ITEM 2 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and is subject to the safe harbor created by those sections. For more information, see "Cautionary Note Regarding Forward-Looking Statements." When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that impact our business. In particular, we encourage you to review the risks and uncertainties described in "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2019, as updated and supplemented in Part II, Item 1A in this Quarterly Report on Form 10-Q. These risks and uncertainties could cause actual results to differ materially from those projected or implied by our forward-looking statements contained in this report. These forward-looking statements are made as of the date of this management's discussion and analysis, and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by law.

The following discussion should be read in conjunction with our condensed consolidated interim financial statements and accompanying notes contained in this Quarterly Report on Form 10-Q and our audited financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2019.

All amounts are expressed in United States dollars unless otherwise stated.

OVERVIEW

Aptose Biosciences Inc. ("we", "our", "us", "Aptose" or the "Company") is a science-driven biotechnology company advancing first-in-class targeted agents to treat life-threatening cancers, such as acute myeloid leukemia ("AML"), high-risk myelodysplastic syndromes ("MDS"), chronic lymphocytic leukemia ("CLL") and other hematologic malignancies. Based on insights into the genetic and epigenetic profiles of certain cancers and patient populations, Aptose is building a pipeline of novel oncology therapies directed at dysregulated processes and signaling pathways. Aptose is developing targeted medicines for precision treatment of these diseases to optimize efficacy and quality of life by minimizing the side effects associated with conventional therapies. We currently have in development two molecules: CG026806 ("CG-806") and APTO-253, both being evaluated for safety, tolerability, pharmacokinetics and signals of efficacy in Phase 1 clinical trials. Each molecule is described below.

CG-806 is an orally administered, highly potent first-in-class FMS-like tyrosine kinase 3 ("FLT3")/Bruton's tyrosine kinase ("BTK") inhibitor that selectively targets defined clusters of kinases that are operative in hematologic malignancies. This mutationally agnostic small molecule anticancer agent is currently being evaluated in a Phase 1a/b study for the treatment of patients having B-cell malignancies including classic CLL, small lymphocytic lymphoma ("SLL") and certain non-Hodgkin's lymphomas ("NHL") that are resistant/refractory/intolerant to other therapies. In addition, Aptose recently received IND allowance and has initiated patient dosing in a Phase 1a/b study to develop CG-806 for the treatment of patients with relapsed/refractory acute myeloid leukemia ("R/R AML"), including the emerging populations resistant to FLT3 inhibitors. In this trial of patients with R/R AML, the CG-806 starting dose of 450 mg BID was selected because the plasma from B-cell cancer patients at that dose completely inhibited phospho-FLT3, suggesting that this starting dose might be active in the AML patient population. It is important to note that CG-806 now is undergoing formal clinical development in both lymphoid and myeloid hematologic malignancies.

APTO-253 is a first-in-class small molecule therapeutic agent that clinically inhibits expression of the MYC oncogene without causing, to date, general myelosuppression of the bone marrow. The MYC oncogene is overexpressed across many hematologic cancers, including AML and certain B cell malignancies, as well as certain solid tumor indications. MYC acts as a transcription factor that regulates cell growth, proliferation, differentiation and apoptosis, and overexpression of MYC amplifies new sets of genes to promote survival of cancer cells. APTO-253 suppresses expression of the MYC oncogene in AML cells and depletes those cells of the MYC oncoprotein, leading to apoptotic cell death. APTO-253 is currently being evaluated in a Phase 1b study for the treatment of patients with R/R AML and high-risk MDS. APTO-253 may serve as a safe and effective MYC inhibitor for AML/MDS patients that combines well with other agents and does not significantly impact the normal bone marrow.

PROGRAM UPDATES

CG-806

Indication and Clinical Trials:

CG-806 is being developed with the intent to deliver the agent as an oral therapeutic for the treatment of R/R AML and for the treatment of a spectrum of B cell malignancies (including but not limited to CLL, SLL and NHL).

On March 25, 2019, we announced that the U.S Food and Drug Administration ("FDA") granted Aptose Investigational New Drug ("IND") allowance to initiate its Phase 1a/b clinical trial for CG-806. The clinical trial is a multicenter, open label, dose-escalation study with additional optional expansion cohorts to assess the safety, tolerability, pharmacokinetics and pharmacodynamic effects, and preliminary efficacy of CG-806 in patients with CLL, SLL or NHL. In this study, CG-806 is administered in gelatin capsules twice daily ("BID") during a 28-day cycle.

As of the date of this report, we have initiated thirty clinical sites for the Phase 1a/b trial in patients with CLL/SLL or NHL which include specialty regional cancer care centers as well as large hospitals and key academic institutions. As of the date of this report, we have completed the first, second, third and fourth dose levels (150 mg, 300 mg, 450 mg and 600 mg BID, respectively). Cohort 5 (750mg) enrollment is ongoing. Under an FDA-approved accelerated titration protocol, only one patient was required at each of the first two dose levels, followed by three patients at each dose level thereafter. Intra-patient dose escalation is allowed if the higher dose is safe in three or more patients, and additional patients may be enrolled at dose levels previously declared safe. To date, we have reported that among enrolled patients with an array of B-cell malignancies, three classic CLL patients have received CG-806 and all three demonstrated inhibition of phospho-BTK and "on-target" lymphocytosis, indicating target engagement and pharmacologic activity of CG-806. As CG-806 moves from low/intermediate dose levels and into the higher dose levels, it is hoped that an optimal dose can be selected that demonstrates formal clinical responses without excessive toxicity.

Aptose is also advancing CG-806 into myeloid malignancies, with an initial focus on AML, in a separate Phase 1a/b trial. On June 29, 2020, the Company announced that it had received allowance from the FDA to proceed into a study in R/R AML with a starting dose of 450 mg BID, and subsequently on October 19, 2020, announced that it had initiated dosing of the first patient with AML. As of the date of this report we have initiated five clinical sites for the Phase 1a/b trial.

The clinical trial is a multicenter, open label, dose-escalation study with additional optional expansion cohorts to assess the safety, tolerability, pharmacokinetics and pharmacodynamic effects, and preliminary efficacy of CG-806 in patients with R/R AML. In this study, CG-806 is administered in gelatin capsules BID during a 28-day cycle. Our strategy was to identify a starting dose of CG-806 that we believe could be therapeutically active in critically ill patients with R/R AML. In our ongoing Phase 1a/b study in patients with CLL and other B-cell malignancies, 450 mg BID CG-806 delivered plasma levels that completely inhibited phospho-FLT3 in a plasma inhibitory activity (PIA) reporter cell assay, suggesting that the 450 mg BID dose may be active in patients with AML. Aptose plans to dose escalate beyond the 450 mg BID dose level, provided the 450 mg BID dose level is safe and well tolerated in R/R AML patients. Based on strong preclinical evidence of CG-806's activity against AML – including demonstration of mutation-agnostic and genotype-agnostic potency, particularly compared against other FLT3 inhibitors, and its ability to safely cure AML in murine leukemia models – we believe CG-806 may offer hope to the fragile and difficult-to-treat AML patient population.

The FDA has granted orphan drug designation to CG-806 for the treatment of patients with AML. Orphan drug designation is granted by the FDA to encourage companies to develop therapies for the treatment of diseases that affect fewer than 200,000 individuals in the United States. Orphan drug status provides research and development tax credits, an opportunity to obtain grant funding, exemption from FDA application fees and other benefits. The orphan drug designation also provides us with seven additional years of marketing exclusivity in this indication.

Manufacturing:

During fiscal years 2017 and 2018, we created a scalable chemical synthetic route for the manufacture of CG-806 drug substance and have scaled the manufacture of API (active pharmaceutical ingredient, or drug substance) to multi-kg levels, we completed the manufacture of a multi-kg batch of API under Good Manufacturing Product ("GMP") conditions as our API supply for our first-in-human clinical trials, and we manufactured under GMP conditions two dosage strengths of capsules to serve as our clinical supply in those human studies. During fiscal 2019, we completed successful manufacture of multiple batches of API and drug product, and planned numerous GMP production campaigns to supply the ongoing trial and planned trials into the future. To date we have been able to manufacture API and capsules to support clinical supplies under GMP conditions. We are continuing our manufacturing campaigns in the current 2020 fiscal period and have commenced scale-up and tech transfer activities to support additional manufacturing capacity for the ongoing and planned clinical trials of CG-806. Additional research and development funds are being utilized to support exploratory formulation studies in an ongoing effort to craft a superior formulation for later stage development of CG-806.

Data presentations:

On April 27, 2020, we presented the early clinical data on CG-806 at the AACR Virtual Annual Meeting I (April 27-28) in lieu of the live oral presentation originally planned. A video summary of Abstract # 9967 - *Early clinical findings from a Phase 1a/b dose escalation trial to evaluate the safety and tolerability of CG-806 in patients with relapsed or refractory CLL/SLL or non-Hodgkin's lymphomas* described the first-in-human tests of CG-806 which are being carried out in a Phase 1a/b clinical study in patients with significant unmet needs including patients with relapsed or refractory CLL, SLL or NHL who had been failed by or been intolerant to two lines of established therapy. We noted that the second patient, treated at the 300 mg BID dose level, represented a classic CLL patient that developed a brisk lymphocytosis (evidence of BTK target engagement and evidence of pharmacologic activity), and that enrollment was continuing.

On June 12, 2020, we presented new clinical data on CG-806 in a poster presentation at the 25th Congress of the EHA. The poster, *Early Clinical Findings from a Phase 1 a/b Dose Escalation Trial to Evaluate the Safety and Tolerability of CG-806 in Patients with Relapsed or Refractory CLL/SLL or Non-Hodgkin's Lymphomas* (EHA2020 Abstract# EP711), reviewed CG-806 data for eight patients (as of the data cut-off date on May 5, 2020) with relapsed or refractory CLL,SLL or NHL in the first in-human Phase 1a/b, open-label, single arm, multicenter dose-escalation clinical study. Data from the ongoing trial demonstrated CG-806 was well-tolerated in patients treated at 150 mg, 300 mg, 450 mg BID over multiple cycles, with no dose-limiting toxicities or serious adverse events observed, supporting continued dose escalation. CG-806 treatment achieved human steady state PK levels known to be effective in murine tumor models and led to complete inhibition of phospho-BTK and multiple CLL survival pathways. CG-806 treatment also led to lymphocytosis in both classic CLL patients entering study with elevated lymphocyte counts and led to complete inhibition of phospho-FLT3, suggesting that dose levels evaluated in this study may be therapeutic in patients with AML.

On June 22, 2020, we presented new preclinical data on CG-806 in a poster presentation at the AACR Virtual Annual II 2020. The poster, *CG-806, a First-in-Class FLT3/BTK Inhibitor, and Venetoclax Synergize to Inhibit Cell Proliferation and to Induce Apoptosis and Aggressive B-cell Lymphomas*, illustrated how CG-806 simultaneously inhibits the driver BCR pathway and PI3K/AKT, NFκB and MAPK-mediated rescue pathways to kill aggressive double-hit and double-expressor B-cell lymphoma cells. Overall, the presented work provided additional mechanistic evidence to support the clinical development of CG-806 as a single agent or in combination with venetoclax in patients with aggressive B-cell lymphomas harboring unfavorable BCL2/MYC/BCL6 translocations and / or overexpression.

APTO-253

Phase 1b Trial

APTO-253, a small molecule inhibitor of MYC gene expression, is being evaluated by Aptose in a Phase 1b clinical trial in patients with R/R hematologic malignancies, particularly R/R AML and high-risk MDS. The Phase 1b, multicenter, open-label, dose-escalation clinical trial of APTO-253 is designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamic responses and efficacy of APTO-253 as a single agent and determine the recommended Phase 2 dose. APTO-253 is being administered once weekly, over a 28-day cycle. The dose escalation stage of the study could potentially enroll up to 20 patients with R/R AML or high-risk MDS. The study is designed to then transition, as appropriate, to single-agent expansion cohorts in R/R AML and/or high-risk MDS.

As of the date of this report, we have multiple active sites recruiting patients in the dose escalation stage of the trial. As of the date of this report, we have completed enrollment and treatment of patients on the first, second, third and fourth dose levels (20, 40, 66, and 100 mg/m^2, respectively). Under an FDA-approved accelerated titration protocol, only one patient was required at each of the first two dose levels, followed by three patients at each dose level thereafter. Aptose is currently enrolling and treating patients in the fifth dose level (150 mg/m^2) of APTO-253. During the second quarter of 2020, the FDA allowed an amendment for Aptose to initiate more aggressive dose escalations with APTO-253, provided the tolerability profile remains favorable. The first four dosing cohorts have enrolled a mix of patients with AML and MDS. To date, we have observed meaningful reductions in MYC expression in peripheral blood mononuclear cells (PBMCs) from treated patients with AML and MDS, demonstrating MYC target engagement and mechanistic proof of concept in different indications.

Manufacturing:

We are continuing to manufacture additional drug substance and drug product for use in the ongoing trial.

We are exploring additional drug delivery methods for APTO-253 and plan to initiate additional non-clinical studies for solid tumor and hematologic cancer development. As preparing, submitting, and advancing applications for regulatory approval, developing drugs and drug product and clinical trials are sometimes complex, costly, and time-consuming processes, an estimate of the future costs is not reasonable at this time.

Impact of COVID 19 on our Research Programs:

We are advancing first-in-class targeted agents to treat life-threatening cancers that, in most cases, are not elective for patients and require immediate treatment. However, COVID-19 has caused global economic and social disruptions that could adversely affect our ongoing or planned research and development and clinical trial activities including enrollment of patients in our ongoing clinical trials, collection and analysis of patient data and eventually, the reporting of top-line results from our trials.

Our team proactively addressed these new challenges swiftly and appropriately, implementing safeguards and procedures to ensure both the safety of our employees and stakeholders, and accommodate the potential challenges due to COVID-19. Aptose was early in directing its employees to work-from-home and provided the tools to minimize productivity disruptions. Our Clinical Operations team reached out to active and future clinical sites to determine their needs and challenges and assist where possible, including virtual monitoring of patients, which reduces patients' visits. We also have contacted our drug manufacturers to identify any potential supply chain disruptions and are adjusting accordingly. During the early part of the first quarter of 2020, we began to carefully monitor the potential impact of COVID-19, and on a regular basis, we communicated with investigators at our clinical sites to gain an evolving understanding of competing COVID-19 related activities and clinical trial related activities.

In the beginning of April 2020, we learned that some of our larger clinical sites that are impacted by COVID-19 may either postpone or face delays in the enrollment of patients on all on-going clinical trials due to a number of factors, including the re-allocation of resources and to avoid clinical trial patients being exposed to COVID-19. Such measures taken at the clinical sites could lead to a slowdown in the enrollment of patients on our trials at these sites. To minimize the impact of COVID-19, we focused efforts on our other larger clinical sites and regional cancer care sites that are not/less impacted by COVID-19 to recruit patients into the fourth cohort. While it is difficult to estimate the duration and impact of COVID-19 on the larger clinical sites and regional cancer care sites, as of the date of this report, we have not experienced and do not foresee material delays to the enrollment of patients or timelines for the CG-806 Phase 1a/b B-cell malignancy trial due to the variety of clinical sites that we have actively recruited for this trial. APTO-253, which is administered intravenously, requires the need for hospital / clinical site resources to assist and monitor patients during each infusion and based on the current conditions caused by COVID-19, future enrollment of patients on this trial is likely to be negatively impacted.

While as of the date of this report we have not experienced any material delays in initiating our CG-806 Phase 1 clinical study in AML due to COVID-19, we are conducting site initiation visits remotely which could result in delays in site activations and negatively impact this trial. Additionally, COVID-19 could negatively impact patient enrollment if our clinical sites are unable to enroll patients due to either a lack of administrative resources at their sites or decisions made at the clinical sites to limit patient exposure to COVID-19.

As of the date of this report, we have not experienced material delays in the manufacturing of CG-806 or APTO-253 related to COVID-19. Should our manufacturers be required to shut down their facilities due to COVID-19 for an extended period of time, our trials may be negatively impacted.

LIQUIDITY AND CAPITAL RESOURCES

We are an early stage development company and we currently do not earn any revenues from our drug candidates. The continuation of our research and development activities and the commercialization of the targeted therapeutic products are dependent upon our ability to successfully finance and complete our research and development programs through a combination of equity financing and payments from strategic partners.

Sources of liquidity:

The following table presents our cash and cash equivalents, investments and working capital as at September 30, 2020 and December 31, 2019.

(in thousands)	Balances at September 30, 2020	Balances at December 31, 2019
Cash and cash equivalents	$ 99,727	$ 79,842
Investments	32,997	17,758
Total	$ 132,724	$ 97,600
Working capital	$ 128,501	$ 93,227

Working capital represents primarily cash, cash equivalents, investments and other current assets less current liabilities.

We believe that our cash, cash equivalents and investments on hand at September 30, 2020 will be sufficient to finance our operations for at least 12 months from the issuance date of these financial statements. Our cash needs for the next twelve months include estimates of the number of patients and rate of enrollment of our clinical trials, the amount of drug product that we will require to support our clinical trials, and our general corporate overhead costs to support our operations, and our reliance on our manufacturers. We have based these estimates on assumptions and plans which may change and which could impact the magnitude and/or timing of operating expenses and our cash runway.

Since our inception, we have financed our operations and technology acquisitions primarily from equity financing, proceeds from the exercise of warrants and stock options, and interest income on funds held for future investment.

On July 20, 2020 and August 10, 2020, the Company completed a confidentially marketed public offering (“CMPO”), with Piper Sandler & Co. as the representative of the underwriters, through the issuance of, in the aggregate, 11,854,472 common shares for gross proceeds of $62.2 million (approximately $58.2 million net of share issue costs).

On May 5, 2020, the Company entered into an “At-The-Market” Facility equity distribution agreement with Piper Sandler & Co. and Canaccord Genuity LLC acting as co-agents (the “2020 ATM”). Under the terms of this facility, the Company may, from time to time, sell common shares having an aggregate offering value of up to $75 million through Piper Sandler and Canaccord Genuity on the Nasdaq Capital Market. During the nine month period ended September 30, 2020, the Company did not issue any shares under this 2020 ATM.

During the year ended December 31, 2019, the Company completed two CMPOs, with RBC Capital Markets, LLC and Canaccord Genuity LLC, as representatives of the underwriters, and Piper Jaffray & Co., as the representative of the underwriters, respectively, through the issuance of, in the aggregate, 30,043,750 common shares for aggregate gross proceeds of $95.45 million (approximately $88.18 million net of share issue costs). The Company also raised capital pursuant to two separate share purchase agreements with Aspire Capital Fund, LLC ("Aspire Capital") through the issuance of an aggregate of 7,302,433 common shares for aggregate gross proceeds of $14.4 million . We do not expect that COVID-19 will have a significant impact on our liquidity and capital resources and we are not incurring significant additional costs to support our ongoing operations during this time. We have not entered into long term manufacturing contracts and should there be a delay in our trials we have flexibility to reduce future planned manufacturing campaigns.

We expect that we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. In December 2019, we filed a short form base shelf prospectus (the "Base Shelf") that allows us to distribute, upon the filing of prospectus supplements, up to $200,000,000 of common shares, warrants, or units comprising any combination of common shares and warrants. The Base Shelf was declared effective by the SEC on January 9, 2020 and expires on January 9, 2023.

Our ability to raise additional funds could be affected by adverse market conditions, the status of our product pipeline, possible delays in enrollment in our trial related to COVID-19, and various other factors and we may be unable to raise capital when needed, or on terms favorable to us. If the necessary funds are not available, we may need to delay, reduce the scope of, or eliminate some of our development programs, potentially delaying the time to market for any of our product candidates.

Cash flows:

The following table presents a summary of our cash flows for the three and nine-month periods ended September 30, 2020 and 2019:

(in thousands)	Three months ended, September 30, 2020	September 30, 2019	Nine months ended, September 30, 2020	September 30, 2019
Net cash provided by (used in):				
Operating activities	$ (8,270)	$ (5,184)	$ (23,540)	$ (15,327)
Investing activities	(4,398)	(1,042)	(15,331)	(9,092)
Financing activities	58,283	17	58,765	29,808
Effect of exchange rates changes on cash and cash equivalents	-	(3)	(9)	(2)
Net (decrease)/increase in cash and cash equivalents	$ 45,615	$ (6,212)	$ 19,885	$ 5,387

Cash used in operating activities:

Our cash used in operating activities for the three months ended September 30, 2020 and 2019 was approximately $8.3 million and $5.2 million, respectively. Our cash used in operating activities for the nine months ended September 30, 2020 and 2019 was approximately $23.5 million and $15.3 million, respectively. Net cash used in operating activities was higher in the three and nine-month periods ended September 30, 2020 as compared with the three and nine-month periods ended September 30, 2019 resulting mostly from higher net loss in the current periods. See "Results of Operations". Our uses of cash for operating activities for both periods primarily consisted of salaries and wages for our employees, facility and facility-related costs for our offices and laboratories, fees paid in connection with preclinical and clinical studies, drug manufacturing costs, laboratory supplies and materials, and office administrative costs.

We do not expect to generate positive cash flow from operations for the foreseeable future due to additional research and development costs, including costs related to drug discovery, preclinical testing, clinical trials, and manufacturing, as well as operating expenses associated with supporting these activities, and potential milestone payments to our collaborators. It is expected that negative cash flow will continue until such time, if ever, that we receive regulatory approval to commercialize any of our products under development and/or royalty or milestone revenue from any such products exceeds expenses.

Cash flow from investing activities:

Our cash used in investing activities for the three months ended September 30, 2020 was $4.4 million, and consisted of net purchases of investments of $4.4 million. Our cash used in investing activities in the three-month period ended September 30, 2019 was $1.0 million, and consisted of net purchases of investments of $1.0 million and property and equipment of $42 thousand.

Our cash used in investing activities in the nine-month period ended September 30, 2020 was $15.3 million, and consisted of net purchases of investments of $15.3 million and purchases of property and equipment of $53 thousand. Our cash used in investing activities in the nine-month period ended September 30, 2019 was approximately $9.1 million, and consisted of net purchases of investments of $9.0 million and property and equipment of $92 thousand.

The composition and mix of cash, cash equivalents and investments is based on our evaluation of conditions in financial markets and our near-term liquidity needs. We have exposure to credit risk, liquidity risk and market risk related to our investments. The Company manages credit risk associated with its cash and cash equivalents and investments by maintaining minimum standards of R1-low or A-low investments. The Company invests only in highly rated financial instruments which are capable of prompt liquidation. The Company manages its liquidity risk by continuously monitoring forecasts and actual cash flows. The Company is subject to interest rate risk on its cash and cash equivalents and investments. The Company does not believe that the results of operations or cash flows would be affected to any significant degree by a sudden change in market interest rates relative to interest rates on the investments, owing to the relative short-term nature of the investments.

Cash flow from financing activities:

Our cash flow from financing activities for the three months ended September 30, 2020 was $58.3 million, and consisted of 11,854,472 shares issued pursuant to the CMPO in July and August 2020 for net proceeds of approximately $58.2 million and proceeds of approximately $49 thousand from the exercise of stock options. Our cash flow from financing activities in the three-month period ended September 30, 2019 was $17 thousand, and consisted of proceeds of approximately $17 thousand from the exercise of stock options.

Our cash flow from financing activities for the nine months ended September 30, 2020 was approximately $58.8 million, consisted mostly of the CMPO we completed in July and August 2020 as described above and of proceeds from the exercise of stock options of $531 thousand. Net cash provided by financing activities in the nine-month period ended September 30, 2019 reflects mostly the 11,500,000 common shares issued pursuant to the CMPO we completed in June 2019 with RBC Capital Markets, LLC and Canaccord Genuity LLC, as representatives of the underwriters, for net proceeds of approximately $19.6 million, 5,502,433 shares issued to Aspire Capital pursuant to the 2018 Aspire Purchase Agreement, as described below, for net proceeds of approximately $10 million, and 77,349 shares issued pursuant to the 2018 ATM Facility with Cantor Fitzgerald, as described below, for net proceeds of approximately $178 thousand.

At-The-Market Facilities

On May 5, 2020, the Company entered into an ATM equity distribution agreement with Piper Sandler & Co. and Canaccord Genuity LLC acting as co-agents. Under the terms of this facility, the Company may, from time to time, sell common shares having an aggregate offering value of up to $75 million through Piper Sandler and Canaccord Genuity on the Nasdaq Capital Market. During the nine months ended September 30, 2020, the Company did not issue any shares under this ATM equity facility.

On March 27, 2018, the Company entered into an ATM equity distribution agreement with Cantor Fitzgerald acting as sole agent (the "2018 ATM Facility"). Under the terms of this facility, the Company was allowed, from time to time, to sell common shares having an aggregate offering value of up to $30 million through Cantor Fitzgerald on the Nasdaq Capital Market. During the nine months ended September 30, 2019, the Company issued 77,349 shares under the 2018 ATM Facility at an average price of $2.37 for gross proceeds of $183 thousand ($178 thousand net of share issue costs). On a cumulative basis to September 30, 2019, the Company had raised a total of $11.2 million gross proceeds ($10.9 million net of share issue costs) under the 2018 ATM Facility. The Company terminated this agreement on May 24, 2019.

Common Share Purchase Agreements

On May 30, 2018, the Company entered into a Common Share Purchase Agreement to sell up to $20.0 million of common shares to Aspire Capital over approximately 30 months (the "2018 Aspire Purchase Agreement"). Pursuant to the terms of this agreement, on June 8, 2018, the Company issued 170,261 common shares to Aspire Capital in consideration for entering into the 2018 Aspire Purchase Agreement for a total cost of $600 thousand. During the nine months ended September 30, 2019, the Company issued 5,502,433 common shares to Aspire Capital pursuant to the 2018 Aspire Purchase Agreement at an average price of $1.82 per share for gross and net proceeds of $10 million. On a cumulative basis, the Company raised a total of approximately $11.9 million gross and net proceeds under the 2018 Aspire Purchase Agreement. As of May 7, 2019 the Company had issued 6,409,980 common shares, the maximum number of shares issuable under this facility without shareholder approval, and the 2018 Aspire Purchase Agreement was accordingly terminated.

On May 7, 2019, the Company entered into the 2019 Aspire Purchase Agreement, which provided that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was committed to purchase up to an aggregate of $20 million of Common Shares over approximately 30 months. Pursuant to the terms of this agreement, on May 13, 2019, the Company issued 171,428 Common Shares ("Commitment Shares") to Aspire Capital in consideration for entering into the 2019 Aspire Purchase Agreement for a total cost of $360 thousand. During the period from October 1, 2019 up to December 16, 2019, the date the 2019 Aspire Purchase Agreement was terminated, the Company issued 1,800,000 common shares under the agreement at an average price of $2.43 per share for gross and net proceeds of $4.4 million.

CONTRACTUAL OBLIGATIONS

There were no material changes to our contractual obligations and commitments described under Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, which can be found on EDGAR at www.sec.gov/edgar.shtml and on SEDAR at www.sedar.com.

RESULTS OF OPERATIONS

A summary of the results of operations for the three-month and nine-month periods ended September 30, 2020 and 2019 is presented below:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2020	2019	2020	2019
Revenues	$ -	$ -	$ -	$ -
Research and development expenses	7,519	4,751	20,319	11,582
General and administrative expenses	5,775	2,276	20,690	7,391
Net finance income	45	183	484	405
Net loss	(13,249)	(6,844)	(40,525)	(18,568)
Other comprehensive gain/(loss)	(2)	(5)	(17)	13
Total comprehensive loss	$ (13,251)	$ (6,849)	$ (40,542)	$ (18,555)
Basic and diluted loss per common share	$ (0.15)	$ (0.12)	$ (0.51)	$($0.39)

The net loss for the three-month period ended September 30, 2020 increased by $6.4 million to $13.2 million as compared with $6.8 million for the comparable period in 2019, primarily as a result of an increase of $4.4 million in stock-based compensation in the current period, a combined increase in costs for our CG-806 development program and related labor costs of approximately $2.5 million and offset by lower costs of approximately $721 thousand on our APTO-253 program. There was also an increase in cash-based general and administrative expenses of $108 thousand and a decrease in net finance income of $138 thousand in the current period compared to the comparative period, mostly as a result of lower yields on investments held during the three-month period ended September 30, 2020.

The net loss for the nine-month period ended September 30, 2020 increased by $22.0 million to $40.5 million as compared with $18.6 million for the comparable period in 2019, primarily as a result of an increase of $15.3 million in stock-based compensation in the current period, a combined increase in program costs and related labor costs of approximately $7.1 million on our CG-806 development program and higher cash-based general and administrative expenses of approximately $492 thousand. These expenses were partially offset by lower costs of $836 thousand on our APTO-253 development programs.

Research and Development

The research and development expenses for the three-month and nine-month periods ended September 30, 2020 and 2019 were as follows:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2020	2019	2020	2019
Program costs – CG-806	4,300	$ 2,223	11,000	$ 5,287
Program costs – APTO-253	725	1,446	2,460	3,296
Personnel related expenses	1,440	1,042	4,060	2,666
Stock-based compensation	1,051	34	2,784	309
Depreciation of equipment	3	6	15	24
	$ 7,519	$ 4,751	$ 20,319	$ 11,582

Research and development expenses increased by $2.8 million to $7.5 million for the three-month period ended September 30, 2020 as compared with $4.8 million for the comparative period in 2019. Changes to the components of our research and development expenses presented in the table above are primarily as a result of the following events:

- Program costs for CG-806 increased by approximately $2.1 million, mostly as a result of higher manufacturing costs, including costs to scale up manufacturing and research costs associated with optimizing the formulation, higher costs associated with the CG-806 Phase 1a/b trial and the costs associated the CG-806 AML trial.

- Program costs for APTO-253 decreased by approximately $721 thousand, mostly as a result of lower manufacturing costs and lower clinical trial costs related to the APTO-253 Phase 1b trial.

- Personnel-related expenses increased by $398 thousand, mostly related to new positions hired since the second quarter of 2019 to support the CG-806 Phase 1a/b and APTO-253 Phase 1b clinical trials and the CG-806 AML Phase 1 clinical trial.

- Stock-based compensation increased by approximately $1.0 million in the three months ended September 30, 2020, compared with the three months ended September 30, 2019, mostly related to an increase in the number of options granted during the nine months ended September 30, 2020 and a higher grant date fair value of options as compared with the nine months ended September 30, 2019, and a higher rate of forfeitures in the comparative period.

Research and development expenses increased by $8.7 million to $20.3 million for the nine-month period ended September 30, 2020 as compared with $11.6 million for the comparative period in 2019 for the same reasons as described above for the three-month period ended September 30, 2020.

- Program costs for CG-806 increased by approximately $5.7 million, mostly as a result of higher manufacturing costs, including costs to scale up manufacturing and research costs associated with optimizing the formulation, higher costs associated with the CG-806 Phase 1a/b trial and the costs associated with the CG-806 AML trial.

- Program costs for APTO-253 decreased by approximately $836 thousand, mostly as a result of lower manufacturing costs and lower clinical trial costs related to the APTO-253 Phase 1b trial.

- Personnel-related expenses increased by $1.4 million, mostly related to new positions hired since the second quarter of 2019 to support the CG-806 Phase 1a/b and APTO-253 Phase 1b clinical trials and the CG-806 AML Phase 1 clinical trial.

- Stock-based compensation increased by approximately $2.5 million in the three months ended September 30, 2020, compared with the three months ended September 30, 2019, mostly related to an increase in the number of options granted during the nine months ended September 30, 2020 and a higher grant date fair value of options as compared with the nine months ended September 30, 2019, and a higher rate of forfeitures in the comparative period in 2019.

General and Administrative

The general and administrative expenses for the three-month and nine-month periods ending September 30, 2020 and 2019 were as follows:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2020	2019	2020	2019
General and administrative, excluding items below:	$ 1,888	$ 1,780	$ 6,367	$ 5,875
Stock-based compensation	3,854	470	14,223	1,425
Depreciation of equipment	33	26	100	91
	5,775	$ 2,276	20,690	$ 7,391

General and administrative expenses for the three-month period ended September 30, 2020 were $5.8 million as compared with $2.3 million for the comparative period in 2019, an increase of approximately $3.5 million. The increase was primarily as a result of the following:

- General and administrative expenses, other than share-based compensation and depreciation of equipment, increased by approximately $108 thousand in the three months ended September 30, 2020, primarily as a result of higher personnel related costs, higher insurance costs and higher office administrative costs offset by lower professional fees and lower travel expenses.

- Stock-based compensation increased by approximately $3.4 million in the three months ended September 30, 2020, compared with the three months ended September 30, 2019, mostly related to an increase in the number of options granted during the nine-month period ended September 30, 2020, and a higher grant date fair value of options as compared with September 30, 2019.

General and administrative expenses for the nine-month period ended September 30, 2020 were $20.7 million as compared with $7.4 million for the comparative period in 2019, an increase of approximately $13.3 million. The increase was primarily as a result of the following:

- General and administrative expenses, other than stock-based compensation and depreciation of equipment, increased by approximately $492 thousand in the nine months ended September 30, 2020 primarily as a result of higher personnel related costs, higher insurance costs and higher office administrative costs and offset by lower financing costs and lower travel expenses.

- Stock-based compensation increased by approximately $12.8 million in the nine months ended September 30, 2020, compared with the nine months ended September 30, 2019 mostly related to an increase in the number of restricted share units and options granted during the nine-month period ended September 30, 2020, and a higher grant date fair value of options as compared with September 30, 2019.

COVID-19 did not have a significant impact on our results of operations for the quarter ended September 30, 2020. We have not experienced and do not foresee material delays to the enrollment of patients or timelines for the CG-806 Phase 1a/b trial due to the variety of clinical sites that we have actively recruited for this trial. Similarly, we do not expect our enrollment of the CG-806 AML trial to be negatively impacted by COVID-19 as we plan to use a variety of clinical sites for this trial as well. APTO-253, which is administered intravenously, requires the need for hospital / clinical site resources to assist and monitor patients during each infusion and, based on the current conditions caused by COVID-19, future enrollment of patients on this trial is likely to be negatively impacted. As of the date of this report, we have not experienced material delays in the manufacturing of CG-806 or APTO-253 related to COVID-19. Should our manufacturers be required to shut down their facilities due to COVID-19 for an extended period of time, our trials may be negatively impacted.

OFF-BALANCE SHEET ARRANGEMENTS

As at September 30, 2020, we were not party to any off-balance sheet arrangements.

CRITICAL ACCOUNTING POLICIES

Critical Accounting Policies and Estimates

We periodically review our financial reporting and disclosure practices and accounting policies to ensure that they provide accurate and transparent information relative to the current economic and business environment. As part of this process, we have reviewed our selection, application and communication of critical accounting policies and financial disclosures. Management has discussed the development and selection of the critical accounting policies with the Audit Committee of the Board of Directors and the Audit Committee has reviewed the disclosure relating to critical accounting policies in this Management's Discussion and Analysis.

Significant accounting judgments and estimates

A "critical accounting policy" is one which is both important to the portrayal of our financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. For additional information, please see the discussion of our significant accounting policies in Note 2 to the Financial Statements included in our Annual Report for the fiscal year ended December 31, 2019 on Form 10-K filed with the United States Securities Exchange Commission (the "SEC") on March 10, 2020. There were no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2020 other than that we have determined that due to an increase in the amount and values of our research contracts, we now consider our estimates related to prepaid and accrued research and development (R&D) activities as significant estimates. Research and development (R&D) costs are expensed as incurred. R&D costs consist primarily of salaries and benefits, stock-based compensation, manufacturing, contract services, clinical trials, intangibles, and research related overhead. Non-refundable advance payments for goods and services that will be used in future research are recorded in prepaid and other assets and are expensed when the services are performed.

We record expenses for research and development activities based on our estimates of services received and efforts expended pursuant to contracts with vendors that conduct research and development on our behalf. The financial terms vary from contract to contract and may result in uneven payment flows as compared with services performed or products delivered. As a result, we are required to estimate research and development expenses incurred during the period, which impacts the amount of accrued expenses and prepaid balances related to such costs as of each balance sheet date. We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Other important accounting policies and estimates made by management are the valuation of contingent liabilities, the valuation of tax accounts, and the assumptions used in determining the valuation of share-based compensation.

Management's assessment of our ability to continue as a going concern involves making a judgment, at a particular point in time, about inherently uncertain future outcomes and events or conditions. Please see the "Liquidity and Capital Resources" section in this Quarterly Report on Form 10-Q for a discussion of the factors considered by management in arriving at its assessment.

Updated share information

As at November 10, 2020, we had 88,861,737 common shares issued and outstanding. In addition, there were 11,996,011 common shares issuable upon the exercise of outstanding stock options and upon the vesting of restricted share units.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Report contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995 and "forward-looking information" within the meaning of applicable Canadian securities law, which we collectively refer to as "forward-looking statements". Such forward-looking statements reflect our current beliefs and are based on information currently available to us. In some cases, forward-looking statements can be identified by terminology such as "may", "would", "could", "will", "should", "expect", "plan", "intend", "anticipate", "believe", "estimate", "predict", "potential", "continue" or the negative of these terms or other similar expressions concerning matters that are not historical facts.

Many factors could cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements that may be expressed or implied by such forward-looking statements, including, among others:

- events outside of our control, such as natural disasters, wars or health crises such as the COVID-19 pandemic, which result in uncertainty and adverse effects on our business;
- our lack of product revenues and net losses and a history of operating losses;
- our early stage of development, particularly the inherent risks and uncertainties associated with (i) developing new drug candidates generally, (ii) demonstrating the safety and efficacy of these drug candidates in clinical studies in humans, and (iii) obtaining regulatory approval to commercialize these drug candidates;
- our need to raise substantial additional capital in the future and our potential inability to raise such funds when needed and on acceptable terms, particularly in light of restrictions and increasing costs of capital related to the COVID-19 pandemic;
- delays to clinical studies and regulatory approvals of our drug candidates, including delays resulting from the COVID-19 pandemic, which may increase our costs and could substantially harm our business;
- difficulties in enrolling patients for clinical trials which may lead to delays or cancellations of our clinical trials;
- the marketplace's refusal to accept our products or product candidates due to intense competition and technological change in our industries, and our inability to compete successfully against other companies in our industries and achieve profitability;
- our inability to protect our intellectual property rights and to not infringe on the intellectual property rights of third parties;
- limits on commercialization of our products because of intellectual property rights owned or controlled by third parties;
- potential exposure to litigation, including product liability and other claims, and the potential need to take action against other parties; and
- extensive government regulation of our industry and our inability to comply with applicable regulations and standards;

More detailed information about risk factors and their underlying assumptions are included in our Annual Report on Form 10-K for the year ended December 31, 2019, under Item 1A – Risk Factors, as they are updated and supplemented in this Report. Except as required under applicable securities legislation, we undertake no obligation to publicly update or revise forward-looking statements, whether as a result of new information, future events or otherwise.

ITEM 3 – QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

Under SEC rules and regulations, as a smaller reporting company, we are not required to provide this information.

ITEM 4 – CONTROLS AND PROCEDURES

As of the end of our fiscal quarter ended September 30, 2020, an evaluation of the effectiveness of our "disclosure controls and procedures" (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the United States Exchange Act of 1934, as amended (the "Exchange Act")), was carried out by our management, with the participation of our principal executive officer and principal financial officer. Based upon that evaluation, our principal executive officer and principal financial officer have concluded that as of the end of our fiscal quarter ended September 30, 2020, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

It should be noted that while our principal executive officer and principal financial officer believe that our disclosure controls and procedures provide a reasonable level of assurance that they are effective, they do not expect that our disclosure controls and procedures or internal control over financial reporting will prevent all errors or fraud. A control system, no matter how well conceived or operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during our fiscal quarter ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1 – LEGAL PROCEEDINGS

We are not involved in any material active legal actions. However, from time to time, we may be subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of our business. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time.

ITEM 1A – RISK FACTORS

The following risk factors update and supplement the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2019, and they should be read in conjunction with those risk factors. Any of the risks and uncertainties described below could significantly and negatively affect our business, prospects, financial condition, operating results, or credit ratings, which could cause the trading price of our common shares to decline. Additional risks and uncertainties not presently known to us, or risks that we currently consider immaterial, could also impair our business operations or financial condition. The following discussion of risk factors contains "forward-looking" statements, as discussed above.

Risks Related to our Business

We need to raise additional capital.

We have an ongoing need to raise additional capital. To obtain the necessary capital, we must rely on some or all of the following: additional share issues, debt issuances (including promissory notes), collaboration agreements or corporate partnerships and grants and tax credits to provide full or partial funding for our activities. Additional funding may not be available on terms that are acceptable to us or in amounts that will enable us to carry out our business plan. Although, as of the date of this report, we do not expect that COVID-19 will have a significant impact on our liquidity and capital resources, the extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted. As such, our ability to raise additional funds could be affected by adverse market conditions resulting from the COVID-19 outbreak and delays in enrollment in our trial related to COVID-19.

Our need for capital may require us to:

- engage in equity financings that could result in significant dilution to existing investors;
- delay or reduce the scope of or eliminate one or more of our development programs;
- obtain funds through arrangements with collaborators or others that may require us to relinquish rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves;
- license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available;
- considerably reduce operations; or
- cease our operations.

In addition, sales of a substantial number of our common shares in the public markets, or the perception that such sales could occur, could depress the market price of our common shares and impair our ability to raise capital through the sale of additional equity securities.

Our operations could be adversely affected by events outside of our control, such as natural disasters, wars or health crises such as the COVID-19 pandemic.

We may be impacted by business interruptions resulting from pandemics and public health emergencies, including those related to COVID-19, geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires. An outbreak of infectious disease, a pandemic or a similar public health threat, such as the COVID 19 pandemic, or a fear of any of the foregoing, could adversely impact us by causing operating, manufacturing, supply chain, clinical trial and project development delays and disruptions, labour shortages, travel and shipping disruption and shutdowns (including as a result of government regulation and prevention measures). The extent to which COVID-19 will impact our business and our financial results will depend on future developments, which are highly uncertain and cannot be predicted, including the scope, severity and duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact, and the direct and indirect economic effects of the pandemic and containment measures, among other future developments. We may incur expenses or delays relating to such events outside of our control, which could have a material adverse impact on our business, operating results and financial condition.

Risks Related to Development, Clinical Testing and Regulatory Approval of Our Product Candidates

Clinical trials are long, expensive and uncertain processes and the FDA or Health Canada may ultimately not approve any of our product candidates. We may never develop any commercial drugs or other products that generate revenues.

In the past five years, none of our product candidates has received regulatory approval for commercial use and sale in North America. We cannot market a pharmaceutical product in any jurisdiction until it has completed thorough preclinical testing and clinical trials in addition to that jurisdiction's extensive regulatory approval process. Approval in one country does not assure approval in another country. In general, significant research and development and clinical studies are required to demonstrate the safety and effectiveness of our product candidates before we can submit any applications for regulatory approval.

Clinical trials are long, expensive and uncertain processes. Clinical trials may not start or be on schedule and the FDA or Health Canada or any other regulatory body may not ultimately approve our product candidates for commercial sale in the relevant territory. Based on the current environment due to COVID-19 and the additional caution applied to the granting of new clinical trial initiations, there is no assurance that the FDA will grant allowance to initiate the planned CG-806 AML study while COVID-19-related restrictions are in place at the FDA. The clinical trials of any of our drug candidates could be unsuccessful, which would prevent us from advancing, commercializing or partnering the drug.

Even if the results of our preclinical studies or clinical trials are initially positive, it is possible that we will obtain different results in the later stages of drug development or that results seen in clinical trials will not continue with longer term treatment. Positive results in Phase 1 clinical trials may not necessarily repeat in larger Phase 2 or Phase 3 clinical trials.

Our preclinical studies and clinical trials may not generate positive results that will allow us to move towards the commercial use and sale of our product candidates. Furthermore, negative preclinical or clinical trial results may cause our business, financial condition, or results of operations to be materially adversely affected. For example, our Phase 1b clinical trial of APTO-253 in patients with R/R AML and high risk MDS was placed on clinical hold by the FDA in November 2015. Those shortcomings of the drug product were addressed and the clinical hold was lifted. However, there can be no assurance that the Company will have the resources, or that we will decide, to continue the development of APTO-253 after the current clinical trial. There is a long development path ahead that will take many years to complete the development and is prone to the risks of failure or delays inherent in drug development. Likewise, our CG-806 product candidate is currently being evaluated in two separate Phase 1a/b studies for patients having B-cell malignancies and R/R AML, respectively, and it is expected to undergo many years of testing and regulatory examinations prior to any potential regulatory approvals.

Preparing, submitting and advancing applications for regulatory approval of products is complex, expensive and time intensive and entails significant uncertainty. A commitment of substantial resources to conduct time-consuming research, preclinical studies and clinical trials is required if we are to complete development of our products.

Clinical trials of our products require that we identify and enroll a large number of patients with the illness under investigation. We may not be able to enroll a sufficient number of appropriate patients to complete our clinical trials in a timely manner, particularly in smaller indications and indications where there is significant competition for patients. If we experience difficulty in enrolling a sufficient number of patients to conduct our clinical trials, we may need to delay or terminate ongoing clinical trials and will not accomplish objectives material to our success. Delays in planned patient enrollment or lower than anticipated event rates in our current clinical trials or future clinical trials also may result in increased costs, program delays, or both.

In addition, unacceptable toxicities or adverse side effects may occur at any time in the course of preclinical studies or human clinical trials or, if any product candidates are successfully developed and approved for marketing, during commercial use of any approved products. The appearance of any unacceptable toxicities or adverse side effects could interrupt, limit, delay or abort the development of any of our product candidates or, if previously approved, necessitate their withdrawal from the market. Furthermore, disease resistance or other unforeseen factors may limit the effectiveness of our potential products.

Our failure to develop safe and commercially viable drugs would substantially impair our ability to generate revenues and sustain our operations and would materially harm our business and adversely affect our share price.

We may not achieve our projected development goals in the time frames we announce and expect.

We set goals for, and make public statements regarding, the expected timing of the accomplishment of objectives material to our success, such as the commencement and completion of clinical trials, the submission of a drug-regulatory application, and the expected costs to develop our product candidates. The actual timing and costs of these events can vary dramatically due to factors within and beyond our control, such as delays or failures in our IND submissions or clinical trials, issues related to the manufacturing of drug supply, uncertainties inherent in the regulatory approval process, market conditions and interest by partners in our product candidates among other things. Our clinical trials may not be completed, we may not make regulatory submissions or receive regulatory approvals as planned; or we may not secure partnerships for any of our product candidates. Any failure to achieve one or more of these milestones as planned would have a material adverse effect on our business, financial condition and results of operations.

Although, as of the date of this report, we do not foresee material delays to the enrollment of patients or timelines for our trials due to COVID-19, the extent to which COVID-19 will impact the projected development goals will depend on future developments, which are highly uncertain and cannot be predicted. In the beginning of April 2020 we learned that certain of our larger sites will not be able to enroll new patients on the fourth dose level of CG-806 due to the current environment caused by COVID-19 and we therefore expect a slowdown in enrollment at these sites . While it is difficult to estimate the duration and impact of COVID-19 on the larger clinical sites and regional cancer care sites, as of the date of this report, we have not experienced and do not foresee material delays to the enrollment of patients or timelines for the CG-806 Phase 1a/b B-cell malignancy trial due to the variety of clinical sites that we have actively recruited for this trial. While as of the date of this report we have not experienced any material delays in initiating our CG-806 Phase 1 clinical study in AML due to COVID 19, we are conducting site initiation visits remotely which could result in delays in site activations and negatively impact this trial. Additionally, COVID 19 could negatively impact patient enrolment if our clinical sites are unable to enroll patients due to either a lack of administrative resources at their sites or decisions made at the clinical sites to limit patient exposure to COVID 19.

Future enrollment of patients on the APTO-253 trial is likely to be negatively impacted as a result of the current environment, as it is administered to patients intravenously, which requires the need for hospital / clinical site resources to assist and monitor patients during each infusion.

Delays in clinical testing could result in delays in commercializing our product candidates and our business may be substantially harmed.

We cannot predict whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Although, as of the date of this report, we do not foresee material delays to the enrollment of patients or timelines for our trials, the extent to which COVID-19 will impact the projected development goals will depend on future developments, which are highly uncertain and cannot be predicted. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before us, which would impair our ability to successfully commercialize our product candidates and may harm our financial condition, results of operations and prospects. The recommencement and completion of clinical trials for our products, including the APTO-253 Phase 1b clinical trial, the Phase 1a/b clinical trial for CG-806 study for the treatment of patients having B-cell malignancies, and the Phase 1a/b study for the development of CG-806 for the treatment of patients with R/R AML may be delayed for a number of reasons, including delays related, but not limited, to:

- failure by regulatory authorities to grant permission to proceed with a clinical trial;
- a regulatory decision to place or placing the clinical trial on hold;
- patients failing to enroll or remain in our trials at the rate we expect;
- suspension or termination of clinical trials by regulators for many reasons, including concerns about patient safety or failure of our contract manufacturers to comply with cGMP requirements;
- any changes to our manufacturing process that may be necessary or desired;
- delays or failure to obtain GMP-grade clinical supply from contract manufacturers of our products necessary to conduct clinical trials;
- product candidates demonstrating a lack of safety or efficacy during clinical trials;
- patients choosing an alternative treatment for the indications for which we are developing any of our product candidates or participating in competing clinical trials;
- patients failing to complete clinical trials due to dissatisfaction with the treatment, side effects or other reasons;
- reports of clinical testing on similar technologies and products raising safety and/or efficacy concerns;
- competing clinical trials and scheduling conflicts with participating clinicians;
- clinical investigators not performing our clinical trials on their anticipated schedule, dropping out of a trial, or employing methods not consistent with the clinical trial protocol, regulatory requirements or other third parties not performing data collection and analysis in a timely or accurate manner;
- failure of our contract research organizations, or CROs, to satisfy their contractual duties or meet expected deadlines;
- inspections of clinical trial sites by regulatory authorities, or IRBs, or ethics committees or boards finding regulatory violations that require us to undertake corrective action, resulting in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study;
- one or more IRBs or ethics committees or boards rejecting, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or
- failure to reach agreement on acceptable terms with prospective clinical trial sites.

Our product development costs will increase if we experience delays in testing or approval or if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur, and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to regulatory authorities or IRBs or ethics committees or boards for re-examination, which may impact the cost, timing or successful completion of a trial. Delays or increased product development costs may have a material adverse effect on our business, financial condition and prospects.

We rely on contract manufacturers over whom we have limited control. If we are subject to quality, cost or delivery issues with the preclinical and clinical grade materials supplied by contract manufacturers, our business operations could suffer significant harm.

We rely on contract manufacturing organizations ("CMOs") to manufacture our product candidates for some preclinical studies and clinical trials. We rely on CMOs for manufacturing, filling, packaging, storing and shipping of drug product in compliance with cGMP regulations applicable to our products. The FDA and other regulatory agencies ensure the quality of drug products by carefully monitoring drug manufacturers' compliance with cGMP regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities and controls used in manufacturing, processing and packing of a drug product.

We contracted with multiple CMOs for the manufacture of APTO-253 and CG-806 to supply the active ingredient and then drug product for our clinical trials. The synthesis of CG-806 is challenging from a scale-up synthetic chemistry perspective. The formulation and manufacture of APTO-253 is a complex process with many variables involved. We pre-qualified CMOs to have the capacity, the systems and the experience to supply CG-806 and APTO-253 for our clinical trials. We have qualified the manufacturing facilities and the FDA has also performed site audits for our selected CMOs. In spite of the efforts to prequalify CMOs, delays and errors may occur, and any such manufacturing failures, delays or compliance issues could cause delays in the completion of our clinical trial programs.

There can be no assurances that CMOs will be able to meet our timetable and requirements. We have contracted with alternate suppliers in the event our current CMOs are unable to scale up production, or if our current CMOs otherwise experience any other significant problems in the manufacture of CG-806 and APTO-253. However, it is possible that all third-party manufacturing sources may experience failure or delays and may demand commercially unreasonable terms, which may lead to further delays in the development of our product candidates. Further, contract manufacturers must operate in compliance with cGMP and failure to do so could result in, among other things, the disruption of product supplies. Our dependence upon third parties for the manufacture of our products may adversely affect our profit margins and our ability to develop and deliver products on a timely and competitive basis.

Although, as of the date of this report, we have not experienced any material delays in the manufacturing of CG-806 and APTO-253 due to COVID-19, the extent to which it will impact the manufacturing of our products will depend on future developments, which are highly uncertain and cannot be predicted. Should our suppliers involved in the manufacture of CG-806 be required to shut down their facilities due to COVID-19 either due to lack of materials or personnel, our trials would be negatively impacted. We are mitigating this risk by continuing to manufacture drug supply, but there is no guarantee that we will have enough drug to supply the trial if any of our manufacturers have a sustained shut down in their operations. COVID-19 may also affect the timing and delivery of labeled and packaged drug product for APTO-253 since it is an intravenous formulation which, compared to orally administered therapies, involves a more complex process. Factors related to COVID-19 caused a delay in the labeling and packaging of the APTO-253 drug product; however, going forward we do not anticipate this to materially affect the patient accrual for the ongoing Phase 1b trial.

Some components of our products are manufactured by third parties outside of the United States, and our business may be harmed by legal, regulatory, economic, political and public health risks associated with international trade and those markets.

We have third-party manufacturing partners in Germany and the United Kingdom; in addition, some materials used by our third-party manufacturers are supplied by companies located in other countries, including but not limited to India and China. Our reliance on suppliers and manufacturers in foreign markets creates risks inherent in doing business in foreign jurisdictions, including: (a) the burdens of complying with a variety of foreign laws and regulations, including laws relating to the importation and taxation of goods; (b) public health crises, such as pandemics and epidemics, in the countries where our suppliers and manufacturers are located; (c) transportation interruptions or increases in transportation costs; and (d) foreign intellectual property infringement risks. For example, the ongoing COVID-19 outbreak emanating at the beginning of 2020 from China, but now affecting most nations, has resulted in extended shutdown of certain businesses and markets in many regions causing reduced availability for certain pharmaceutical ingredients. This public health crisis or any further political developments or health concerns in markets in which our products are manufactured or from which we obtain necessary pharmaceutical ingredients could adversely affect the supply of our drug products and, in turn, our business, financial condition, and results of operations.

If we have difficulty enrolling patients in clinical trials, the completion of the trials may be delayed or cancelled.

As our product candidates advance from preclinical testing to clinical testing, and then through progressively larger and more complex clinical trials, we will need to enroll an increasing number of patients that meet our eligibility criteria. There is significant competition for recruiting cancer patients in clinical trials, and we may be unable to enroll the patients we need to complete clinical trials for cancer indications on a timely basis or at all. Certain factors that affect enrollment of patients in our clinical trials are impacted by external forces that may be beyond our control. Such factors include, but are not limited to, the following:

- size and nature of the patient population;
- eligibility and exclusion criteria for the trial;
- design of the study protocol;
- competition with other companies for clinical sites or patients;
- the perceived risks and benefits of the product candidate under study;
- the patient referral practices of physicians; and
- the number, availability, location and accessibility of clinical trial sites.

Although, as of the date of this report, we do not foresee material delays to the enrollment of patients or timelines for our trials due to COVID-19, the extent to which COVID-19 will impact the projected development goals will depend on future developments, which are highly uncertain and cannot be predicted.

As a result of intense competition and technological change in the biotechnical and pharmaceutical industries, the marketplace may not accept our products or product candidates, and we may not be able to compete successfully against other companies in our industry and achieve profitability.

Many of our competitors have:

- drug products that have already been approved or are in development;
- large, well-funded research and development programs in the biotechnical and pharmaceutical fields;
- substantially greater financial, technical and management resources, stronger intellectual property positions and greater manufacturing, marketing and sales capabilities, areas in which we have limited or no experience; and
- significantly greater experience than we do in undertaking preclinical testing and clinical trials of new or improved pharmaceutical products and obtaining required regulatory approvals.

Consequently, our competitors may obtain FDA, Health Canada and other regulatory approvals for product candidates sooner and may be more successful in manufacturing and marketing their products than we or our collaborators are.

Our competitors' existing and future products, therapies and technological approaches will compete directly with the products we seek to develop. Current and prospective competing products may be more effective than our existing and future products insofar as they may provide greater therapeutic benefits for a specific problem or may offer easier delivery or comparable performance at a lower cost.

For CG-806 and APTO-253 in AML, examples of potential competitors include companies that have developed approved or are currently developing inhibitors that directly target the wild type include AbbVie (IMBRUVICA) and AstraZeneca (CALQUENCE) and Beigene Co., Ltd. (Zanubrutinib).

Others that are developing inhibitors that target the C481S-mutant BTK include Arqule, Inc. (ARQ 531), Roche, Sunesis Pharmaceuticals (SNS-062) and Eli Lilly among others.

For CG-806 and APTO-253 in AML, examples of potential competitors include companies that have developed approved or are currently developing non-targeted therapies include Jazz (VYXEOS), Pfizer (MYLOTARG) and Roche (VENCLEXTA), among others. Others that have developed or are developing highly targeted therapies such as FLT3 include Novartis (RYDAPT), Astellas (XOSAPTA), Daiichi Sankyo (QUIZARTINIB), Arog (CRENOLANIB), and IDH1 include Agios (TIBSOVO) and Celgene/BMS (IDHIFA) among others.

Any product candidate that we develop and that obtains regulatory approval must then compete for market acceptance and market share. Our products may not gain market acceptance among physicians, patients, healthcare payers, insurers, the medical community and other stakeholders. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- sufficient third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

Further, any products we develop may become obsolete or face generic entry before we recover any expenses we incurred in connection with the development of these products. As a result, we may never achieve profitability.