence requirements of Rule 10A-3 of the Exchange Act. Under our articles of association, our board of directors must consist of not less than three and no more than 11 directors. Pursuant to our articles of association, the vote required to appoint a director is a simple majority vote of holders of our voting shares participating and voting at the relevant meeting.

In addition, our articles of association allow our board of directors to appoint new directors to fill vacancies which occurred for any reason or as additional directors, provided that the number of board members shall not exceed the maximum numbers of directors mentioned above. The appointment of a director by the board shall be in effect until the following annual general meeting of the shareholders or until the end of his tenure in accordance with our articles of association. Our board of directors may continue to operate for as long as the number of directors is not less than the minimum number of directors mentioned above.

In addition, under the Companies Law, our board of directors must determine the minimum number of directors who are required to have financial and accounting expertise. Under applicable regulations, a director with financial and accounting expertise is a director who, by reason of his or her education, professional experience and skill, has a high level of proficiency in and understanding of business accounting matters and financial statements. He or she must be able to thoroughly comprehend the financial statements of the company and initiate discussion regarding the manner in which financial information is presented. In determining the number of directors required to have such expertise, the board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our board of directors has determined that we require at least one director with the requisite financial and accounting expertise and that Ms. Ruth Alon, Mr. Isaac Kohlberg, Mr. Neil Cohen and Mr. Stan Polovets have such expertise.

Private Financings

In February 2018, CBI, which at the time was our controlling shareholder, extended bridge financing to us in the principal amount of $1.0 million, which was pending completion of the private placement of equity securities described below, and subsequently provided an additional $2.0 million principal amount of bridge financing. The unpaid principal amount of the bridge financing bore annual interest at the rate payable on three-month U.S. Treasury bills. The repayment of the bridge financing was made by deducting the repayment amount from the $5.0 million purchase price of the securities acquired by CBI pursuant to the Securities Purchase Agreement described below.

Pursuant to a Securities Purchase Agreement ("SPA"), dated March 29, 2018, between us and the investors identified therein, in June 2018 we issued 5,960,787 ordinary shares, and warrants to purchase an additional 4,768,629 ordinary shares, as well as price protection and certain other rights. The gross proceeds from the sale of the ordinary shares amounted to $22.9 million. As a result of our February 2019 initial public offering, price protection rights included in the SPA were triggered, resulting in the issuance of 8,262,800 ordinary shares and adjustments to the warrants, whereby they can be exercised for 6,207,330 additional ordinary shares, each at a price of $1.932 per share. For information regarding the current shareholdings of Shavit Capital Funds and CBI, see "Item 12—Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

Information Rights Agreement

We entered into an information rights agreement, effective as of December 19 2018, with one of our principal shareholders, CBI. The information rights agreement provides CBI with rights to receive our annual and quarterly financial statements, auditor consent letters and valuation reports, and other information reasonably required by CBI to enable it to prepare its financial statements. The information rights agreement also requires that we provide CBI with information material to the Company and mandated to be disclosed by the requirements applicable to CBI, as well as certain other material information of the Company. The information rights agreement contains customary confidentiality provisions and terminates when CBI, and any company that controls CBI, is no longer required to issue public reports relating to us pursuant to the Exchange Act.

Item 14. Principal Accountant Fees and Services

The following table sets forth fees billed to us by our independent registered public accounting firm during the fiscal years ended December 31, 2020 and 2019 for (i) services rendered for the audit of our annual financial statements and the review of our quarterly financial statements; (ii) services by our independent registered public accounting firm that are reasonably related to the performance of the audit or review of our financial statements and that are not reported as Audit Fees; (iii) services rendered in connection with tax compliance, tax advice and tax planning; and (iv) all other fees for services rendered.

	Year Ended December 31,	
	2020	**2019**
Audit Fees	160	255
Audit-Related Fees	-	-
Tax Fees	3	3
All Other Fees	-	-
Total	163	258

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors

Our Audit Committee has the sole authority to approve the scope of the audit and any audit-related services, as well as all audit fees and terms. The Audit Committee must pre-approve any audit and non-audit services provided by our independent registered public accounting firm. The Audit Committee will not approve the engagement of the independent registered public accounting firm to perform any services that the independent registered public accounting firm would be prohibited from providing under applicable laws, rules and regulations, including those of self-regulating organizations. The Audit Committee will approve permitted non-audit services by our independent registered public accounting firm only if it determines that using a different firm to perform such services will be less efficient or cost-effective. The Audit Committee reviews and pre-approves the statutory audit fees that can be provided by the independent registered public accounting firm on an annual basis.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Exhibit No.	Description
1.1	Anchiano Therapeutics Ltd. Amended and Restated Articles of Association (previously filed as Exhibit 3.2 of Amendment No. 4 to our Registration Statement on Form F-1 (File No. 333-229155) as filed with the SEC on February 11, 2019 and incorporated by reference herein).
2.1	Agreement and Plan of Merger between Anchiano Therapeutics Ltd. and CMB Acquisition Ltd. and Chemomab Ltd., dated December 14, 2020 (previously filed as Exhibit 2.1 to our Current Report on Form 8-K (File No. 001-38807) as filed with the SEC on December 15,2020 and incorporated by reference herein).
3.1	Deposit Agreement between Anchiano Therapeutics Ltd., the Bank of New York Mellon as Depositary, and owners and holders from time to time of ADSs issued thereunder (previously filed as Exhibit 4.1 to our Current Report on Form 6-K (File No. 001-38807) as filed with the SEC on February 14, 2019 and incorporated by reference herein).
4.1	Collaboration and License Agreement, dated as of September 13, 2019, by and between Anchiano Therapeutics Inc. and ADT Pharmaceuticals, LLC (previously filed as Exhibit 10.1 to our Current Report on Form 6-K (File No. 001-38807) as filed with the SEC on September 23, 2019 and incorporated by reference herein).
4.4	2011 Incentive Plan for Employees, Officers and Consultants (previously filed as Exhibit 10.6 of our Registration Statement on Form F-1 (File No. 333-229155) as filed with the SEC on January 7, 2019 and incorporated by reference herein).
4.5	Compensation Policy for Officers, dated February 2017 (previously filed as Exhibit 10.7 of our Registration Statement on Form F-1 (File No. 333-229155) as filed with the SEC on January 7, 2019 and incorporated by reference herein).
4.6	2017 Equity-Based Incentive Plan (previously filed as Exhibit 10.8 of our Registration Statement on Form F-1 (File No. 333-229155) as filed with the SEC on January 7, 2019 and incorporated by reference herein).
4.7	Information Rights Agreement between Anchiano Therapeutics Ltd. and Clal Biotechnology Industries Ltd., dated December 19, 2018 (previously filed as Exhibit 10.10 of our Registration Statement on Form F-1 (File No. 333-229155) as filed with the SEC on January 7, 2019 and incorporated by reference herein).
4.9	Proxy Statement / Prospectus (previously filed in our Registration Statement on form S-4 (File No. 335-252070) as filed with the SES on February 12, 2021.
21.1	List of Subsidiaries (filed herewith).
23.1	Consent of Independent Registered Public Accounting Firm83 (filed herewith).
24.1	Power of Attorney (filed herewith).
31.1	Certification of the Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended (filed herewith).
31.2	Certification of the Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended (filed herewith).
32.1	Certification of the Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.2	Certification of the Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

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

ANCHIANO THERAPEUTICS LTD.

Date: March 7, 2021

By: /s/ Neil Cohen
Neil Cohen
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Neil Cohen and Andrew Fine, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and re-substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that said attorneys-in-fact and agents, or any of them, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Neil Cohen Neil Cohen	Chief Executive Officer (Principal Executive Officer) and Director	March 7, 2021
/s/ Andrew Fine Andrew Fine	Chief Financial Officer (Principal Financial and Accounting Officer)	March 7, 2021
/s/ Stan Polovets Stan Polovets	Chairman	March 7, 2021
/s/ Ruth Alon Ruth Alon	Director	March 7, 2021
/s/ Isaac Kohlberg Isaac Kohlberg	Director	March 7, 2021

ANCHIANO THERAPEUTICS LTD. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2020

ANCHIANO THERAPEUTICS LTD. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2020

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Anchiano Therapeutics Ltd.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Anchiano Therapeutics Ltd. and subsidiaries (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity, and cash flows for each of the years in the two year period ended December 31, 2020, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two year period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses and cash flow deficits from operations that together with other matters described in the aforesaid note, raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Somekh Chaikin

Member Firm of KPMG International

We have served as the Company's auditor since 2004.

Tel Aviv, Israel

March 7, 2021

ANCHIANO THERAPEUTICS LTD. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share and per share data)

	Note	December 31, 2020	December 31, 2019
ASSETS			
Current assets:			
Cash and cash equivalents	3	$ 5,392	$ 17,575
Prepaid expenses and other		724	636
Total current assets		6,116	18,211
Property and equipment, net		12	158
Operating lease right-of-use	4	-	1,199
Long-term pledged deposits		-	130
Other non-current assets		51	57
Total assets		$ 6,179	$ 19,755
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Trade payables		$ 678	$ 875
Accrued expenses and other	8a	1,729	2,855
Operating lease liability	4	179	391
Total current liabilities		2,586	4,121
Non-current operating lease liability	4	16	725
Total liabilities		2,602	4,846
Commitments and contingencies			
Shareholders' equity:			
Ordinary shares, no par value - authorized 500,000,000 shares as of December 31, 2020 and 100,000,000 shares as of December 31,2019; issued and outstanding 37,099,352 shares at December 31, 2020 and December 31,2019		-	-
Additional Paid-in capital	6	119,745	119,468
Currency translation differences reserve		872	872
Accumulated deficit		(117,040)	(105,431)
Total shareholders' equity		3,577	14,909
Total liabilities and shareholders' equity		$ 6,179	$ 19,755

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

ANCHIANO THERAPEUTICS LTD. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(U.S. dollars in thousands, except share and per share data)

	Note	Year ended December 31,	
		2020	2019
Operating Expenses:			
Research and development		$ 3,783	$ 13,303
General and administrative		7,180	6,245
Restructuring expense	5b	749	3,350
Total operating expenses		11,712	22,898
Finance (income) expense, net	8b	(103)	4,226
Net loss and comprehensive loss		$ 11,609	$ 27,124
Loss per share basic and diluted		$ 0.31	$ 0.79
Weighted average number of shares outstanding used in computation of basic and diluted loss per share in thousands		37,099	34,446

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

ANCHIANO THERAPEUTICS LTD. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(U.S. dollars in thousands, except share and per share data)

	Ordinary shares		Additional Paid-in capital	Currency translation differences reserve	Accumulated deficit	Total
	Number of shares	Amounts (*)				
Balance at January 1, 2019	15,575,682	$ -	$ 87,240	$ 872	$ (78,307)	$ 9,805
Changes during 2019:						
Issuance of shares, net	21,523,670	-	26,500	-	-	26,500
Reclassification of warrants due to reassessment (see note 6b)	-	-	(3,628)	-	-	(3,628)
Reclassification of warrants due to modification (see note 6b)			8,198			8,198
Share-based compensation	-	-	1,158	-	-	1,158
Net loss for the year	-	-	-	-	(27,124)	(27,124)
Balance at December 31, 2019	37,099,352	-	119,468	872	(105,431)	14,909
Changes during 2020:						
Share-based compensation	-	-	(20)	-	-	(20)
Refund on share issuance expenses			297			297
Net loss	-	-	-	-	(11,609)	(11,609)
Balance at December 31, 2020	37,099,352	$ -	$ 119,745	$ 872	$ (117,040)	$ 3,577

(*) No par value

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

ANCHIANO THERAPEUTICS LTD. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF CASH FLOWS
(U.S. dollars in thousands, except share and per share amounts)

	Year ended December 31,	
	2020	**2019**
Operating activities:		
Net loss	$ (11,609)	$ (27,124)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Financing costs, net	-	4,570
Depreciation	80	281
Gain on sale of property and equipment	(36)	-
Share-based payments	(20)	1,158
Write-off of right-of-use	278	-
Changes in operating asset and liabilities:		
Prepaid and other current	(88)	2,305
Other non-current assets	6	975
Trade payables	(197)	1,076
Accrued expenses and other	(1,126)	301
Net cash used in operating activities	(12,712)	(16,458)
Investing activities:		
Purchase of property and equipment	(34)	(95)
Proceeds from sale of property and equipment	136	-
Net cash provided by (used in) investing activities	102	(95)
Financing activities:		
Proceeds from issuance of ordinary shares and warrants	-	30,500
Share issuance costs	297	(3,879)
Net cash provided by financing activities	297	26,621
Increase (decrease) in cash, cash equivalents and restricted cash	(12,313)	10,068
Cash, cash equivalents and restricted cash at, beginning of period	17,705	7,637
Cash, cash equivalents and restricted cash at, end of period	$ 5,392	$ 17,705
Reconciliation in amounts on consolidated balance sheets:		
Cash and cash equivalents	$ 5,392	$ 17,575
Restricted cash	-	130
Total cash, cash equivalents and restricted cash	$ 5,392	$ 17,705

NOTE 1 - NATURE OF OPERATIONS

Anchiano Therapeutics Ltd. (the "Company") is a biopharmaceutical company dedicated to the discovery, development, and commercialization of novel, targeted therapies to treat cancer in areas of significant clinical need. Anchiano is developing small-molecule pan-RAS inhibitors and inhibitors of PDE10 and the β-catenin pathway, having discontinued active clinical development of inodiftagene vixteplasmid in November 2019. After a thorough evaluation of the 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, evaluating the gene therapy inodiftagene vixteplasmid in patients with BCG-unresponsive non-muscle-invasive bladder cancer (NMIBC), and announced the discontinuation of the study. In January 2020, our Board of Directors approved management's recommendation to close the Company's office and laboratories located in Israel. Following the closure of the Israeli facilities at the end of May 2020, and as of December 31, 2020, the Company's sole remaining office was located at One Kendall Square, Building 1400E, Suite 14-105, Cambridge, Massachusetts. In February 2021, in light of the effects the situation in which offices were no longer required under the circumstances, the Company signed a lease termination agreement related to this office, effective as of February 28, 2021. (for details, see Note 10 below).

On July 2, 2020, the Company's Chief Executive Officer Dr. Frank Haluska sent a letter to the Chairman of the Company's board of directors outlining Dr. Haluska's belief that events had occurred that were sufficient to trigger his ability to resign for "Good Reason" under his employment agreement. The company's board of directors informed Dr. Haluska that it disagreed with the letter's assertions regarding "Good Reason" and treated the letter as a constructive resignation effective as of July 2, 2020. On July 12, 2020, Dr. Frank Haluska tendered his written resignation from the Company's board of directors, effective immediately. See Note 9 for further detail.

In light of business circumstances, and in order to conserve cash and preserve optionality while alternatives are being identified and assessed, the Company made a decision during July 2020 to undertake reductions in headcount and other cost saving measures. These included plans to temporarily reduce the Company's internal and external research and development work on the Company's pan-RAS-inhibitor program until there is greater clarity regarding Anchiano's ability to fund the program. We continue to undertake actions for the promotion of the program and its assets and towards strengthening the protection of all related intellectual property.

On October 20, 2020, the Company appointed Mr. Neil Cohen as its Chief Executive Officer. Mr. Cohen was a member of the Company's board of directors prior to his appointment as CEO and continues to serve in this capacity. The Company also appointed Mr. Andrew Fine to serve as its Chief Financial Officer. Mr. Fine previously served as the Company's Interim Chief Financial Officer pursuant to a subcontracting agreement as of July 2020.

On December 14, 2020 the Company entered into an Agreement and Plan of Merger with Chemomab, an Israeli limited company and a clinical-stage biotech company focusing on the discovery and development of innovative therapeutics for fibrosis-related diseases with high unmet need, which included the proposed Merger of CMB Acquisition Ltd., a wholly owned subsidiary of ours, with Chemomab as the surviving company. The merger is, subject to shareholder approval as well as, amongst other things, the completion of a financing of no less than $30 million concurrently with the closing of the merger, and the listing of the Anchiano ADSs on Nasdaq,

At the effective time of the merger, the Company anticipates that each share of Chemomab common stock outstanding immediately prior to the effective time of the Merger will be converted into the right to receive approximately 1,028.99 shares of Anchiano common stock, subject to adjustment to account for a reverse split of Anchiano common stock at a reverse split ratio to be determined by Anchiano's board of directors, subject to shareholder approval, and to be implemented prior to the consummation of the merger.

Immediately following the merger, and prior to any private investment as part of the merger, the former Chemomab security holders will own approximately 90% of the aggregate number of shares of Anchiano common stock and the security holders of Anchiano as of immediately prior to the merger will own approximately 10% of the aggregate number of shares of Anchiano common stock on a fully diluted basis.

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". Its ordinary shares were 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. (formerly BioCanCell Therapeutics Israel Ltd.), which itself wholly owns a Delaware-incorporated subsidiary, Anchiano Therapeutics, Inc. (formerly BioCanCell USA, Inc.) for the purposes of operating in the United States. This subsidiary is subject to the tax laws of the State of Delaware.

The Company is subject to a number of risks including with regard to the successful development of therapeutics, the ability to obtain adequate financing, the ability to obtain FDA approval and reimbursement for any products the Company may develop, protection of intellectual property, fluctuations in operating results, dependence on key personnel and collaborative partners, rapid technological changes inherent in the target markets of any products the Company may develop, product liability, the introduction of substitute products and competition from larger companies.

In March 2020 the World Health Organization declared the global novel coronavirus (COVID-19) outbreak a pandemic. As of December 31, 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.

Liquidity

The 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 December 31, 2020 of $117 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 completion of the contemplated merger with Chemomab during the first half 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, and should the contemplated merger with Chemomab not be completed, 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.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES:

a. Basis of presentation

The Company’s financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”).

b. Use of estimates in the preparation of financial statements

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 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 consolidated financial statements, and the reported amounts of expenses during the reporting periods. Actual results could differ from those estimates.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

c. Functional currency

Items included in the financial statements of the Company's entities are measured using the currency of the primary economic environment in which the Company operates. The Company's functional currency from inception through December 31, 2018 was the New Israeli Shekel ("NIS"), as this was the functional currency of its significant operations. Effective January 1, 2019, due to significant business developments and changes to its economic circumstances, the Company, as well as its Israeli subsidiary, reassessed its functional currency and determined to change its functional currency to the U.S. dollar ("dollar", "USD" or "$") from the NIS. The change in functional currency was accounted for prospectively from January 1, 2019, and the financial statements prior to and including the period ended December 31, 2018 were not restated for the change in functional currency.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

d. Principles of consolidation

The consolidated financial statements include the financial statements of Anchiano Therapeutics Ltd. and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated upon consolidation.

e. Cash and cash equivalents

Cash equivalents are short-term, highly-liquid deposits that are not restricted as to withdrawal and are readily convertible to cash with original maturities of three months or less, at the date acquired.

f. Restricted cash

Restricted cash deposited in an interest-bearing saving accounts which is used as a security for the Company's office rent and car leasing. Cash expected to be restricted for more than one year from the balance sheet date is classified as long-term restricted cash in the consolidated balance sheets.

g. Property and equipment:

1) Property and equipment are stated at cost, net of accumulated depreciation and amortization.

2) The Company’s property and equipment are depreciated by the straight-line method on the basis of their estimated useful life.

h. Impairment of long-lived assets

The Company tests long-lived assets for impairment whenever events or circumstances present an indication of impairment. If the sum of expected future cash flows (undiscounted and without interest charges) of the assets is less than the carrying amount of such assets, an impairment loss would be recognized. The assets would be written down to their estimated fair values, calculated based on the present value of expected future cash flows (discounted cash flows), or some other fair-value measure.

i. Derivatives

Measurement of derivative financial instruments

Derivatives are recognized initially at fair value; attributable transaction costs are recognized in profit or loss as incurred. Subsequent to initial recognition, derivatives are measured at fair value, and changes therein are accounted for by recognizing them in profit or loss, as financing income or expense.

Reassessment of derivatives

The classification of a contract shall be reassessed at each balance sheet date. If the classification required changes as a result of events during the period, the contract shall be reclassified as of the date of the event that caused the reclassification. There is no limit on the number of times a contract may be reclassified. If a contract is reclassified from permanent or temporary equity to an asset or a liability, the change in fair value of the contract during the period the contract was classified as equity shall be accounted for as an adjustment to shareholders' equity. The contract subsequently shall be marked to fair value through earnings.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

i. Derivatives (continued)

Issuance of parcel of securities

The consideration received from the issuance of a parcel of equity securities is allocated according to the relative fair value of the instruments.

Direct issuance costs are attributed to the specific securities in respect of which they were incurred, whereas joint issuance costs are attributed to the securities on a proportionate basis according to the allocation of the consideration from the issuance of the parcel, as described above.

j. Severance pay

The Israeli Severance Pay Law, 1963 ("Severance Pay Law"), specifies that employees are entitled to severance payment following the termination of their employment. Under the Severance Pay Law, the severance payment is calculated as one-month salary for each year of employment (and pro rata for a portion thereof). Under Section 14 of the Severance Pay Law, employees are entitled to monthly deposits, at a rate of 8.33% of their monthly salary, made on behalf of the employee with investment firms or insurance companies. Payments in accordance with Section 14 release the Group from any future severance payments in respect of those employees. As a result, the Group does not recognize any liability for severance pay from the time Section 14 has been adopted with respect to an employee, and the deposits under Section 14 are not recorded as an asset in the Company's balance sheet.

For the period during which the Group's employees in Israel were not subject to Section 14 are accounted for under the Shut Down method of accounting. Accordingly, the Company calculated the liability for severance pay pursuant to the Severance Pay Law based on the most recent salary of these employees, multiplied by the number of years of employment as of the balance sheet date. The Company's liability for these employees is fully provided for via monthly deposits with severance pay funds, insurance policies and accruals. The value of these deposits is recorded as an asset on the Company's balance sheet under Funds in respect of employee rights upon retirement and other short-term assets.

k. Contingencies

Certain conditions may exist, as of the date of the financial statements, which may result in a loss to the Company but which will only be resolved when one or more future events occur or fail to occur. The Company's management assesses such contingent liabilities, and such assessment inherently involves an exercise of judgment. In assessing loss contingencies related to legal proceedings that are pending against the Company or unasserted claims that may result in such proceedings, the Company's management evaluates the perceived merits of any legal proceedings or unasserted claims as well as the perceived merits of the amount of relief sought or expected to be sought.

Management applies the guidance in ASC 450-20-25 when assessing losses resulting from contingencies. If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability is recorded as accrued expenses in the Company's financial statements. If the assessment indicates that a potential material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, together with an estimate of the range of possible loss if determinable and material, are disclosed.

Loss contingencies considered to be remote by management are generally not disclosed unless they involve guarantees, in which case the guarantees are disclosed.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

l. Share-based compensation

Share-based compensation expense related to share awards is recognized based on the fair value of the awards granted. The fair value of each option award is estimated on the grant date using the Black-Scholes-Merton option pricing model. The Black-Scholes-Merton option pricing model requires the input of highly subjective assumptions, including the expected term of the option, the expected volatility of the price of the Company's ordinary shares and the expected dividend yield of ordinary shares. The assumptions used to determine the fair value of the option awards represent management's best estimates. These estimates involve inherent uncertainties and the application of management's judgment. The Company elected to recognize compensation costs for awards conditioned only on continued service that have a graded vesting schedule using the accelerated method based on the multiple-option award approach. Forfeitures are accounted for by estimating the number of awards expected to be forfeited instead of as they occur.

m. Research and development

Research and development expenses include costs directly attributable to the conduct of research and development programs, including clinical trial and materials, management development of production processes, salaries, wages and incidentals, laboratory rent and maintenance. All costs associated with research and developments are expensed as incurred.

Intangible assets that are purchased from others for use in R&D activities in a transaction other than a business combination are capitalized only if they have alternative future use. Otherwise, such assets are expensed.

For the two years ended December 31, 2020, the Company did not capitalize any intangible asset purchased at an asset acquisition.

n. Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expenses as incurred, since the recoverability of such expenditures is uncertain.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

o. Income taxes:

1) Deferred taxes

Income taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently-enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future. Given the Company's losses, the Company has provided a full valuation allowance with respect to its deferred tax assets.

2) Uncertainty in income tax

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the available evidence indicates that it is more likely than not that the position will be sustained based on technical merits. If this threshold is met, the second step is to measure the tax position as the largest amount that has more than a 50% likelihood of being realized upon ultimate settlement.

p. 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:

	Year ended December 31	
	2020	**2019**
Outstanding stock options	2,565,301	3,822,374
Warrants	10,975,950	10,975,950

NOTE 2−SIGNIFICANT ACCOUNTING POLICIES (continued):

q. Fair value measurement

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data or active market data of similar or identical assets or liabilities.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value. See Note 6c.

r. Concentration of credit risks

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash and cash equivalents, and pledged deposits. The Company deposits cash and cash equivalents with highly-rated financial institutions and, as a matter of policy, limits the amounts of credit exposure to any single financial institution. The Company has not experienced any material credit losses in these accounts and does not believe it is exposed to significant credit risk on these instruments.

(U.S. dollars in thousands, except share and per share data)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Continued):

s. Newly issued and recently adopted accounting pronouncements:

Accounting pronouncements recently adopted

1) In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). ASU 2016-02 requires lessees to recognize most leases on their balance sheet as a right-of-use (ROU) asset and a lease liability. Leases are classified as either operating or finance based on criteria similar to existing lease accounting, with the classification affecting the pattern and classification of expense recognition in the statement of operations. This standard became effective on January 1, 2019. A modified retrospective transition approach is allowed, applying the new standard to all leases existing at the date of initial application.

Operating-lease ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term, while the ROU assets are also adjusted for any prepaid or accrued lease payments. The Company uses its incremental borrowing rate, based on the information available at the commencement date, to determine the present value of the lease payments. For lease modifications that decrease the scope of the lease, the Company recognizes a decrease in the carrying amount of the right-of-use asset in order to reflect the partial or full cancellation of the lease, and recognizes in profit or loss a profit (or loss) that equals the difference between the decrease in the right-of-use asset and re-measurement of the lease liability.

The lease term is the non-cancellable period of the lease plus periods covered by an extension or termination option, if it reasonably certain that the Company will exercise the option.

After lease commencement, the Company measures the lease liability at the present value of the remaining lease payments using the discount rate determined at lease commencement (as long as the discount rate hasn't been updated as a result of a reassessment event).

The Company subsequently measures the ROU asset at the present value of the remaining lease payments, adjusted for the remaining balance of any lease incentives received, any cumulative prepaid or accrued rent if relevant and any unamortized initial direct costs. Lease expenses for lease payments are recognized on a straight-line basis over the lease term. Lease terms will include options to extend or terminate the lease when it is reasonably certain that the Company will exercise or not exercise the option to renew or terminate the lease.

t. Reclassifications

Certain prior year amounts shown in the accompanying 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.

NOTE 3 – CASH AND CASH EQUIVALENTS:

	December 31, 2020	December 31, 2019
In US dollars		
Cash	$ 1,110	$ 9,349
Cash equivalents	4,001	7,451
In New Israeli Shekels		
Cash	281	775
	$ 5,392	**$ 17,575**

Cash equivalents are comprised of short-term bank deposits with original maturities of three months or less, at the date acquired.

(U.S. dollars in thousands, except share and per share data)

NOTE 4 - LEASES:

The Group leases facilities, labs offices and cars for use in its operations, which are classified as operating leases. In addition to rent, the leases may require the Group to pay directly for fees, insurance, maintenance and other operating expenses.

In May 2018, Anchiano Therapeutics, Inc. signed an agreement to rent space for offices in Cambridge, Massachusetts, until December 2021. This agreement was amended in October 2019 with the agreement ending in January 2022 with annual rent of approximately $185 thousand.

In February 2021, in light of the situation in which offices were no longer required under the circumstances, the Company signed a lease termination agreement (See note 10 below for further details). Given that the Company is no longer using the asset as of December 31, 2020 there is a need for an impairment of the asset. As of December 31, 2020, the Company recognized a decrease of approximately $195 thousand in the carrying amount of the right-of-use asset to reflect the impairment of the right of use asset. In addition to this the Company recognized a decrease of approximately $83.0 thousand in Q1 2020 on account of impairment of its right of use asset for its facilities in Israel that the Company vacated.

The cash flow information related to operating leases and the lease term and the discount rate related to Company's operating lease right-of-use assets and related lease liabilities are as follows:

	Year ended December 31, 2020
Operating cash flow from operating leases	$ 247
Weighted Average Remaining Lease Term (years)	1.33
Weighted Average Discount rate	10.20%

	Year ended December 31, 2020
Operating lease expense	$ 242

Supplemental balance sheet information related to operating leases was as follows

	December 31, 2020
Assets	
Operating lease right of use	$ -
Liabilities	
Operating lease liabilities, current portion	$ 179
Operating lease liabilities, non-current portion	16
Total	$ 195

(U.S. dollars in thousands, except share and per share data)

NOTE 4 – LEASES (continued):

As of December 31, 2020, the maturity of lease liabilities under our non-cancelable operating leases were as follows:

	Operating Lease
2021	189
2022	16
Total future minimum lease payments, undiscounted	205
Less: Imputed interest	-10
Present value of future minimum lease payments	$ 195

NOTE 5 - COMMITMENTS:

A. Royalty Commitments:

1. Liability for royalty payments to the Israel Innovation Authority

The Company is obligated to pay royalties to the Israel Innovation Authority (the "IIA") on proceeds from the sale of products developed from research and development activities that were partially funded by grants from the IIA, relating to inodiftagene, development of which the Company discontinued in 2019. See Note 1 above for details.

Under the specific terms of the funding arrangements with the IIA, royalties of 3.5% to 25% are payable on the sale of products developed with funding received from the IIA, which payments shall not exceed, in the aggregate, 300% of the amount of the grant received (dollar linked), plus interest at annual rate based on LIBOR.

As of December 31, 2020, the Company had recognized and received grants (cumulatively) from the IIA in the amount of $4 million. At the time the Company received the grants, successful development of the program was not probable and, accordingly, no related liability has been recognized in the financial statements.

The Company did not receive any grants from the IIA for the years ended December 31, 2020 and 2019.

The Company did not successfully commercialize the products developed from research and development activities related to inodiftagene that were partially funded by grants from the IIA. In January 2021 the Company submitted a request to the IIA to close its files with the IIA and to receive approval from the IIA that the Company has no obligations to pay royalties as no commercialization resulted from the research and development activities. As of the date of these financial statements no response has been received from the IIA.

(U.S. dollars in thousands, except share and per share data)

NOTE 5 – COMMITMENTS (continued):

A. Royalty Commitments (continued):

2. Liability for royalty payments to Yissum

The research and development activities of the Group relating to inodiftagene, development of which the Company discontinued in 2019, were based on an exclusive license granted to the Group to use patent-protected technology and/or applications for the registration of patents developed by the Group.

The rights to these patents originally belonged to Yissum Technology Transfer, the research development Company of The Hebrew University of Jerusalem (hereinafter, "Yissum"). Under the 2005 license agreement between Yissum and the Group, as amended (the "License Agreement"), Yissum granted an exclusive license to the Group for the global development, use, manufacture and commercialization of products that are based on the patents. In return, the Group undertook to pay royalties to Yissum. The Group does not recognize a liability for royalties until the event underlying the liability actually probable and reasonably and therefore the financial statements do not include a liability for these royalties.

In April 2020, the Company notified Yissum that as a result of the Company's decision to discontinue clinical development of inodiftagene, the Company will cease payments to maintain the intellectual property that was licensed from Yissum that supported the development and as related to a licensing and development agreement between the parties ("License Agreement"). In August 2020 the Company agreed with Yissum on termination of the License Agreement and the return of all intellectual property.

B. 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 clinical research organizations (CRO's) 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 clinical research organizations (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 was terminated in the second quarter of 2020.

In July 2020, the Company made the strategic decision to temporarily reduce development of the Company's RAS program and to institute various cost savings measures to preserve liquid resources. At the same time the Company continued to actively pursue the maintenance of its Licensing Agreement with ADT and protection of its intellectual property assets. The cost saving activities included severing 3 employees and contract termination with outsourced contractors working on clinical activities.

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

	CRO, Manufacturing and other related	Severance-related	Facility and Leases	Total
Balance, January 1, 2020	$ 2,572	$ 336	$ -	$ 2,908
Expenses	502	-	247	749
Paid or consumed	(2,836)	(336)	(247)	(3,419)
Balance, December 31, 2020	**$ 238**	**$ -**	**$ -**	**$ 238**

NOTE 5 — COMMITMENTS (continued):

C. Acquisition

In September 2019, the Company announced that its fully-owned subsidiary, Anchiano Therapeutics, Inc. 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 Group 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 Anchiano. In connection with the agreement, ADT also granted Anchiano 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, Anchiano 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. Anchiano may 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 Company accounted for the upfront fee as a research and development expense.

NOTE 6 - SHARE CAPITAL:

a. Rights of the Company's ordinary shares

Each ordinary share is entitled to one vote. The holders of ordinary shares are also entitled to receive dividends if declared by the Board of Directors, whenever funds are legally available. Since its inception, the Company has not declared any dividends.

b. 2018 Private Placement

In June 2018, the Company completed a $22.9 million fundraising round from investors in the United States and Israel, led by Shavit Capital Funds. In consideration for the investment, the Company issued 5,960,787 ordinary shares (constituting approximately 38% of the Company's issued and outstanding share capital after completion of the transaction) at a price per share of approximately $3.842, as well as 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 the closing date of the transaction, as of December 31, 2018, 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 6c below.

The warrants and shares were recorded within equity on the issuance date (see note 2s on the adoption of ASU2017).

As detailed in Note 2c, the Company changed its 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 the Company's functional currency and therefore not considered indexed to the Company's own stock according to ASC 815-40

(U.S. dollars in thousands, except share and per share data)

NOTE 6 - SHARE CAPITAL (continued):

b. 2018 Private Placement (continued)

Additionally, upon the Company's Nasdaq IPO of February 14, 2019, the warrants' term modified such that the exercise price currency was changed to USD. As a result, the warrants were reclassified within equity on that date.

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.

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

	2019
Fair value on January 1, 2019	3,628
Adjustments- finance expenses	4,570
Fair value on February 14, 2019	8,198

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 (USD)	$1.84	$2.50
Expected term	End of 2022	End of 2022
Risk free rate	2.49%	1.37%
Volatility	52%	48%

In December 2020, in connection with, and conditional on completion of the contemplated merger, investors in the June 2018 fundraising round executed an agreement in which they agree to exercise all of their warrants upon the completion of the merger; reduce the number of shares in the Company to which they are entitled as a result of the merger pursuant to the price protection provisions and waive their rights to the balance of the price protection. Under this agreement the investors will (i) receive additional shares equal to only 80% of the number shares currently held by each investor for no additional consideration; and (ii) in respect of the price protection rights applicable to warrants held by such investors, the number of shares into which the warrants shall be exercisable shall be increased, for no additional consideration, only by the number shares necessary to ensure that, upon a cashless exercise of the warrants upon the merger, the aggregate number of shares held by each investor shall equal 80% more than the shares currently purchasable under the warrants; See also note 9D below.

c. 2019 Public offering

On February 14, 2019, the Company raised $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 6b above for details and accounting treatment), the Company allocated 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).

d. 2018 Reverse Split and Capitalization

In June 2018, the Company completed a 10:1 reverse share split, canceled the par value of its ordinary shares and increased its authorized capital to 30 million ordinary shares. In December 2018, the Company increased its authorized capital to 100 million ordinary shares. All amounts of shares, underlying shares, share prices and exercise prices in these financial statements reflect such adjustments.

NOTE 6 - SHARE CAPITAL (continued):

e. Share-based compensation

Until 2016, the Company issued options to purchase shares to its employees, directors and other service providers/consultants pursuant to its 2011 Share Option Plan. From 2017, the Company has issued options pursuant to its 2017 Equity-Based Incentive Plan (the "2017 Plan"). As of December 31, 2020 and 2019, 6,218,798 shares and 3,501,486 shares respectively remain available for grant under the 2017 Plan.

In accordance with the terms of the 2017 Plan, on January 1 of each calendar year during the term of the 2017 Plan, the number of shares available for issuance under the 2017 Plan shall be increased by 4% of the total number of company shares outstanding on December 31 of the immediately preceding calendar year, or such lesser number as shall be determined by the administrator of the 2017 Plan, subject to adjustments required for recapitalization events.

The Plan is designed to enable the Company to grant options to purchase ordinary shares under various and different tax regimes including, without limitation, as ISOs or non-qualified stock options for U.S. residents, and pursuant and subject to Sections 102 or 3(i) of the Israeli Tax Ordinance.

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.

(U.S. dollars in thousands, except share and per share data)

NOTE 6 - SHARE CAPITAL (continued):

e. Share-based compensation (Continued):

Options granted to employees and directors:

In the years ended December 31, 2020 and December 31, 2019, the Company granted options to purchase ordinary shares as follows:

	Year ended December 31, 2020			
	Award amount	**Exercise price range**	**Vesting period**	**Expiration**
Employees	775,000	$0.23-$0.24	4 years	2030
Directors	110,000	$0.165	3 years	2030

	Year ended December 31, 2019			
	Award amount	**Exercise price range**	**Vesting period**	**Expiration**
Employees	1,098,590	$0.60-$1.55	4 years	2029
Directors	495,000	$0.47-$1.03	3 years	2029

The fair value of options granted during 2020 and 2019 was $0.1 million and $0.8 million, respectively.

The fair value of options granted to employees and directors is based on the share price on grant date and was computed using the Black-Scholes model. The underlying data used for computing the fair value of the options are as follows:

	Year ended December 31, 2019
Value of ordinary share	$0.47 - $1.54
Dividend yield	0%
Expected volatility	51.5% - 68.8%
Risk-free interest rate	1.7% - 2.5%
Expected term (years)	4.95 - 7

	Year ended December 31, 2020
Value of ordinary share	$0.15 - $0.24
Dividend yield	0%
Expected volatility	64.9% - 67.4%
Risk-free interest rate	0.30% to 0.45%
Expected term (years)	5.5 - 7

The total unrecognized share-based compensation cost at December 31, 2020 is $0.14 million, which is expected to be recognized over a weighted-average period of 1.3 years.

(U.S. dollars in thousands, except share and per share data)

NOTE 6 - SHARE CAPITAL (continued):

e. Share-based compensation (Continued):

Summary of outstanding and exercisable options:

The following table summarizes the number of options outstanding for the years ended December 31, 2020 and December 31, 2019, and related information. As a result of the Company restructuring that resulted in the termination of the employment of senior employees and as a result of the resignation of the Company's CEO a significant number of granted options were forfeited during the period :

	Number of Options	Weighted Average Exercise Price [1]	Weighted Average Remaining Contractual Life in Years
Options outstanding - December 31, 2018	2,453,767	$ 3.32	9.0
Granted	1,593,590	$ 1.03	9.6
Forfeited	(221,611)	$ 1.30	9.4
Expired	(3,372)	$ 13.32	5.8
Exercised	-	$ -	-
Options outstanding - December 31, 2019	3,822,374	$ 2.50	8.5
Granted	885,000	$ 0.22	9.3
Forfeited	(1,677,286)	$ 1.01	8.6
Expired	(505,398)	$ 2.58	7.7
Exercised	-	-	-
Options outstanding - December 31, 2020	2,524,691	$ 2.62	7.45
Options exercisable - December 31, 2020	1,998,264	$ 3.16	7.02

(1) Weighted-average exercise price per ordinary share. NIS-denominated exercise prices were converted to USD using the year-end Bank of Israel representative rate.

The following tables summarizes information concerning outstanding and exercisable options as of December 31, 2020, in terms of ordinary shares:

December 31, 2020				
Options outstanding			Options exercisable	
Exercise prices per share (USD)	Number of options outstanding at end of year	Weighted Average Remaining Contractual Life	Number of options exercisable at end of year	Weighted average remaining contractual life
$25-77	5,535	1.21	5,535	1.21
$6-8	6,757	3.35	6,757	3.35
$3-5	938,203	7.47	938,203	7.47
$2-3	865,577	6.25	852,470	6.24
$1-2	349,750	8.50	175,410	8.50
$0-1	358,870	9.39	19,890	8.50
	2,524,691		1,998,264	

The aggregate intrinsic value of the total of both the outstanding and exercisable options as of December 31, 2020, is $0.

(U.S. dollars in thousands, except share and per share data)

NOTE 6 - SHARE CAPITAL (continued):

e. Share-based compensation expenses (Continued):

The following table illustrates the effect of share-based compensation on the statements of operations:

	Year ended December 31	
	2020	**2019**
Research and development	**$ (162)**	$ 470
General and administrative	**$ 142**	$ 688
	$ (20)	$ 1,158

NOTE 7 - INCOME TAX:

a. Corporate tax rates

1) Ordinary taxable income in Israel is subject to a corporate tax rate of 23%.

2) The Company's US-based subsidiary, Anchiano Therapeutics, Inc., is taxed separately under the U.S. tax laws.

The US-based subsidiary is subject to a federal flat tax rate of 21% and state taxes as applicable.

b. As of December 31, 2020, the Company had estimated net operating loss carryforwards in Israel of approximately $13 million that can be carried forward indefinitely, and estimated carryforward capital losses of approximately $14.1 million.

As of December 31, 2020, the Company's Israeli subsidiary had estimated net operating loss carryforwards of approximately $87.5 million in Israel that can be carried forward indefinitely and estimated carryforward capital losses of approximately $1.6 million.

The Company's US-based subsidiary had no net operating loss carryforwards as of December 31, 2019. As of December 31, 2020 the U.S. subsidiary had estimated federal and state net operating loss carryforwards available to offset future taxable income of approximately $5.5 million**.** Net operating loss carryforwards may be carried forward indefinitely until the loss is fully recovered, but they are limited to 80% of the taxable income in any one tax period.

c. As of December 31, 2020, the Company's and the Company's subsidiary's tax years until December 31, 2014 are closed to audit inspections by the taxing authority due to statute of limitation rules effective in Israel. The U.S. subsidiary's tax years until December 31, 2016 are closed to audit inspections by the taxing authority due to statute of limitation rules effective in the U.S.

d. The components of the net loss (following which there is no provision for income taxes) were as follows:

	Year ended December 31,	
	2020	**2019**
Israel	5,725	22,678
U.S.	5,884	4,446
	11,609	27,124

e. There was no provision made for income taxes in 2020 or 2019. Prior to 2019 our U.S. subsidiary provided us with general and clinical trial management services. For these services, our US subsidiary was compensated on a cost-plus basis, and recorded income taxes accordingly on the profits. In 2019, following our acquisition of the programs from ADT, our U.S. subsidiary ceased to provide us with general clinical trial management services and expenses related to the ADT programs are not part of the cost-plus compensation and accordingly our US subsidiary does not have taxable income for the current year

(U.S. dollars in thousands, except share and per share data)

NOTE 7 - INCOME TAX (continued):

f. A reconciliation of the Company's theoretical income tax expense to actual income tax expense is as follows:

	Year ended December 31,	
	2020	**2019**
Loss before income tax	(11,609)	(27,124)
Tax rate	23%	23%
Computed "expected" tax benefit	(2,670)	(6,238)
Decrease (increase) in tax refund resulting from:		
- change in temporary differences for which deferred taxes were not recognized	(1,965)	2,133
- Different tax rate in subsidiaries operating outside of Israel	(240)	(1)
- Non-deductible items	(25)	1,195
- Tax credits		-
- Losses and benefits for tax purposes for the year, for which deferred taxes were not recorded	4,900	2,911
Actual tax expense	-	-

g. The following table presents the significant components of the Company's deferred tax asset:

	December 31,	
	2020	**2019**
Deferred tax assets:		
Net operating loss carry forward	24,650	17,811
Capital loss carry forward	3,638	3,421
Research and development	2,392	4,297
Share based compensation	900	890
Other	1	67
Less - valuation allowance	(31,581)	(26,486)
Net deferred tax assets	-	-

A valuation allowance is provided when it is more likely than not that the deferred tax assets will not be realized. The Company has established a valuation allowance to offset deferred tax assets at December 31, 2020 and 2019 due to the uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets. The net change in the total valuation allowance for the year ended at December 31, 2020 was an increase of $5.1 million.

(U.S. dollars in thousands, except share and per share data)

NOTE 8 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

a. Balance sheets:

Certain prior year amounts shown below for December 31, 2019 have been reclassified to conform to the 2020 presentation. These reclassifications did not have any effect on the total liabilities.

Other payables:

	December 31, 2020	December 31, 2019
Accrued expenses	$ 1,459	$ 372
Restructuring accrual	238	2,161
Payroll and related	32	60
Liability for employee rights upon retirement	-	262
	$ 1,729	**$ 2,855**

Certain prior year amounts shown in the accompanying 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 See also note 2t above.

b. Statements of operations:

Finance expenses, net:

	Year ended December 31,	
	2020	**2019**
Finance expenses:		
Foreign exchange rates, net	-	40
Interest expenses, bank fees and other	6	9
Changes in fair value of warrants (see note 6b)	-	4,570
Total finance expenses	6	4,619
Finance income:		
Foreign exchange rates, net	89	-
Interest on bank deposit	20	393
Total finance income	109	393
Total finance expenses (income), net	(103)	4,226

NOTE 9 - RELATED PARTY TRANSACTIONS:

A. On July 2, 2020, the Company's Chief Executive Officer Dr. Frank Haluska sent a letter to the Chairman of the Company's board of directors outlining Dr. Haluska's belief that events had occurred that were sufficient to trigger his ability to resign for "Good Reason" under his employment agreement. The Company's board of directors informed Dr. Haluska that it disagreed with the letter's assertions regarding "Good Reason" and treated the letter as a constructive resignation effective as of July 2, 2020. On July 12, 2020, Dr. Frank Haluska tendered his written resignation from the Company's board of directors, effective immediately. Dr. Haluska referenced the matters articulated in his letter of July 2, 2020, and the Company's response and actions following receipt of the letter as the basis for his resignation from the Board. The Company has a potential maximum exposure of up to $0.4 million relating to claims of "Good Reason" resignation. It is the Company's position, based on its legal counsel, that the CEO resigned without Good Reason, is not entitled to severance, and the Company will contest any and all claims for severance. The Company has not accrued any provision in its financial statements in this regard.

B. In July 2020, the Company's compensation committee approved allocations of options to each of Mr. Stan Polovets, a director in the Company, and to Mr. Neil Cohen, a shareholder and a director in the Company, to purchase 55,000 ordinary shares (currently equivalent to 11,000 ADSs).. The options vest over a period of 36 months (33% after 12 months 8.33% at the end of each 3 month period thereafter) with an exercise price of $0.165 per ordinary share or $0.823 per ADS. See note 6e for further details on and description of the value of the grants .)..

C. On October 20, 2020, the Company appointed Mr. Neil Cohen as Chief Executive Officer of the Company, effective immediately. Pursuant to his employment agreement, in his capacity as Chief Executive Officer of the Company Mr. Cohen will receive a gross salary of $12,000 per month. Mr. Cohen will continue to serve as a member of the Company's board of directors.

D. In December 2020 in connection with , and contingent on the completion of, the contemplated merger, and pursuant to price protection rights granted to private investors in 2018 under a securities purchase agreement, shareholders and warrant holders that are related parties of the Company executed an agreement in which related parties (and other investors) agree to exercise all of their warrants in the Company upon the closing of the merger; reduce the number of shares in the Company to which they are entitled as a result of the merger pursuant to the price protection provisions granted to such holders, and waive their rights to the balance of the price protection; and upon the completion of the merger, release the Company from any further obligations under the securities purchase agreement, and terminate the price protection rights and an Investors Rights Agreement related to Company shares and warrants held by such investors. See note 6b for further detail.

NOTE 10 - SUBSEQUENT EVENTS:

A. In February 2021, in light of the situation in which offices were no longer required under the circumstances, the Company signed a lease termination agreement related to its office located in Cambridge, Massachusetts, effective immediately. The Company paid $0.1 million as a buy-out on future lease commitments and forgave a deposit of approximately $0.05 million held by the landlord on account of future lease payments. The Company moved its corporate activities to offices in Jerusalem, Israel, that are owned by the firm that provides bookkeeping services to the Company and made available for the Company's CFO and CEO as required.

B. Between February 3 and February 18, 2021, five separate complaints were filed by putative stockholders of the Company challenging the proposed merger. Two complaints were filed in the United States District Court for the Southern District of New York (*Bispo v. Anchiano Therapeutics Ltd., et al.*, No. 1:21-cv-00964-JSR ("*Bispo* Action") and *Jace v. Anchiano Therapeutics Ltd., et al.*, No. 1:21-cv-01114-JSR ("*Jace* Action")). One complaint was filed in the United States District Court for the Eastern District of New York (*Daly v. Anchiano Therapeutics Ltd., et al.*, No. 1:21-cv-00621 ("*Daly* Action")). The remaining two complaints were filed in United States District Court for the District of Delaware (*Ciccotelli v. Anchiano Therapeutics Ltd., et al.*, No. 1:21-cv-00153-RGA ("*Ciccotelli* Action") and *Wilhelm v. Anchiano Therapeutics Ltd., et al.*, No. 1:21-cv-00226 ("*Wilhelm* Action")). All five actions assert violations of Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder against Anchiano and each member of the Anchiano board, and violations of Section 20(a) of the Exchange Act against the individual defendants. The *Ciccotelli* also asserts violations of Section 20(a) of the Exchange Act against Chemomab. Additionally, the *Bispo* Action asserts a breach of fiduciary duty claim against the individual defendants. In general, the complaints each allege that the Registration Statement on Form S-4 filed with the SEC by Anchiano on January 13, 2021, omitted or misrepresented material information regarding the merger. The complaints seek, among other things, injunctive relief, damages, and an award of plaintiff's costs, including attorneys' fees and expenses. The Company has submitted an amendment to the registration statement that included additional information not previously provided and that addresses the claims of omission and misrepresentation.

It is still too early to assess and determine the possible / probable outcome of these complaints

Exhibit 21.1

Anchiano Therapeutics Ltd.

List of Subsidiaries

Name	Jurisdiction of Incorporation	Parent	% Ownership
Anchiano Therapeutics Israel Ltd.	Israel	Anchiano Therapeutics Ltd.	100%
Anchiano Therapeutics, Inc.	Delaware	Anchiano Therapeutics Israel Ltd.	100%

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors

Anchiano Therapeutics Ltd.:

We consent to the incorporation by reference in the registration statement (No. 333-252070) on Form S-4 of Anchiano Therapeutics Ltd. of our report dated March 7, 2021, with respect to the consolidated balance sheets of Anchiano Therapeutics Ltd. and subsidiaries as of December 31, 2020 and 2019, and the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity and cash flows for each of the years in the two-year period ended December 31, 2020, and the related notes, which report appears in the December 31, 2020 annual report on Form 10-K of Anchiano Therapeutics Ltd.

Our report dated March 7, 2021 contains an explanatory paragraph that states that the Company has suffered recurring losses and cash flow deficits from operations that together with other matters described in Note 1 to the consolidated financial statements raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

Somekh Chaikin

Member firm of KPMG International

Tel Aviv, Israel

March 7, 2021

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULE 13A-14(A)/15D-14(A) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Neil Cohen, certify that:

1. I have reviewed this annual report on Form 10-K of Anchiano Therapeutics Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

b) Designed such internal 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; and

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

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

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

Date: March 7, 2021

/s/ Neil Cohen

Neil Cohen, Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULE 13A-14(A)/15D-14(A) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Fine, certify that:

1. I have reviewed this annual report on Form 10-K of Anchiano Therapeutics Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

b) Designed such internal 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; and

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

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

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

Date: March 7, 2021

/s/ Andrew Fine

Andrew Fine, Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Anchiano Therapeutics Ltd. (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2020 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 7, 2021

/s/ Neil Cohen
Neil Cohen, Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Anchiano Therapeutics Ltd. (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2020 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 7, 2021

/s/ Andrew Fine
Andrew Fine, Chief Financial Officer (Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.