RAFAEL HOLDINGS, INC.

RAFAEL
Holdings, Inc.

2021 ANNUAL REPORT

RAFAEL
Holdings, Inc.

Dear Fellow Stockholders:

During the past year, Rafael Holdings, Inc. made progress in building out our team and capabilities, strengthening our balance sheet, and progressing with our early-stage development pipeline in collaboration with world class scientific advisors. While the results of Rafael Pharmaceuticals' two Phase 3 clinical trials for CPI-613® (devimistat) in metastatic pancreatic cancer and relapsed or refractory acute myeloid leukemia were disappointing, we continue to work with Rafael Pharmaceuticals to evaluate clinical activities. We remain focused on developing cancer and immune metabolism therapeutics with the potential to improve the lives of cancer patients.

Cancer treatment has shown significant advancements in recent years, but unfortunately, many patients do not respond to current treatment options. A few years ago, we launched the Barer Institute to focus on creating a pipeline of therapeutic compounds to regulate cancer and immune metabolism. Our research platform seeks to unlock the benefits of cancer therapy by both sensitizing cancer cells through targeting tumor metabolism and stimulating the immune system. We have partnered with key thought leaders to identify novel targets and mechanisms for killing tumor cells and restoring T-cell function. We are expanding our scientific team to rapidly advance these targets through discovery and develop transformational medicines that will benefit patients.

As our programs are now in earlier stages of development, Ameet Mallik will transition the role of Chief Executive Officer back to me as of February 1, 2022, while I remain the Chairman of the Board. I am pleased that Ameet will remain an active member of our Board of Directors, and as part of his board duties, he will chair the Transition Committee to oversee the management transition and the company's evolution. I would like to thank Ameet for his substantial contributions and I look forward to working closely with Patrick Fabbio, President and Chief Financial Officer, and Dr. Mimi Huizinga, Chief Medical Officer and Head of Research and Development, to lead the company forward.

We look forward to updating you on our progress throughout the year.

Sincerely,

Howard Jonas
Chairman of the Board

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

FORM 10-K

☒ Annual report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934
for the fiscal year ended July 31, 2021.

or

☐ Transition report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934.

Commission File Number: 000-55863

RAFAEL HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**82-2296593**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

520 Broad Street, Newark, New Jersey 07102
(Address of principal executive offices, zip code)

(212) 658-1450
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Class B common stock, par value $0.01 per share	RFL	New York Stock Exchange

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, smaller reporting company, or an emerging growth company. See 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. ☐

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, based on the closing price on January 29, 2021 (the last business day of the registrant's most recently completed second fiscal quarter) of the Class B common stock of $23.48 per share, as reported on the New York Stock Exchange, was approximately $330.2 million.

The number of shares outstanding of the registrant's common stock as of October 11, 2021 was:

Class A common stock, par value $0.01 per share:	787,163 shares
Class B common stock, par value $0.01 per share:	19,873,219 shares

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant's Annual Meeting of Stockholders, to be held January 19, 2022, is incorporated by reference into Part III of this Form 10-K to the extent described therein.

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RAFAEL HOLDINGS, INC.

Annual Report on Form 10-K

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including statements that contain the words "believes," "anticipates," "expects," "plans," "intends" and similar words and phrases. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from the results projected in any forward-looking statement. In addition to the factors specifically noted in the forward-looking statements, other important factors, risks and uncertainties that could result in those differences include, but are not limited to, those discussed under Item 1A to Part I "Risk Factors" in this Annual Report. The forward-looking statements are made as of the date of this Annual Report, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements. Investors should consult all of the information set forth in this report and the other information set forth from time to time in our reports filed with the Securities and Exchange Commission pursuant to the Securities Act of 1933 and the Securities Exchange Act of 1934, including our reports on Forms 10-Q and 8-K.

Our business, operating results or financial condition could be materially adversely affected by any of the following risks associated with any one of our businesses, as well as the other risks highlighted elsewhere in this document. The trading price of our common stock could decline due to any of these risks. Note that references to "our", "us", "we", "the Company", etc. used in each risk factor below refers to the business about which such risk factor is provided.

Our business is subject to numerous risks as described in this section. Some of these risks include:

- *We depend heavily on the future success of Rafael Pharmaceuticals' lead product candidate (CPI-613® (devimistat)). Clinical trials of the product candidate may not be successful. If Rafael Pharmaceuticals is unable to gain regulatory approval or commercialize its product candidates or experience significant delays in doing so, our business will be materially harmed.*

- *We are dependent upon third parties for a variety of functions. These arrangements may not provide us with the benefits we expect.*

- *The Pharmaceutical Companies may expend their limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.*

- *Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.*

- *The Pharmaceutical Companies face substantial competition, and if their competitors develop and market technologies or products more rapidly than the Pharmaceutical Companies do or that are more effective, safer or less expensive than the product candidates the Pharmaceutical Companies develop, our commercial opportunities will be negatively impacted.*

- *We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our and the Pharmaceutical Companies' businesses effectively.*

- *Economic, regulatory, and socio-economic changes that impact the real estate market generally, or that could affect patterns of use of commercial office space, may cause our operating results to suffer and decrease the value of our real estate properties.*

- *Eight trusts for the benefit of sons and daughters of Howard S. Jonas, our former Chief Executive Officer and Chairman of the Board of Directors, hold shares that, in the aggregate, represent more than a majority of the combined voting power of our outstanding capital stock, which may limit the ability of other stockholders to affect our management.*

- *If we are unable to adequately protect our proprietary technology and product candidates, if the scope of the patent protection obtained is not sufficiently broad, or if the terms of our patents are insufficient to protect our product candidates for an adequate amount of time, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our product candidates may be materially impaired.*

- *We hold a Warrant to purchase a significant stake in Rafael Pharmaceuticals, as well as other equity and governance rights in Rafael Pharmaceuticals, which we can't exercise, in full, at this time and may never be able to exercise.*
- *The relationships between Howard S. Jonas and IDT Corporation, Genie Energy and Rafael Pharmaceuticals, Inc. could conflict with our stockholders' interests.*
- *Public health threats could have an adverse effect on the Company's operations and financial results.*

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Part I

As used in this Annual Report, unless the context otherwise requires, the terms the "Company," "Rafael Holdings," "we," "us," and "our" refer to Rafael Holdings, Inc., a Delaware corporation, and its subsidiaries, collectively. Each reference to a fiscal year in this Annual Report refers to the fiscal year ending in the calendar year indicated (for example, fiscal 2021 refers to the fiscal year ended July 31, 2021).

Item 1. Business.

OVERVIEW

Rafael Holdings, Inc. (NYSE:RFL), ("Rafael Holdings", "we" or the "Company"), a Delaware corporation, holds interests in clinical and early stage pharmaceutical companies, including an investment in Rafael Pharmaceuticals, Inc., or Rafael Pharmaceuticals, a late-stage cancer metabolism-based therapeutics company, its preclinical cancer metabolism research institute, the Barer Institute ("Barer"), and commercial real estate assets. The Company focuses its efforts on funding, discovering and developing novel cancer therapies through its continued investment in Rafael Pharmaceuticals, the creation of the Barer Institute in 2019 and continued investments in advancing its preclinical portfolio as well as investments in other early-stage oncology companies with a goal of building a focused cancer metabolism therapeutics company with the potential to improve and extend the lives of patients. On June 17, 2021, the Company entered into a merger agreement to acquire full ownership of Rafael Pharmaceuticals in exchange for issuing Company Class B common stock to the other stockholders of Rafael Pharmaceuticals. We expect to bring the merger to a vote of our stockholders this calendar year.

The Company's investment in Rafael Pharmaceuticals includes preferred and common equity interests and a warrant to purchase additional equity. In 2019, the Company established Barer, as an early-stage small molecule research institute focused on developing a pipeline of novel therapeutic compounds, including compounds to regulate cancer metabolism with potentially broader application in other indications beyond cancer. Barer is led by a team of scientists and academic advisors considered to be among the leading experts in cancer metabolism, chemistry, and drug development. In addition to its own internal discovery efforts, Barer is pursuing collaborative research agreements and in-licensing opportunities with leading scientists from top academic institutions. Farber Partners, LLC ("Farber"), was formed around one such agreement with Princeton University's Office of Technology Licensing for technology from the laboratory of Professor Joshua Rabinowitz, in the Department of Chemistry, Princeton University, for an exclusive worldwide license to its SHMT (serine hydroxymethyltransferase) inhibitor program. The Company also holds a majority equity interest in LipoMedix Pharmaceuticals Ltd. ("LipoMedix"), a clinical stage oncological pharmaceutical company based in Israel. In addition, the Company has recently initiated efforts to develop other early stage pharmaceutical ventures including Levco Pharmaceuticals Ltd. ("Levco"), an Israeli company, established to partner with Dr. Alberto Gabizon and a leading institution in Israel on the development of novel compounds for cancer.

The Company's commercial real estate holdings consist of a building at 520 Broad Street in Newark, New Jersey that serves as headquarters for the Company and certain other affiliate entities and tenants and an associated 800-car public garage, and a portion of a building in Israel. The Company sold other real estate holdings in 2020.

Financial information by segment is presented in Note 15 in the Notes to our Consolidated Financial Statements in Item 8 of this Annual Report.

Our headquarters are located at 520 Broad Street, Newark, New Jersey 07102. The main telephone number at our headquarters is (212) 658-1450 and our corporate web site's home page is *www.rafaelholdings.com*.

We make available free of charge our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to these reports, and all beneficial ownership reports on Forms 3, 4 and 5 filed by directors, officers and beneficial owners of more than 10% of our equity through the investor relations page of our web site (*https://rafaeholdings.com/irpass.com*) as soon as reasonably practicable after such material is electronically filed with the Securities and Exchange Commission. Our web site also contains information not incorporated into this Annual Report on Form 10-K or our other filings with the Securities and Exchange Commission.

RECENT DEVELOPMENTS

On September 24, 2021, we entered into a Line of Credit Loan Agreement ("Line of Credit Agreement") with Rafael Pharmaceuticals, which provided for loan commitments in the amount of $25 million. The funds loaned under the Line of Credit Agreement are to be used by Rafael Pharmaceuticals in accordance with the budget that has been approved by us. Of the aggregate amount, $1.9 million was advanced on September 24, 2021 and the remaining amount was funded on October 1, 2021.

In August 2021, the Company consummated a private offering with gross proceeds of approximately $105 million. The Company sold (i) an aggregate of 2,833,425 shares of its Class B common stock, par value $0.01 per share (the "Class B Common Stock"), to institutional investors, at a purchase price of $35.00 per share and (ii) an aggregate of 112,561 shares of Class B Common Stock to an affiliate of Howard S. Jonas, our chairman of the board, at a purchase price of $44.42 per share.

In June 2021, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with RH Merger I, Inc., a Delaware corporation and a wholly-owned subsidiary of Holdings, RH Merger II, LLC, a Delaware limited liability company and a wholly-owned subsidiary of Holdings and Rafael Pharmaceuticals, Inc., a Delaware corporation ("Pharma"), whereby Pharma will become our wholly-owned limited liability subsidiary.

In October 2020, Rafael Pharmaceuticals announced two milestones in its clinical trial programs for CPI-613® (devimistat) including completing target enrollment of 500 patients in its pivotal phase 3 clinical trial in metastatic pancreatic cancer ahead of schedule in August 2020 and in October 2020 crossing enrollment of its hundredth patient in its pivotal phase 3 study for relapsed or refractory Acute Myeloid Leukemia study.

On August 28, 2020, we sold a 3-story, 65,253 square foot office building located at 225 Old New Brunswick Road in Piscataway, New Jersey for $3,875,000.

BUSINESS DESCRIPTION

We own and operate assets in two separate lines of business: pharmaceuticals and commercial real estate.

Pharmaceuticals

Overview

We have an investment in Rafael Pharmaceuticals, a late-stage cancer metabolism-based therapeutics company. In 2019, the Company established Barer as a wholly-owned early-stage small molecule research institute focused on developing a pipeline of novel therapeutic compounds, including compounds to regulate cancer metabolism with potentially broader application in other indications beyond cancer. The venture is comprised of scientists and academic advisors considered to be among the leading experts in cancer metabolism, chemistry, and drug development. In addition to its own internal discovery efforts, the Barer is pursuing collaborative research agreements and in-licensing opportunities with leading scientists from top academic institutions. Farber was formed around one such agreement with Princeton University's Office of Technology Licensing for technology from the laboratory of Professor Joshua Rabinowitz, in the Department of Chemistry, Princeton University, for an exclusive worldwide license to its SHMT (serine hydroxymethyltransferase) inhibitor program. The Company also holds a majority equity interest in LipoMedix, a clinical stage oncological pharmaceutical company based in Israel. In addition, the Company has recently initiated efforts to develop other early-stage pharmaceutical ventures including Levco, an Israeli company, established to partner with Dr. Alberto Gabizon and a top institution in Israel on the development of novel compounds for cancer. In 2021, the Company established Rafael Medical Devices, LLC ("Rafael Medical Devices"), a wholly-owned orthopedic device company developing instruments and implants to advance minimally invasive surgeries in the upper and lower extremities.

Rafael Pharmaceuticals

We own our interest in Rafael Pharmaceuticals through a 90%-owned non-operating subsidiary, Pharma Holdings, LLC ("Pharma Holdings"). Pharma Holdings owns 50% of CS Pharma Holdings, LLC ("CS Pharma"), a non-operating entity that owns equity interests in Rafael Pharmaceuticals, and 44.0 million shares of Rafael Pharmaceuticals Series D Convertible Preferred Stock, 979,617 common shares and a warrant to increase ownership to up to 56% of the fully

diluted equity interests in Rafael Pharmaceuticals (the "Warrant"). The Warrant is exercisable at the lower of 70% of the price sold in an equity financing, or $1.25 per share, subject to certain adjustments, and will expire upon the earlier of (i) upon the occurrence of the effective time of the Merger (the "Effective Time"), or (ii) if the Effective Time does not occur, the date that is calculated by adding (A) the number of calendar days the Merger Agreement has been in effect prior to its termination in accordance with its terms, to (B) August 15, 2021. Accordingly, the Company holds an effective 90% interest in the Rafael Pharmaceuticals interests held by Pharma Holdings directly, and an effective 45% indirect interest in the assets held by CS Pharma.

Science and Preclinical:

CPI-613® (devimistat) is a stable analog of normally transient, acylated catalytic intermediates of lipoate. The CPI-613 intermediates disrupt mitochondrial function and thereby decrease the TCA cycle function; thus, CPI-613® (devimistat) misinforms these tumor systems, triggering mitochondrial stress and turning off the cancer cell TCA cycle. CPI-613 broadly affects tumor metabolism, including disrupting mitochondria and potentially intercalating in cancer cell membranes. The metabolic and mitochondrial stress trigger apoptotic and necrotic cell death pathways in tumor cells (Zachar et al., J Mol Med, 2011, 89:1137-48; Stuart et al., Cancer Metab. 2014, 2, 4: reviewed in Bingham et al., Expert Rev Clin Pharmacol. 2014, 7:837-46 and Hammoudi et al., Chin J Cancer. 2011, ;30:508-25). Thereby CPI-613® is believed to have anti-cancer activity. Combining CPI-613® with generalized metabolic stressors like chemotherapy can result in effective killing of even the most intractable tumors like pancreatic cancer. These effects are observed in Rafael's Pharmaceuticals' Phase 1/2 trials to date (Alistar, et al., 2017; Pardee et al., 2018). CPI-613 has been found to be selectively accumulated in tumors in animal studies. CPI-613 is a lipoic acid analog with a fatty acid tail that may be able to utilize fatty acid transporters. Cancer cells have been shown to up-regulate fatty acid metabolism to support tumorigenesis. Rafael Pharmaceuticals continues to study devimistat and its mechanism of action.

There are potential advantages of CPI-613® (devimistat) over alternative anti-metabolism and anti-cancer drugs. It is believed to be selectively taken up by cancer cells. Therefore, CPI-613® (devimistat) is expected to be minimally toxic to healthy cells (i.e., safe, and well tolerated), potentially allowing extended treatment courses. Moreover, its toxicity profile allows CPI-613® (devimistat) to be used in combination with other drugs and in older patients. These combination regimens include established standards of care for major malignancies, allowing potential treatment of surgically unresectable cancers. Additionally, this toxicity profile supports the administration of cocktails of anti-cancer drugs that may work synergistically with CPI-613®. Thus, CPI-613® (devimistat) is being investigated for broad spectrum activity, and the potential to treat diverse tumor types, including difficult-to-treat cancers, high risk cancers, solid tumors as well as hematologic malignancies and advanced stage cancers by targeting cancer metabolism.

Several pre-clinical pharmacology and toxicology studies (including good laboratory practice toxicology (GLP Tox) studies) were conducted to investigate the pharmacokinetics (PK), drug metabolism, safety, and anticancer activity of CPI-613® (devimistat). In vitro and ex vivo studies, CPI-613® (devimistat) exhibited anticancer activities against a tumor cell lines and cells. CPI-613® (devimistat) was taken up less in non-malignant cells. In vivo animal models bearing diverse tumor types were used to evaluate dose response, PK, and metabolism of CPI-613® (devimistat). The drug was well tolerated in animal models studied. Prolonged survival was observed when compared to untreated controls. GLP toxicology studies showed that any adverse events related to CPI-613® (devimistat) were considered transient and mostly observed during acute dosing; animals returned to normal post-dose (i.e., toxicities were reversable or recoverable). Toxicokinetic (TK) exposures of C_{max} (peak concentration) and area under curve (AUC) of CPI-613® (devimistat) from GLP Tox studies in rats and minipigs have shown safety margins expected to cover PK exposures of C_{max} and AUC of CPI-613® (devimistat) in AML and pancreatic cancer patients at doses studied.

Clinical Highlights:

More than 750 patients have been dosed with CPI-613® (devimistat) to date in 21 ongoing or completed clinical trials.

Currently seven clinical trials are ongoing, one of which has completed enrolling patients while the remaining six trials are continuing to enroll patients as of the date of this report.

Pancreatic Cancer: CPI-613® (devimistat) in Combination with Modified FOLFIRINOX in First-Line Metastatic Pancreatic Cancer.

Twenty patients were enrolled in a Phase 1 study. The MTD of CPI-613® (devimistat) was 500 mg/m². The median number of treatment cycles given at the maximum tolerated dose was 11. Two patients were enrolled at a higher dose of 1,000 mg/m², and both had a dose-limiting toxicity. No deaths due to adverse events were reported. For the 18 patients given the maximum tolerated dose, the most common grade 3–4 non-hematological adverse events were hyperglycaemia, hypokalaemia, peripheral sensory neuropathy, diarrhea, and abdominal pain. The most common grade 3–4 hematological adverse events were neutropenia, lymphopenia, anaemia, and thrombocytopenia. Sensory neuropathy (all grade 1–3) was recorded in 17 out of the 18 patients and was managed with dose de-escalation or discontinuation of oxaliplatin per standard of care. Of the 18 patients given the maximum tolerated dose, 11 (61%) patients achieved an objective response (complete or partial). Patients exhibited a median overall survival (OS) of 19.9 months and median progression-free survival (PFS) of 9.9 months. The interim result of this study was published in Lancet Oncology (Alistar et al., Lancet Oncol. 2017 Jun;18(6):770-778.). In a Phase 3 clinical trial evaluating the FOLFIRINOX regimen in metastatic pancreatic cancer patients, an objective response rate (ORR) of 31.6%, median OS of 11.1 months and median PFS of 6.4 months (Conroy et al., N Engl J Med 2011;364:1817-25.) was reported.

Based on the clinical experience of this trial in pancreatic cancer, Rafael Pharmaceuticals initiated a Phase 3 pivotal trial (AVENGER 500®) of CPI-613® (devimistat) in combination with modified FOLFIRINOX as first-line treatment for patients with metastatic pancreatic cancer in December 2018. This trial compares the efficacy and safety of FOLFIRINOX (FFX, control arm) with CPI-613® (devimistat) in combination with modified FOLFIRINOX (CPI-613® + mFFX, test arm). Patients 18-75 years old of both sexes with metastatic (stage IV) pancreatic adenocarcinoma, not previously treated for metastatic disease and with ECOG performance status of 0–1 are eligible for enrollment in this study. This trial completed enrollment of 528 patients ahead of schedule in August 2020. Top line results are expected to be available this calendar year.

Acute Myeloid Leukemia (AML): CPI-613® (devimistat) in Combination with High Dose Cytarabine and Mitoxantrone in Patients with Relapsed or Refractory Acute Myeloid Leukemia (AML).

Two trials were conducted to investigate the safety and efficacy of CPI-613® (devimistat) in combination with high dose cytarabine and mitoxantrone in patients with relapsed or refractory AML. The result of the Phase 1 study was published in Clinical Cancer Research (Pardee et al., Clin Cancer Res. 2018 May 1;24(9):2060-2073). Overall, the treatment was well tolerated. Pooled dataset of both Phase 1 and Phase 2 trials in elderly patients (≥ 50 years) with relapsed or refractory AML demonstrated 52% CR + CRi and median OS of 10.4 months. In contrast, a clinical trial evaluating high dose cytarabine, mitoxantrone and L-asparaginase in relapsed or refractory AML in elderly patients (≥ 60 years) demonstrated 33% CR + CRi and median OS of only 5.2 months (Ahmed et al., Leuk Res. 2015 September; 39(9): 945–949.).

Based on the clinical experience in these trials in AML, Rafael Pharmaceuticals initiated a Phase 3 pivotal trial (ARMADA 2000) of CPI-613® (devimistat) in patients with relapsed or refractory AML in November 2018. This study is designed to compare the efficacy and safety of CPI-613® (devimistat) in combination with high dose cytarabine and mitoxantrone (CHAM) with high dose cytarabine and mitoxantrone (HAM, control arm). The study was later amended to allow additional control arm standard of care treatments, including: combination of mitoxantrone, etoposide and cytarabine (MEC) and combination of fludarabine, cytarabine, and filgrastim (FLAG). Patients ≥ 50 years with relapsed or refractory AML and an ECOG performance status of 0 to 2 are eligible for this study. In July 2021, Rafael Pharmaceuticals reported a positive outcome from its preplanned interim futility analysis in this trial. Based on 142 intent-to-treat (ITT) patient data, the independent data monitoring committee (IDMC) declared that the trial is non-futile and recommended that the trial continue as is. A planned interim futility analysis is expected this calendar year.

Other Ongoing Clinical Trials:

- *A Phase 2 study of CPI-613® (devimistat) in combination with modified FOLFIRINOX in patients with locally advanced pancreatic cancer*
- *A Phase 1 study of CPI-613® (devimistat) in Combination with Gemcitabine and Nab-paclitaxel in First Line Locally Advanced or Metastatic Pancreatic Cancer*

- *A Phase 2 study of CPI-613® (devimistat) in patients with relapsed or refractory Burkitt lymphoma/leukemia or high-grade B-cell lymphoma with rearrangements of MYC and BCL2 and/or BCL6*
- *A multi-center randomized Phase 1b/2 study of gemcitabine and cisplatin with or without CPI-613® (devimistat) as first line therapy for patients with advanced unresectable biliary tract cancer*
- *A Phase 1/2 study of CPI-613® (devimistat) in combination with hydroxychloroquine in patients with relapsed or refractory clear cell sarcoma of soft tissue*

Planned Clinical Trials:

- *A Phase 1 study of CPI-613® (devimistat) in combination with FOLFOXIRI plus bevacizumab in patients with metastatic colorectal cancer*
- *A Phase 2 randomized, multicenter trial of CPI-613® (devimistat) in combination with bendamustine, compared to bendamustine monotherapy in patients with relapsed or refractory peripheral t-cell lymphoma (PTCL)*
- *A Phase 1/2 study of CPI-613® (devimistat) in combination with hydroxychloroquine in patients with relapsed or refractory myelodysplastic syndrome (MDS)*

Barer

The Barer Institute is an early-stage small molecule research institute formed in 2019 to focus on developing a pipeline of novel therapeutic compounds, including compounds to regulate cancer metabolism and potentially other indications appropriate for the assets under development.

Barer has assembled a world renowned scientific and medical advisory team that is helping it discover and develop novel therapeutics designed to target metabolic pathways while inhibiting pro-cancer immune guardians such as MDSC, Tregs and M2 macrophages that protect the tumor and stimulate or preserve CD8, CTL, NK and M1 macrophages to harness the anti-cancer immune system to kill the tumor. Barer's pipeline programs focus on areas of cancer metabolism that have shown high clinical activity and are based on Barer's leadership position in understanding cancer and immune metabolism. Barer has multiple early stage programs targeting nucleotide and folate metabolism.

Nucleotide and folate metabolism are proven anticancer targets, underlying medicines including 5FU, methotrexate, and pemetrexed. Barer is using deep knowledge of metabolism and rigorous science to develop next generation nucleotide inhibitors by pursuing yet unanswered provocative questions. Barer is also targeting alternative nutrient acquisition strategies the cancer cells use under stress, like autophagy. In short, Barer is pursuing targets where clinical data shows novel metabolic intervention opportunities.

Barer focuses on nucleotide metabolism with a richer understanding of how to energize anti-tumor immunity and diminish cancer cell viability. Barer's SHMT Inhibitor program is based on hitting one of the most altered metabolic enzymes in human cancer. Preclinical data shows single agent activity in T acute leukemia and synergy with methotrexate. Barer is working towards an IND filing in late 2022/early 2023. Barer also has a complementary folate metabolic engineering program to drive anti-tumor immunity. A focus on untapped nucleotide salvage pathways provides additional proprietary pipeline cancer targets, which are distinctive to the Company.

Dual-SHMT inhibitor

- Targeting T-ALL, and other tumor types
- Orally available lead, Phase 1 planned for late 2022/early 2023

One Carbon Immune Enhancer (OCIE)

- Animal testing
- Combine with PD-1

TK1 inhibitor

- Lead generation stage programs addressing novel targets

In addition to its own internal discovery efforts, Barer is pursuing collaborative research agreements and in-licensing opportunities with leading scientists from top academic institutions. Farber Partners, LLC ("Farber"), was formed around one such agreement with Princeton University's Office of Technology Licensing for technology from the laboratory of Professor Joshua Rabinowitz, in the Department of Chemistry, Princeton University, for an exclusive worldwide license to its SHMT (serine hydroxymethyltransferase) inhibitor program.

LipoMedix

LipoMedix is a clinical stage Israeli company focused on the development of an innovative, safe, and effective cancer therapy based on liposome delivery. As of July 31, 2021, the Company's ownership interest in LipoMedix was 68%.

Science and Preclinical:

LipoMedix was established to advance the pharmaceutical and clinical development of a patented prodrug of mitomycin-C and its efficient delivery in liposomes to cancer-affected target organs. This formulation, known as Promitil® — Pegylated Liposomal Mitomycin-C Lipidic Prodrug (PL-MLP) — overcomes the toxicity associated with the clinical use of mitomycin-C and turns it into a targeted, anticancer prodrug that could potentially become the therapy of choice in a variety of cancers. The inventor and scientific founder, of LipoMedix is Alberto Gabizon, M.D., Ph.D., of the Hebrew University — Shaare Zedek Medical Center, Israel. He is the co-inventor and co-developer of Doxil® (pegylated liposomal doxorubicin), a successful and widely-used anticancer product based on a similar drug development strategy. Prof. Gabizon is one of the few scientists intimately familiar with the successful development and commercialization process of liposomal drugs.

Promitil® is an innovative nanomedicine designed for controlled delivery of a chemotherapeutic agent in a proprietary prodrug form. LipoMedix believes it may have advantages in single or combination therapy over conventional anticancer agents that have serious adverse side effects, and limited efficacy with resistance to treatment. Promitil® is based on this breakthrough technology and could potentially help cancer patients receive safer therapy with a more potent antitumor effect.

In preclinical trials, Promitil® inhibited a range of cancer types in animal models (pancreatic, colorectal, stomach, breast, ovarian, melanoma, bladder), including multidrug (MDR-1)-resistant tumors, and potentiated the activity of radiotherapy and various co-administered cancer drugs. The API (MLP), a prodrug of mitomycin C, is carried by a pegylated liposomal delivery system that confers an extended circulation time in vivo and enhanced delivery to tumors. The API is stable in plasma but activated to mitomycin-C by reductive cleavage in some tissues and in tumors where abundant reductive systems are present. In preclinical trials, Promitil® was more efficacious and less toxic than mitomycin-C by a 3-fold factor. Preclinical indications of the efficacy of Promitil® in combination with radiation was observed in *in vivo* mouse models of colon cancer. Promitil® improved antitumor efficacy of radiotherapy in mouse models of colorectal cancer, while equitoxic doses of mitomycin C did not. Promitil® is a l radio-sensitizer that, in combination with radiotherapy, may result in improvements in the treatment of locally advanced cancers. Use of a liposomal delivery system in a chemo-radiotherapy combination is a novel approach, not yet explored in cancer treatment.

Clinical:

LipoMedix has completed 3 clinical studies of Promitil® including:

1. Phase 1A, a dose escalation study of Promitil in patients with advanced cancers. (Golan et al., "Pegylated liposomal mitomycin C prodrug enhances tolerance of mitomycin C: a Phase 1 study in advanced solid tumor patients." *Cancer Medicine*, 4:1472–1483, 2015).

2. Phase IB in advanced colorectal cancer patients with Promitil as single agent and in combination with capecitabine and/or bevacizumab. (Gabizon et al, "Pharmacokinetics of mitomycin-c lipidic prodrug entrapped in liposomes and clinical correlations in metastatic colorectal cancer patients" *Investigational New Drugs*, 38(5):1411-1420, 2020).

3. Phase 1B of Promitil-based chemo-radiotherapy in patients with advanced cancers. These study results are not yet published.

A total of 149 patients have been treated with Promitil® as a single agent or in combination with other anticancer drugs or radiotherapy under the framework of Phase 1A, Phase IB clinical studies and named-patient approval for compassionate use. Promitil® is given by intravenous infusion once every 3 or 4 weeks and is well-tolerated. Except for mild myelosuppression, Promitil® does not appear to cause other toxicities such as skin irritation, mouth ulcers, neuropathic pain, diarrhea, or hair loss. It is a robust product with a shelf life under refrigerated storage of several years (Gabizon et al., "Development of Promitil®, a lipidic prodrug of mitomycin c in pegylated liposomes: From bench to bedside." *Advanced Drug Delivery Reviews*, 154-155:13-26, 2020).

Promitil®-based pipeline products:

In addition to Promitil®, LipoMedix has developed other Promitil®-based products with potentially important applications:

- Folate-targeted Promitil® (Promi-Fol), aimed at local treatment (intravesical) of superficial bladder cancer. Decorating Promitil® with folate ligands exploits the frequent overexpression of folate receptors in urothelial cancers for selective and enhanced delivery of Promitil® to cancer cells. Promi-Fol could be a safe and effective therapeutic alternative to widely used instillation of mitomycin-c for local treatment of the growing elderly patient population with superficial bladder cancer (Patil Y, et al.: "Targeting of pegylated liposomal mitomycin-C prodrug to the folate receptor of cancer cells: Intracellular activation and enhanced cytotoxicity." *Journal of Controlled Release*, 225:87-95, 2016).
- Promi-Dox, a highly potent dual drug liposome with MLP and doxorubicin for a basket of tumors (Gabizon et al., "Liposome co-encapsulation of anti-cancer agents for pharmacological optimization of nanomedicine-based combination chemotherapy." Cancer Drug Resistance, 4:463-484, 2021). There are several possible cancer settings with substantial patient numbers and significant unmet need where Promi-Dox could be utilized. This formulation requires further product development. A patent application to cover Promi-Dox has been submitted and recently granted in the US.

Levco

Levco Pharmaceuticals Ltd. (Levco), established in September 2020, is an Israel-based company located in Jerusalem and led by Dr. Alberto Gabizon. Levco is in the process of developing a novel liposomal dual drug product for the treatment of cancer, with an initial focus on the treatment of soft tissue sarcomas (STS).

Levco's pipeline is based on combining advanced liposome technology, including pegylated ("stealth") liposomes, together with co-encapsulation of two active pharmaceutical ingredients (API's) using passive and gradient generated remote loading. The primary product in development is LVC-2020, referred also as PLAD: Pegylated Liposomal Alendronate of Doxorubicin, a liposome product co-encapsulating an aminobisphosphonate (Alendronate) and an anthracycline (Doxorubicin), under a patented technology licensed from Shaare Zedek Scientific Co. and Yissum Hebrew University Co.

Levco has completed scaled-up pre-GMP batch production by external CRO and initial safety studies.

The Orphan Drug Designation (ODD) Application for PLAD for the treatment of Soft Tissue Sarcoma (STS) disease was submitted to the United States Food and Drug Administration ("FDA") in August 2021.

OUR STRATEGY

Our goal is to build a fully integrated focused cancer metabolism therapeutics company to improve and extend the lives of patients. We seek to accomplish that goal through funding, discovering and developing novel cancer therapies through our continued investment in, and planned merger with, Rafael Pharmaceuticals, through our continued investment in the Barer Institute and our other investments in other early-stage oncology companies as well as other investments we will seek to make in the future.

We plan to continue to invest in Rafael Pharmaceuticals, the Barer Institute and LipoMedix, as approved by our Board and deemed strategic, and based on the progress and results of clinical trials and other operational developments for these companies to execute on their plans and continue clinical trials as warranted by results and developments. We also expect to continue to seek other opportunities to invest in additional pharmaceutical or biotechnology assets.

The proposed merger with Rafael Pharmaceuticals is central to our goal of becoming a fully integrated focused cancer metabolism therapeutics company.

The mission of Rafael Pharmaceuticals is to develop innovative, highly selective, well tolerated and highly effective small molecule anticancer agents by selectively targeting cancer metabolism broadly.

Rafael Pharmaceutical's goal is to extend and enhance the lives of patients with hard-to-treat cancers with significant unmet need in selected solid tumors and hematological malignancies.

Consistent with the above criteria, Rafael Pharmaceuticals would seek to continue the efforts of the currently ongoing clinical trials for CPI-613® (devimistat) and to pursue trials for other indications.

Our establishment of Barer is a key part of these goals to develop a pipeline of therapeutic compounds, including compounds to regulate cancer metabolism and potentially other indications appropriate for the assets under development. Barer is pursuing collaborative research agreements with scientists from top academic institutions to complement its early-stage pharmaceutical programs in pre-clinical development. We intend to continue to invest in Barer's preclinical development and move toward clinical stage programs as results warrant.

At LipoMedix, our goals are to secure reliable manufacturing of Promitil® to allow progress on clinical trials, including in combination with radiotherapy and concurrent chemoradiation therapy, as well as continuing research and development, toxicity, and product development of LipoMedix's pipeline.

At Levco, we are currently evaluating our next steps.

REGULATION

Review And Approval Of Drugs In The United States

In the United States, the FDA approves and regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implements regulations. The failure to comply with requirements under the FDCA and other applicable laws at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

Each of Rafael Pharmaceuticals', LipoMedix's, Barer, Levco and Farber Partners (collectively referred to as the "Pharmaceutical Companies") product candidates must be approved by the FDA through a New Drug Application, or NDA. An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an Investigational New Drug, or IND, application, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;

- preparation and submission to the FDA of an NDA requesting marketing for one or more proposed indications;
- review by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

Before an applicant begins testing a compound with potential therapeutic value in humans, the drug candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, and the purity and stability of the drug substance, as well as *in vitro* and animal studies to assess the potential safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved NDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval. Such studies must be conducted in accordance with GCP, including review and approval by an independent ethics committee, or IEC, and informed consent from subjects. The GCP requirements encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND before a clinical trial can begin in the US. In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects.

Human clinical trials are typically conducted in four sequential phases, which may overlap or be combined:

Phase 1. The drug is initially introduced into a small number of healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition (e.g., cancer) and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

Phase 2. The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3. These clinical trials are commonly referred to as "pivotal" studies, which denotes a study which presents the data that the FDA or other relevant regulatory agency will use to determine whether or not to approve a drug. The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Phase 4. Post-approval studies may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the investigator brochure.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

If clinical trials are successful, the next step in the drug development process is the preparation and submission to the FDA of an NDA or BLA, Biologics License Application. The NDA or BLA is the vehicle through which drug applicants formally propose that the FDA approve a new drug or biologic for marketing and sale in the United States for one or more indications. The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. For example, products with orphan drug designation are not subject to user fees.

The FDA reviews all NDAs submitted to identify if there are any deficiencies before it can officially accept them for in-depth review, also known as "filing" of the NDA. The FDA may also request additional information before deciding whether to accept an NDA application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity and has appropriate labeling of the product for its intended use. There is a two-tiered system of review times — standard review and priority review. A priority review designation means FDA's goal is to take action on an application within six months (compared to 10 months under standard review) in addition to the 2-month validation period. During the approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the drug or biologic. If the FDA concludes that a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if deemed required.

Before approving an NDA, the FDA will typically inspect the facilities at which the product is to be manufactured. These preapproval inspections may cover all facilities associated with an NDA submission, including drug component manufacturing (e.g., active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions about the approval of the drug.

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If a complete response letter is issued, the applicant may either submit a Complete Response, addressing all of the deficiencies identified in the letter, or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require phase 4 testing which involves clinical trials designed to further assess a product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Fast track, breakthrough therapy and priority review designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation, and priority review designation.

Accelerated approval pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval. If post-marketing clinical studies fail to verify clinical benefit, FDA may withdraw approval.

Post-Approval Requirements

Any drug that receives FDA approval is subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, by submitting supplemental NDAs, are subject to

prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, or complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, and its implementing regulations, as well as the Drug Supply Chain Security Act, or DSCA, which regulate the distribution and tracing of prescription drugs and prescription drug samples at the federal level, and set minimum standards for the regulation of drug distributors by the states. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

Abbreviated new drug applications for generic drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug, or RLD.

505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA pursuant to an NDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant. If the 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically and legally appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the previously approved reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Pediatric studies and exclusivity

Under the Pediatric Research Equity Act, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of FDASIA 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and any other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to waiver requests, deferral requests and requests for extension of deferrals are contained in FDASIA. Unless and until FDA promulgates a regulation stating otherwise, the pediatric data requirements do not apply to products with orphan designation. However, in accordance with FDARA 2017, certain orphan designated drugs are no longer exempt from having to conduct pediatric studies. FDARA requires that any original NDA or BLA submitted on or after August 18, 2020, for a new active ingredient, must contain studies of molecularly targeted pediatric cancers, unless a deferral or a waiver is granted, if the drug that is intended for the treatment of an adult cancer and directed at a molecular target that has been determined to be substantially relevant to the growth or progression of a pediatric cancer.

Orphan drug designation and exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition, generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product. A company must request orphan drug designation before submitting an NDA for the drug and rare disease or condition. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan drug designation does not shorten the PDUFA goal dates for the regulatory review and approval process, although it does convey certain advantages such as tax benefits and exemption from the PDUFA application fee. The first applicant to obtain approval of an orphan drug is eligible for seven years of exclusivity, or twelve years of exclusivity for a biologic, during which FDA may not approve another drug with the same active ingredient for the approved orphan indication unless the subsequent product is shown to be clinically superior.

Patent term restoration and extension

A patent claiming a new drug product or its method of use may be eligible for a limited patent term extension, also known as patent term restoration, under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. Patent term extension is generally available only for drug products whose active ingredient has not previously been approved by the FDA. 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 extension 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 United States Patent and Trademark Office reviews and approves the application for any patent term extension in consultation with the FDA.

FDA approval and regulation of companion diagnostics

If safe and effective use of a therapeutic depends on an *in vitro* diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and *in vitro* companion diagnostics. According to the guidance, for novel drugs, a companion diagnostic device and its corresponding therapeutic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product's labeling.

Review And Approval Of Drugs In Europe And Other Foreign Jurisdictions

In addition to regulations in the United States, a manufacturer is subject to a variety of regulations in foreign jurisdictions to the extent they choose to sell any drug products in those foreign countries. Even if a manufacturer obtains FDA approval of a product, it must still obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. To obtain regulatory approval of an investigational drug or biological product in the European Union, a manufacturer must submit a marketing authorization application (MAA) to the European Medicines Agency or EMA. For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, clinical trials are to be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Pharmaceutical Coverage, Pricing And Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed 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. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Even if our product candidate is approved, sales of our products will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenue from product candidates that the Pharmaceutical Companies may successfully develop and for which they may obtain marketing approval and may affect their overall financial condition and ability to develop product candidates.

Healthcare Law And Regulation

In addition to FDA restrictions on marketing of drug products, federal and state fraud and abuse laws restrict business practices in the pharmaceutical industry. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs;
- the federal False Claims Act, which prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers;
- state laws requiring pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government. 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.

COMPETITION

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. While we believe that Rafael Pharmaceuticals' technology, development experience and scientific knowledge provide it with competitive advantages, Rafael Pharmaceuticals faces potential competition from many different companies, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that Rafael Pharmaceuticals successfully develops and commercializes will compete with existing therapies and new therapies that may become available in the future.

Rafael Pharmaceuticals competes in the segments of the pharmaceutical, biotechnology companies that either address cancer metabolism, or developing drugs for pancreatic cancer or AML. Various companies working to develop therapies in the field of cancer metabolism include, but are not limited to, Celgene, Inc. (now part of Bristol-Myers Squibb), Servier Pharmaceuticals, LLC, Pfizer, Inc., Calithera Biosciences, Inc., Sagimet Biosciences, Inc. (previously known as 3V Biosciences. Inc.), Aeglea Bio Therapeutics, Inc., Polaris Pharmaceuticals, Inc., Berg Health, Inc., Rgenix, Inc., Eleison Pharmaceuticals LLC, Forma Therapeutics Holdings LLC, TYME Technologies Inc., and ERYtech Pharma. Some of the key companies developing drugs for pancreatic cancer include, but are not limited to, Celgene, Inc. (now part of Bristol-Myers Squibb), Novartis, Cantargia, AB Science, Inc., Ipsen, TYME Technologies Inc. and some of the key companies developing drugs for AML including, but not limited to, Roche, Novartis, GlycoMimetics, Inc., Jazz Pharmaceuticals plc, Daiichi Sankyo Company Ltd., AROG Pharmaceuticals, Inc., Delta-Fly Pharma, Astex Pharmaceuticals, and Actinium Pharmaceuticals Inc.

INTELLECTUAL PROPERTY

Licenses

Rafael Pharmaceuticals maintains an exclusive license agreement with the Research Foundation of the State University of New York at Stony Brook, or RF, granting Rafael Pharmaceuticals the exclusive right to make, use and sell products covered under specified technology relating to lipoic acid derivatives with the right to grant sublicenses. This license agreement was subsequently amended in 2004, 2007 and 2017 and relates to Rafael Pharmaceutical's AEMD class of compounds. Rafael Pharmaceuticals maintains a low single-digit royalty agreement with Altira Capital and Consulting, LLC, pursuant to which Rafael Pharmaceuticals is granted sole ownership of patents directed to lipoic acid derivatives and other technology.

Rafael Pharmaceuticals maintains an exclusive license agreement with Ono Pharmaceutical Co., Ltd, or Ono, whereby Rafael Pharmaceuticals granted Ono an exclusive right to make, use and sell CPI-613® (devimistat) and related products in Japan, South Korea, Taiwan, and certain countries in Southeast Asia under specified intellectual property held by Rafael Pharmaceuticals. Ono granted to Rafael Pharmaceuticals a non-exclusive right under intellectual property held by Ono to make, use, and sell CPI-613® (devimistat) and related products in countries other than Japan, South Korea, Taiwan, and certain countries in Southeast Asia. Under the license agreement, Ono is required to use commercially reasonable efforts to develop the licensed products in territories licensed to Ono. The agreement may be terminated without cause by Ono or by Rafael Pharmaceuticals for material breach by Ono.

Farber Partners, a subsidiary of the Barer Institute, has executed a worldwide, exclusive and sub-licenseable license from the Trustees of Princeton University from work done in the Rabinowitz lab regarding metabolites that are able to stimulate anti-cancer immune responses to support its ongoing Barer Institute immuno-metabolism pipeline. The in-licensed intellectual property is foundational work for a potentially transformative immunotherapy combination developed in the Barer Institute.

LipoMedix maintains an exclusive license agreement with Yissum Research and Development Company, the technology transfer arm of the Hebrew University of Jerusalem granting LipoMedix the exclusive right to make, use and sell products covered under specified patents relating to the mitomycin lipophilic prodrug and its liposomal formulation (Promitil®) with the right to grant sublicenses. LipoMedix also maintains an exclusive license agreement with Shaare Zedek Scientific Company, the technology transfer arm of Shaare Zedek Medical Center (SZMC) granting LipoMedix the exclusive right to license any new I.P. developed at SZMC relating to the mitomycin lipophilic prodrug and its liposomal formulation (Promitil®) with the right to grant sublicenses.

Patents

Rafael Pharmaceuticals patents its technology, inventions, and improvements that it considers important to the development of its business. A patent gives the patent holder the right to exclude any unauthorized use of the subject matter of the patent in those jurisdictions in which a patent is granted. As of August 19, 2021, Rafael Pharmaceuticals owns or in-licenses more than one dozen U.S. patents, several dozen foreign patents registered in various countries, and many pending U.S. and foreign patent applications. Additional patent applications will be filed as studies continue.

Patents that Rafael Pharmaceuticals has obtained for its platform technologies and patents that may issue in the future based on Rafael Pharmaceuticals' currently pending patent applications are scheduled to expire in years 2028 through 2042. These dates do not include potential patent term extensions. Rafael Pharmaceuticals has obtained U.S. orphan drug designation for CPI-613® (devimistat) in the treatment of pancreatic cancer, AML, MDS, Burkitt's Lymphoma, Peripheral T-cell Lymphoma (PTCL), soft tissue sarcoma, and biliary cancer.

Rafael Pharmaceuticals maintains U.S. and international trademarks covering its lead development compound (CPI-613® (devimistat)) and pancreatic cancer clinical trial (AVENGER 500®). U.S. and international trademarks are also maintained for potential brand names of devimistat.

As of October 9, 2020, LipoMedix owns or in-licenses several families of U.S. patents. Additional patent applications will be filed as studies continue. Patents that LipoMedix has obtained and patents that may issue in the future based on LipoMedix's currently pending patent applications for its platform technologies are scheduled to expire in years 2032 through 2035. These dates do not include potential patent term extensions.

Three new patent applications covering the use of Promitil®, in combination with other chemotherapies and with radiotherapy, and a reformulation of Promitil with co-encapsulated mitomycin prodrug and doxorubicin have been approved by the USPTO in 2018-2020. The patent portfolio currently comprises 5 granted families of patents and another two applications under review.

Rafael Medical Devices patents its technology, inventions, and improvements that it considers important to the development of its business. As of October 1, 2021 Rafael Medical Devices has two provisional patents related to its devices filed with the USPTO and Rafael Medical Devices expects to file non-provisional submissions this calendar year.

Additional patent applications will be filed as development progresses.

MANUFACTURING

The Pharmaceutical Companies do not own or operate, and currently have no plans to establish, any manufacturing facilities or fill-and-finish facilities. The Pharmaceutical Companies currently rely, and expect to continue to rely, on third parties for the manufacture of their product candidates for preclinical and clinical testing, as well as for commercial manufacture of any products that they may commercialize. The Pharmaceutical Companies obtain supplies from these established contract manufacturers on a purchase order basis and do not have long-term supply arrangements in place. The Pharmaceutical Companies do not currently have arrangements in place for redundant supply for bulk drug substance or drug product, however, we may seek to add that capability if we move toward commercialization of specific candidates. For all of the product candidates, the Pharmaceutical Companies intend to identify and qualify additional manufacturers to provide the active pharmaceutical ingredient and the formulation and fill-and-finish. We have no current plans to develop internal manufacturing facilities of fill-and-finish facilities, including following consummation of the merger with Rafael Pharmaceuticals and potential commercialization of product candidates.

For Rafael Pharmaceuticals, the compounds are organic compounds of low molecular weight, generally called small molecules. They can be manufactured in reliable and reproducible synthetic processes from readily available starting materials. The chemistry is amenable to scale-up and does not require unusual equipment in the manufacturing process. Rafael Pharmaceuticals expects to continue to develop drug candidates that can be produced relatively cost-effectively at contract manufacturing facilities.

LipoMedix's Promitil® and other pipeline candidates, are based on an active pharmaceutical ingredient (API) referred to as MLP (abbreviation of mitomycin-C lipid-based prodrug) that is formulated into customized nanoparticles. These nanoparticles consist of lipids and a polyethylene-glycol (PEG) polymer and are known as pegylated liposomes.

LipoMedix obtains supplies from established contract manufacturers on a purchase order basis and does not have long-term supply arrangements in place. LipoMedix does not currently have arrangements in place for commercial supply or redundant supply for bulk drug substance or drug product.

EMPLOYEES

As of October 3, 2021, Rafael Holdings had 23 full-time employees and 2 part-time employees as follows: 11 employees primarily dedicated to the corporate entity, 7 employees dedicated to the real estate group and 7 dedicated to the Barer group. Rafael Pharmaceuticals employs 26 full-time and 4 part-time employees, who are involved in operations, research and development and LipoMedix employs 1 full-time and 2 part-time employees involved in operations, research and development, in addition to Prof. Gabizon, and Levco employs 1 full-time and 3 part-time employees.

Real Estate

The commercial real estate holdings consist of the building at 520 Broad Street in Newark, New Jersey that serves as headquarters for the Company and, certain affiliated entities, an 800-car public garage, and a portion of a building in Israel.

520 Broad Street in Newark New Jersey is a 20-story commercial office building containing approximately 496,000 square feet. The building was completed in 1957 and is of steel-frame construction with cast-in-place concrete floors. The facade is constructed of stone and metal framed glass curtain wall sections. The public garage has three levels, plus additional surface parking that, in total, can accommodate approximately 800 parking spaces. The Newark market is undergoing a renewal with major commercial and residential projects currently in development or coming to the market. The building also sits within an Opportunity Zone. The opportunity zone designation provides multiple potential benefits to an acquirer of an asset in an opportunity zone including a temporary deferral of inclusion in taxable income for capital gains reinvested in an opportunity zone investment; a step-up in basis for capital gains reinvested in an opportunity zone investment; and a permanent exclusion from taxable income of capital gains from the sale or exchange of an investment in an opportunity zone investment if the investment is held for at least 10 years. We continue to seek opportunities to maximize the value of our real estate holdings in multiple ways and we are also evaluating other avenues of maximizing value through redevelopment of vacant space into more marketable and thereby valuable uses.

On July 9, 2021, the Company as guarantor, Rafael Holdings Realty, Inc., a wholly-owned subsidiary as pledgor, and Broad Atlantic Associates, LLC, a wholly-owned subsidiary of Realty as borrower, entered into a loan agreement with 520 Broad Street LLC, a third-party lender (the "Lender"). The Loan Agreement provides for a loan in the amount of $15 million secured by (i) a first mortgage on 520 Broad Street, Newark, New Jersey 07102; and (ii) a first priority security interest in the equity of the Borrower.

The building serves as the headquarters of Rafael Holdings, IDT Corporation, and Genie Energy, Ltd. ("Genie"), who occupy the second through fourth floors. Currently, approximately 25% of the building is leased, including leases to IDT and Genie.

The IDT lease expires in April 2025 and is for 80,000 square feet and includes two parking spots per thousand square feet of space leased. The annual base rent is approximately $1.6 million. IDT has the right to terminate the lease upon four months' notice and, upon early termination, IDT will pay a penalty equal to 25% of the portion of the rent due over the course of the remaining term. IDT has the right to lease an additional 50,000 square feet in the building at the same terms as the base lease, in 25,000 square feet increments. Upon expiration of the lease, IDT has the right to renew the lease for another five years on substantially the same terms, with a 2% annual increase in the rental payments.

The Genie lease expires in April 2025 and is for 8,631 square feet and includes two parking spots per thousand square feet of space leased. The annual base rent is approximately $214,800. Genie has the right to terminate the lease upon four months' notice and, upon early termination, Genie will pay a penalty equal to 25% of the portion of the rent due over the course of the remaining term. Upon expiration of the lease, Genie has the right to renew the lease for another five years on substantially the same terms, with a 2% annual increase in the rental payments.

In addition to the IDT and Genie leases, there are three additional leases for space in the building. The first lease is for a portion of the sixth floor for an eleven-year term, of which the first six years are non-cancellable. The second lease is for a portion of the ground floor and basement for a term of ten years, seven months and the third lease is for another portion of the ground floor for a term of ten years, four months. The leases have all commenced. At July 31, 2021 and 2020, the carrying value of the land, building and improvements at 520 Broad Street was $41.7 million and $42.9 million, respectively.

The real estate holding in Israel is a condominium portion of an office building built in 2004 located in the Har Hotzvim section of Jerusalem, Israel. The condominium is one floor of approximately 12,400 square feet. Har Hotzvim is a high-tech industrial park located in northwest Jerusalem. It is the city's main zone for science-based and technology companies, among them Intel, Teva and Mobileye. As of July 31, 2021, the space is fully leased to two tenants; one is IDT and another third-party tenant.

Depreciation expense of property, plant and equipment was $1.5 million and $1.9 million in fiscal 2021 and fiscal 2020, respectively.

COMPETITION

With respect to our real estate business, we compete for commercial (office and retail) tenants in the areas our buildings are located. The commercial real estate market is highly competitive. Numerous commercial properties compete with us for tenants based on location, rental rates, tenant allowances, operating expenses and the quality and design of the property. Other factors tenants consider are; quality and breadth of tenant services provided, onsite amenities and reputation of the owner and property manager.

There is also competition to acquire real estate, including competition from domestic and foreign financial institutions, REITs, life insurance companies, pension trusts, trust funds, partnerships, individual investors and others. Should we decide to dispose of a property, we will also be in competition with sellers of comparable properties seeking suitable purchasers. In 2020 we sold a 3-story, 65,253 square foot office building located in Piscataway, New Jersey for a sales price of $3,875,000, and net proceeds of $3,675,638.

OUR STRATEGY

Our strategy related to our real estate business includes:

- capitalizing on knowledge of the marketplaces to enhance our leasing and property management capabilities in order to achieve stabilized occupancy;
- attracting additional tenants to our buildings and public parking garage; and
- executing timely monetization through sales or joint ventures of current real estate holdings.

Item 1A. Risk Factors.

RISK FACTORS

Our business, operating results or financial condition could be materially adversely affected by any of the following risks associated with any one of our businesses, as well as the other risks highlighted elsewhere in this document. The trading price of our common stock could decline due to any of these risks. Note that references to "our", "us", "we", "the Company", etc. used in each risk factor below refers to the business about which such risk factor is provided.

Risks Related to Our Financial Condition and Capital Needs

We have limited resources and could find it difficult to raise additional capital.

We may need to raise additional capital for operations and in order for stockholders to realize increased value on our securities. Given the current global economy and other factors, if we need to raise additional capital there can be no assurance that we will be able to obtain the necessary funding on commercially reasonable terms in a timely fashion. Failure to receive the funding could have a material adverse effect on our business, prospects, and financial condition.

We hold a Warrant to purchase a significant stake in Rafael Pharmaceuticals, as well as other equity and governance rights in Rafael Pharmaceuticals, which we can't exercise, in full, at this time and may never be able to exercise.

We hold a Warrant to purchase a significant stake in Rafael Pharmaceuticals, as well as other equity and governance rights in Rafael Pharmaceuticals, which we can't exercise, in full, at this time and may never be able to exercise. We currently own 51% of the issued and outstanding equity in Rafael Pharmaceuticals. Approximately 8% of the issued and outstanding equity is owned by our subsidiary CS Pharma and 43% is held by our subsidiary Pharma Holdings. Our subsidiary Pharma Holdings holds a non-dilutive option to increase our total ownership to 56%. Based on the current shares issued and outstanding of Rafael Pharmaceuticals as of July 31, 2021, we, and our affiliates, would need to pay approximately $17 million to exercise the Warrant in full. On an as-converted fully diluted basis (for all convertible securities of Rafael Pharmaceuticals outstanding), we, and our affiliates, would need to pay approximately $126 million to exercise the Warrant in full including additional issuances under the Line of Credit. Howard Jonas holds 10% of the interest in Pharma Holdings and would need to contribute 10% of any cash necessary to exercise any portion of the Warrant. Following any exercise, a portion of our interest in Rafael Pharmaceuticals would continue to be held for the benefit of the other equity holders in Pharma Holdings and CS Pharma. Subject to certain adjustments, the Warrant will expire upon the earlier of (i) the occurrence of the Effective Time of the Merger, or (ii) if the Effective Time does not occur, the date that is calculated by adding (A) the number of calendar days the Merger Agreement has been in effect prior to its termination in accordance with its terms, to (B) August 15, 2021. If the Merger is not consummated, the Warrant may expire unexercised. Further, given the Company's anticipated available cash, we would not be able to exercise the Warrant in its entirety and we may never be able to exercise the Warrant in full. Rafael Pharmaceuticals may also issue additional equity interests, such as stock options, which will require us to pay additional cash to maintain our ownership percentage or exercise the Warrant in full.

Howard Jonas has the contractual right to receive "Bonus Shares" for an additional 10% of the fully diluted capital stock of Rafael Pharmaceuticals at the time of issuance which is contingent upon achieving certain milestones. If any of the milestones are met and the Bonus Shares are issued, we will need additional cash to maintain our ownership percentage or exercise the Warrant in full.

In connection with entering into the Line of Credit Agreement, Rafael Pharmaceuticals agreed to issue to RP Finance shares of its common stock representing 12% of the issued and outstanding shares of Rafael Pharmaceuticals common stock, with such interest subject to anti-dilution protection as set forth in the Line of Credit Agreement. If additional shares are issued, we will need additional cash to maintain our ownership percentage or exercise the Warrant in full.

Given our complicated ownership in Rafael Pharmaceuticals as described herein, the market may or may not appropriately value our investment in Rafael Pharmaceuticals.

Our limited operating history makes it difficult to evaluate our business and prospects and may increase your investment risk.

We have only a limited operating history upon which our business and prospects can be evaluated. We expect to encounter risks and difficulties frequently encountered by early-stage companies in the industries in which we operate.

We have not yet demonstrated our ability to successfully complete any clinical trials, including large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial scale medicine, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes about ten to fifteen years to develop one new medicine from the time it is discovered to when it is available for treating patients. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical stage biopharmaceutical companies in rapidly evolving fields. We will also need to transition from a company with a research focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer, our future revenue potential may be impacted and our ability to pursue our growth strategy and attain profitability could be compromised.

We hold significant cash, cash equivalents, restricted cash and investments that are subject to various market risks.

As of July 31, 2021, we held approximately $12.9 million in cash and cash equivalents and restricted cash, approximately $0.835 million in third-party and related party receivables, approximately $7.5 million due from RP Finance, approximately $5.3 million in interests in hedge funds and approximately $0.5 million in securities in another entity that are not liquid. In August 2021, we closed a private placement offering for total gross proceeds of approximately $104 million. Investments in hedge funds carry a degree of risk, as there can be no assurance that we will be able to redeem any hedge fund investments at any time or that our investment managers will be able to accurately predict the course of price movements of securities and other instruments and, in general, the securities markets have in recent years been characterized by great volatility and unpredictability. Our passive interests in other entities are not currently liquid and we cannot assure that we will be able to liquidate them when we desire, or ever. As a result of these different market risks, our holdings of cash, cash equivalents, and investments could be materially and adversely affected.

We are dependent on IDT and Genie for a large portion of our revenue and the loss of, or a significant reduction in revenue from IDT and its affiliates would reduce our revenue and adversely impact our results of operations.

We have generated the majority of our revenue from IDT and Genie. In the fiscal year ended July 31, 2021, IDT and Genie accounted for approximately 65% of our revenue. The loss of, or a significant reduction in, revenue from IDT and Genie would materially and adversely affect our revenue and results of operations.

Risks Related to our Pharmaceuticals Business

We depend heavily on the future success of Rafael Pharmaceuticals' lead product candidate devimistat (CPI-613® (devimistat)). If Rafael Pharmaceuticals is unable to gain regulatory approval or commercialize its product candidates or experiences significant delays in doing so, our business will be materially harmed.

We have invested a significant amount of capital into Rafael Pharmaceuticals. All of Rafael Pharmaceuticals current and any future product candidates will require preclinical and clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before Rafael Pharmaceuticals can generate any revenue from product sales.

The success of devimistat (CPI-613® (devimistat)) and any other product candidates that may be developed will depend on many factors, including the following:

- timely initiation, successful enrollment and timely completion of clinical trials and preclinical studies, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- allowance to proceed with clinical trials of product candidates under investigational new drug applications, or INDs, by the U.S. Food and Drug Administration, or the FDA, or under similar regulatory submissions by comparable foreign regulatory authorities;
- the frequency, duration and severity of potential adverse events in clinical trials;

- whether Rafael Pharmaceuticals is required by the FDA or other comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of their product candidates;
- maintaining and establishing relationships with contract research organizations, or CROs, and clinical sites for the clinical development of any product candidates both in the United States and internationally;
- Rafael Pharmaceuticals' ability to demonstrate the safety, and efficacy of its product candidates to the satisfaction of the FDA and comparable regulatory authorities;
- timely receipt of marketing approvals from applicable regulatory authorities, including new drug applications, or NDAs, or other comparable submissions from the FDA and maintaining such approvals;
- Rafael Pharmaceuticals' ability and the ability of third parties with whom it contracts to manufacture adequate clinical and commercial supplies of CPI-613® (devimistat) or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMPs;
- establishing sales, marketing and distributing capabilities and launching commercial sales of any products, if and when approved, whether alone or in collaboration with others;
- establishing and maintaining patent and trade secret protection or regulatory exclusivity for CPI-613® (devimistat) or any other product candidates;
- the willingness of physicians, operators of clinics and patients to utilize or adopt CPI-613® (devimistat) or any other product candidates over alternative or more conventional therapies, such as chemotherapy, to treat cancers;
- maintaining an acceptable safety profile of CPI-613® (devimistat) or any other products following approval, if any; and
- maintaining and growing an organization of people who can develop and commercialize product candidates and technology.

Many of these factors are beyond our or Rafael Pharmaceuticals' control and could cause significant delay or prevent Rafael Pharmaceuticals from obtaining or commercializing CPI-613® (devimistat) or any other product candidates. If Rafael Pharmaceuticals is unable to develop, obtain regulatory approval for, or, if approved, successfully commercialize its product candidates, we may not be able to generate sufficient revenue to continue our business.

The Pharmaceutical Companies may not be successful in their efforts to identify or discover potential product candidates.

The key elements of our strategy are for the Barer Institute to identify, create and test compounds that target alterations found in cancer cells related to its production of energy widely known as cancer metabolism, for Rafael Pharmaceuticals to develop and clinically advance CPI-613 and for LipoMedix to find drug carrier systems such as liposomes or other nanoparticles to deliver effectively and safely powerful anticancer compounds for which minimizing toxicity is critical. A significant portion of the research that the Pharmaceutical Companies are conducting involves new compounds and drug discovery methods and suitable drug delivery systems, including the Pharmaceutical Companies' proprietary technology. The drug discovery that the Pharmaceutical Companies are conducting using the Pharmaceutical Companies' proprietary technology may not be successful in identifying compounds that are useful in treating cancer. The Pharmaceutical Companies' research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying appropriate biomarkers, potential product candidates or effective carrier systems to confer a drug delivery advantage.
- potential product candidates may, on further study, be shown to not be effective, have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. The Pharmaceutical Companies may choose to focus the Pharmaceutical Companies' efforts and resources on a potential product candidate that ultimately proves to be unsuccessful.

If the Pharmaceutical Companies are unable to identify suitable compounds for preclinical and clinical development, the Pharmaceutical Companies will not be able to obtain product revenue in future periods, which likely would result in significant harm to the Pharmaceutical Companies' financial position and adversely impact the Pharmaceutical Companies' valuation.

The Pharmaceutical Companies may expend their limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because the Pharmaceutical Companies have limited financial and managerial resources, their focus on research programs and product candidates that they may or will identify for specific indications may not be exhaustive. As a result, the Pharmaceutical Companies may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. The Pharmaceutical Companies' resource allocation decisions may cause them to fail to capitalize on viable commercial medicines or profitable market opportunities. The Pharmaceutical Companies' spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable medicines. If the Pharmaceutical Companies do not accurately evaluate the commercial potential or target market for a particular product candidate, they may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for them to retain sole development and commercialization rights to such product candidate.

Preclinical and clinical drug development is a lengthy and expensive process, with an uncertain outcome. The Pharmaceutical Companies' preclinical and clinical programs may experience delays or may never advance, which would adversely affect their ability to obtain regulatory approvals or commercialize their product candidates on a timely basis or at all, which could have an adverse effect on their business.

In order to obtain FDA approval to market a new drug, the product sponsor must demonstrate the safety and efficacy of the new drug in humans to the satisfaction of the FDA. To meet these requirements, the Pharmaceutical Companies will have to conduct adequate and well-controlled clinical trials. Clinical testing is expensive, time-consuming and subject to uncertainty.

Before the Pharmaceutical Companies can commence clinical trials for a product candidate, they must complete extensive preclinical studies that support their planned and future INDs in the United States. We cannot be certain of the timely completion or outcome of the Pharmaceutical Companies' preclinical studies and cannot predict if the FDA will allow their proposed clinical programs to proceed or if the outcome of their preclinical studies will ultimately support further development of their programs. We also cannot be sure that the Pharmaceutical Companies will be able to submit INDs or similar applications with respect to their product candidates on the timelines we expect, if at all, and we cannot be sure that submission of IND or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing and clinical trials represents a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which the Pharmaceutical Companies are conducting preclinical studies may cause them to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical studies;
- timely completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- approval by an independent Institutional Review Board, or IRB, ethics committee at each clinical site before each trial may be initiated;

- delays in reaching a consensus with regulatory agencies on study design and obtaining regulatory authorization to commence clinical trials;
- delays in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in recruiting suitable patients to participate in clinical trials;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of product candidates for use in clinical trials;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting, screening and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by CROs, other third parties or the Pharmaceutical Companies to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practice requirements, or GCPs, or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies;
- changes to the clinical trial protocols;
- clinical sites deviating from trial protocol or dropping out of a trial;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- the cost of clinical trials of our product candidates being greater than anticipated;
- clinical trials of the Pharmaceutical Companies' product candidates producing negative or inconclusive results, which may result in our or their deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization, or CMO, and delays or failure by CMOs or the Pharmaceutical Companies to make any necessary changes to such manufacturing process; and
- third parties being unwilling or unable to satisfy their contractual obligations to us or the Pharmaceutical Companies.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that the Pharmaceutical Companies encounter such difficulties or delays in initiating, enrolling, conducting or completing any planned and ongoing preclinical studies and clinical trials. Any inability by the Pharmaceutical Companies to successfully initiate or complete preclinical studies or clinical trials could result in additional costs or impair our ability to generate revenue from product sales. In addition, if the Pharmaceutical Companies make manufacturing or formulation changes to their product candidates, they may be required to or may elect to conduct additional studies to bridge modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which any marketed products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize the Pharmaceutical Companies' product candidates and may seriously harm our business.

Further, conducting clinical trials in foreign countries, as the Pharmaceutical Companies may do for their product candidates, presents additional risks that may delay completion of clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for the Pharmaceutical Companies' clinical trials may serve as scientific advisors or consultants to them from time to time and receive compensation in connection with such services. Under certain circumstances, the Pharmaceutical Companies may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between the Pharmaceutical Companies and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more product candidates.

Delays in the completion of any preclinical studies or clinical trials of the Pharmaceutical Companies' product candidates will increase our costs, slow down product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval a product candidate. Any delays to the Pharmaceutical Companies' preclinical studies or clinical trials that occur as a result could shorten any period during which we or they may have the exclusive right to commercialize such product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of any product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

If the Pharmaceutical Companies experience delays or difficulties in the enrollment of patients in clinical trials, the Pharmaceutical Companies' receipt of necessary regulatory approvals could be delayed or prevented.

The Pharmaceutical Companies or their collaborators may not be able to initiate or continue clinical trials for the Pharmaceutical Companies' product candidates if the Pharmaceutical Companies or such collaborators are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or analogous regulatory authorities outside the United States.

Enrollment may be particularly challenging for some of the orphan diseases the Pharmaceutical Companies target in the Pharmaceutical Companies' programs. In addition, there may be limited patient pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of the Pharmaceutical Companies' clinical studies will further limit the pool of available study participants as they may require that patients have specific characteristics that they can measure or to assure their disease is either severe enough or not too advanced to include them in a study. In addition, some of the Pharmaceutical Companies' competitors may have ongoing clinical trials for product candidates that are in development to treat the same indications as the Pharmaceutical Companies' product candidates, and patients who would otherwise be eligible for the Pharmaceutical Companies' clinical trials may instead enroll in clinical trials of the Pharmaceutical Companies' competitors' product candidates.

Patient enrollment is also affected by other factors including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved or future product candidates being investigated for the indications we are investigating;
- delays in or temporary suspension of the enrollment of patients in our planned clinical trials due to the COVID-19 pandemic;
- ability to obtain and maintain patient consents;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion, including as a result of contracting COVID-19 or other health conditions or being forced to quarantine, or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

These factors may make it difficult for the Pharmaceutical Companies to enroll enough patients to complete their clinical trials in a timely and cost-effective manner. The Pharmaceutical Companies' inability to enroll a sufficient number of patients for their clinical trials would result in significant delays or may require them to abandon one or more clinical trials altogether. Enrollment delays in clinical trials may result in increased development costs for the Pharmaceutical Companies' product candidates and jeopardize their ability to obtain marketing approval. Rafael Pharmaceuticals experienced some delays in enrollment particularly in the early days of the pandemic. In the case of the AVENGER 500® trial metastatic pancreatic cancer, they were ultimately able to attain their enrollment goals in a timely manner. Furthermore, even if the Pharmaceutical Companies are able to enroll a sufficient number of patients for their clinical trials, they may have difficulty maintaining participation in their clinical trials through the treatment and any follow-up periods.

The Pharmaceutical Companies' product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

If the Pharmaceutical Companies' product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs the Pharmaceutical Companies may need to interrupt, delay or abandon their development or limit development to more narrow 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. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may adversely affect our business, financial condition and prospects significantly.

In addition, many compounds that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. Further, we expect that certain product candidates, including CPI-613 (devimistat) will be used in patients that have weakened immune systems, which may exacerbate any potential side effects associated with their use. Patients treated with CPI-613 (devimistat)

or other oncology product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to CPI-613 (devimistat) but may still impact the success of clinical trials. The inclusion of critically ill patients in clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If significant adverse events or other side effects are observed in any of the Pharmaceutical Companies' current or future clinical trials, the Pharmaceutical Companies may have difficulty recruiting patients to the clinical trials, patients may drop out of such trials, or they may be required to abandon the trials or our development efforts of a product candidate altogether. The Pharmaceutical Companies, the FDA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects.

Further, if any of the Pharmaceutical Companies' product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a number of potentially significant negative consequences, including, but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including "boxed" warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- the Pharmaceutical Companies may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- the Pharmaceutical Companies may be required to create a risk evaluation and mitigation strategy, or REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients;
- the Pharmaceutical Companies may be subject to fines, injunctions or the imposition of criminal penalties;
- we or the Pharmaceutical Companies could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent the Pharmaceutical Companies from achieving or maintaining market acceptance of the particular product candidate, if approved, and could seriously harm our business.

Interim, "top-line" and preliminary data from clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we and/or the Pharmaceutical Companies may publicly disclose preliminary or top-line data from preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We and/or the Pharmaceutical Companies may also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we or they may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results reported may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we and/or the Pharmaceutical Companies may also disclose interim data from preclinical studies and clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from such clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could materially adversely affect our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our or the Pharmaceutical Companies' assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we or they choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we or the Pharmaceutical Companies report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, the Pharmaceutical Companies' ability to obtain approval for, and commercialize, their product candidates may be adversely affected, which could materially adversely affect our business, financial condition and results of operations.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and the Pharmaceutical Companies could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. The Pharmaceutical Companies have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if the Pharmaceutical Companies, or future collaborators, believe that the results of clinical trials for the Pharmaceutical Companies' product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of the Pharmaceutical Companies' product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. If the Pharmaceutical Companies fail to receive positive results in clinical trials of the Pharmaceutical Companies' product candidates, the development timeline and regulatory approval and commercialization prospects for the Pharmaceutical Companies' most advanced product candidates, and, correspondingly, the Pharmaceutical Companies' business and financial prospects would be negatively impacted.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if the Pharmaceutical Companies are ultimately unable to obtain regulatory approval for their product candidates, their business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. The Pharmaceutical Companies have not obtained regulatory approval for any product candidate and it is possible that any product candidates they may seek to develop in the future will never obtain regulatory approval. Neither the Pharmaceutical Companies nor any future collaborator is permitted to market any new drug in the United States until we receive regulatory approval of an NDA, or other comparable submission, from the FDA.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, the Pharmaceutical Companies or their collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for the Pharmaceutical Companies' product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require the Pharmaceutical Companies to conduct additional preclinical studies or clinical trials for their product candidates either prior to or post-approval, or it may object to elements of a proposed clinical development program.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of the Pharmaceutical Companies' product candidates or require them to conduct additional nonclinical or clinical testing or abandon a program for, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of clinical trials;
- the Pharmaceutical Companies may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects experienced by participants in clinical trials or by individuals using drugs similar to the Pharmaceutical Companies' product candidates;
- the Pharmaceutical Companies may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with the Pharmaceutical Companies' interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of the Pharmaceutical Companies' product candidates may not be acceptable or sufficient to support the submission of a NDA or other comparable submission or to obtain regulatory approval in the United States or elsewhere, and they may be required to conduct additional clinical studies;
- the FDA's or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of the Pharmaceutical Companies' product candidates;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which the Pharmaceutical Companies contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in the Pharmaceutical Companies failing to obtain regulatory approval to market their product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if the Pharmaceutical Companies were to obtain approval, regulatory authorities may approve any of their product candidates for fewer or more limited indications than requested, may not approve the prices they intend to charge for any approved products, may grant approval contingent on the performance of costly post-marketing clinical trials, including Phase 4 clinical trials, and/or the implementation of a REMS, which may be required to assure safe use of the drug after approval. The FDA or the applicable foreign regulatory authority also may approve a product candidate for a more limited indication or patient population than originally requested, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for the Pharmaceutical Companies product candidates.

If the FDA does not conclude that certain of the Pharmaceutical Companies' product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as they expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

The Pharmaceutical Companies may develop product candidates for which they plan to seek approval under the 505(b)(2) regulatory pathway in the United States. For example, we expect that LipoMedix may ultimately seek FDA approval of Promitil through the 505(b)(2) pathway.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act, or FDCA. Section 505(b)(2) of the FDCA permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable under the FDCA, would allow an NDA submitted to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for certain of the Pharmaceutical Companies' product candidates by potentially decreasing the amount of nonclinical and/or clinical data that they would need to generate in order to obtain FDA approval.

If the FDA does not allow any of the Pharmaceutical Companies to pursue the Section 505(b)(2) regulatory pathway as anticipated, they may need to conduct additional nonclinical studies and/or clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for such product candidates, and complications and risks associated with such product candidates, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than any product candidates the Pharmaceutical Companies are developing, which could adversely impact our competitive position and prospects. Even if the Pharmaceutical Companies are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that any product candidates the Pharmaceutical Companies develop will receive the requisite approval for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2), certain pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to certain requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of a new product. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if the Pharmaceutical Companies are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to streamlined product development or earlier approval.

The Pharmaceutical Companies may not be able to obtain orphan drug designation or obtain or maintain the benefits associated with orphan drug designation, such as orphan drug exclusivity and, even if they do, that exclusivity may not prevent the FDA or other comparable foreign regulatory authorities from approving competing products.

As part of their business strategy, the Pharmaceutical Companies may seek orphan drug designation, or ODD, for any eligible product candidates they develop, but they may be unsuccessful in obtaining or maintaining the benefits of such designations.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing and making available the drug will be recovered from sales in the United States. Rafael Pharmaceuticals has received ODD for CPI-613 (devimistat) for the treatment of pancreatic cancer, acute myeloid leukemia, myelodysplastic syndrome, Burkitt's lymphoma, peripheral T-cell lymphomas, soft tissue sarcoma and biliary cancer.

In the United States, ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has ODD subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not

approve any other applications, including a full NDA or other comparable submission, to market the same drug for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity or if FDA finds that the holder of the orphan exclusivity has not shown that it can ensure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the product was designated.

Even if the Pharmaceutical Companies obtain ODD for a product candidate, they may not be able to obtain or maintain orphan drug exclusivity for that product candidate. The Pharmaceutical Companies may not be the first to obtain marketing approval of any product candidate for which they have obtained ODD for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if the Pharmaceutical Companies seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if they are unable to ensure that they will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Further, even if the Pharmaceutical Companies obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active ingredients be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, 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, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the US government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products, and on March 18, 2020 the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process the Pharmaceutical Companies' regulatory submissions, which could have a material adverse effect on our business.

Even if the Pharmaceutical Companies receive regulatory approval for any product candidate, they will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

Any regulatory approvals that the Pharmaceutical Companies may receive for their product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS as a condition of approval of a product candidate, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP requirements for any clinical trials that are conducted post-approval. Manufacturers of approved products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. Later discovery of previously unknown problems with marketed products, including adverse events of unanticipated severity or frequency, or with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenue, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit the Pharmaceutical Companies' ability to commercialize their product candidates and generate revenue and could require the Pharmaceutical Companies to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of the Pharmaceutical Companies' product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, the results of the 2020 US Presidential Election impacted our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that imposed significant burdens on, or otherwise materially delayed, the FDA's ability to engage in routine oversight activities, such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these orders will be will be rescinded and replaced under the Biden administration. The policies and priorities of any administration are unknown and could materially impact the regulations governing our product candidates. If we or the Pharmaceutical Companies are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or they are not able to maintain regulatory compliance, we or they may be subject to enforcement action and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of the Pharmaceutical Companies' product candidates are approved and if they are found to have been improperly promoted for unapproved uses of those products, the Pharmaceutical Companies may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as the Pharmaceutical Companies' product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If the Pharmaceutical Companies receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If the Pharmaceutical Companies are found to have promoted such unapproved, or off-label, uses, they may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If the Pharmaceutical Companies cannot successfully manage the promotion of their product candidates, if approved, they could become subject to significant liability, which would materially adversely affect our business and financial condition.

Even if any of the Pharmaceutical Companies' product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

If any of the Pharmaceutical Companies' product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments. If the Pharmaceutical Companies' product candidates do not achieve an adequate level of acceptance, the Pharmaceutical Companies may not generate significant product revenue and may not become profitable. The degree of market acceptance of the Pharmaceutical Companies' product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety profile and potential advantages compared to alternative treatments;
- the approval, availability, market acceptance and reimbursement for the companion diagnostic;
- the ability to offer the Pharmaceutical Companies' medicines 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;
- ensuring uninterrupted product supply;
- the strength of marketing and distribution support;
- sufficient third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

If any of the Pharmaceutical Companies' product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, they may not generate or derive sufficient revenue from that product candidate and their financial results could be negatively impacted.

We are dependent upon third parties for a variety of functions. These arrangements may not provide us with the benefits we expect.

We rely on third parties to perform a variety of functions. We are party to numerous agreements that place substantial responsibility on clinical research organizations, contract manufacturing organizations, consultants and other service providers for the development of our product candidates. We also rely on medical and academic institutions to perform aspects of our clinical trials of product candidates. In addition, an element of our research and development strategy

has been to in-license technology and product candidates from academic and government institutions in order to minimize or eliminate investments in early research. We may not be able to enter new arrangements without undue delays or expenditures, and these arrangements may not allow us to compete successfully. Moreover, if third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct clinical trials in accordance with regulatory requirements or applicable protocols, our product candidates may not be approved for marketing and commercialization or such approval may be delayed. If that occurs, we or our collaborators will not be able, or may be delayed in our efforts, to commercialize our product candidates.

If, in the future, the Pharmaceutical Companies are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market the Pharmaceutical Companies' product candidates, the Pharmaceutical Companies may not be successful in commercializing their product candidates if and when they are approved.

The Pharmaceutical Companies do not have a sales or marketing infrastructure and have little experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved medicine for which the Pharmaceutical Companies retain sales and marketing responsibilities, they must either develop a sales and marketing organization or outsource these functions to other third parties. In the future, the Pharmaceutical Companies may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with their collaborators for, some of their product candidates if and when they are approved.

There are risks involved with both establishing the Pharmaceutical Companies' own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which the Pharmaceutical Companies recruit a sales force and establishes marketing capabilities is delayed or does not occur for any reason, they would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if the Pharmaceutical Companies cannot retain or reposition their sales and marketing personnel.

Factors that may inhibit the Pharmaceutical Companies' efforts to commercialize their medicines on their own include:

- the Pharmaceutical Companies' inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future medicines;
- the lack of complementary medicines to be offered by sales personnel, which may put them at a competitive disadvantage relative to companies with more extensive product lines;
- our inability to equip medical and sales personnel with effective materials, including medical and sales literature to help them educate physicians and other healthcare providers regarding applicable diseases and our future products;
- our inability to develop or obtain sufficient operational functions to support our commercial activities; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If the Pharmaceutical Companies enter into arrangements with third parties to perform sales, marketing, reimbursement and distribution services, their product revenue or the profitability of product revenue to them are likely to be lower than if the Pharmaceutical Companies were to market and sell any medicines that they develop themselves. In addition, the Pharmaceutical Companies may not be successful in entering into arrangements with third parties to sell and market their product candidates or may be unable to do so on terms that are favorable. The Pharmaceutical Companies likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market the Pharmaceutical Companies' medicines effectively. If the Pharmaceutical Companies do not establish sales and marketing capabilities successfully, either on their own or in collaboration with third parties, the Pharmaceutical Companies will not be successful in commercializing their product candidates.

The Pharmaceutical Companies face substantial competition, and if their competitors develop and market technologies or products more rapidly than the Pharmaceutical Companies do or that are more effective, safer or less expensive than the product candidates the Pharmaceutical Companies develop, our commercial opportunities will be negatively impacted.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. The development and commercialization of new drug products is highly competitive. The Pharmaceutical Companies face competition with respect to their current product candidates, and the Pharmaceutical Companies and their collaborators will face competition with respect to any product candidates that they or their collaborators may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which the Pharmaceutical Companies are developing their product candidates, such as pancreatic cancer and acute myelogenous leukemia amongst others. Some of these competitive products and therapies are based on scientific approaches that are similar to the Pharmaceutical Companies' approach. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

The Pharmaceutical Companies are developing most of their initial product candidates for the treatment of cancer. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy, and cancer drugs are frequently prescribed off-label by healthcare professionals. Some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic or biosimilar basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. The Pharmaceutical Companies expect that if their product candidates are approved, they will be priced at a significant premium over competitive generic or biosimilar products. This may make it difficult for them to achieve their business strategy of using their product candidates in combination with existing therapies or replacing existing therapies with their product candidates.

We and Rafael Pharmaceuticals are focused on an area known as cancer metabolism and there are also a number of product candidates in preclinical or clinical development by third parties to treat cancer by targeting cancer metabolism. These companies include large pharmaceutical companies, including, but not limited to, AstraZeneca plc, Eli Lilly and Company, Roche Holdings Inc. and its subsidiary Genentech, Inc., GlaxoSmithKline plc, Merck & Co., Novartis, Pfizer, Inc., and Genzyme, a Sanofi company. There are also biotechnology companies of various sizes that are developing therapies to target cancer metabolism, including, but not limited to, 3V Biosciences, Threshold Pharmaceuticals, Eleison Pharmaceuticals, Forma Therapeutics, Alexion Pharmaceuticals, Inc., BioMarin Pharmaceutical Inc., Calithera Biosciences, Inc., Agios Pharmaceuticals, Inc., Forma Therapeutics Holdings LLC, Shire Biochem Inc., Raze Therapeutics, Inc. and Selvita S.A.

LipoMedix faces competition from (i) other liposome and nanomedicine products in solid tumors (for example, Doxil (Janssen), Onivyde (Ipsen), Abraxane (Celgene)); (ii) other non-liposomal chemotherapeutic drugs in gastrointestinal malignancies recently developed or under development (for example, TAS-102 (Taiho) in colorectal cancer); (iii) biological therapy (including small molecule kinase inhibitors) recently developed or under development for colon cancer (for example, Regorafenib (Bayer)); (iv) immunotherapy approaches in gastrointestinal malignancies (for example, Merck USA), antibodies and/or vaccinations; and (v) other large companies such as Roche.

The Pharmaceutical Companies' competitors may develop products that are more effective, safer, more convenient or less costly than any that they are developing or that would render their product candidates obsolete or non-competitive. In addition, the Pharmaceutical Companies' competitors may discover biomarkers that more efficiently measure metabolic pathways than the Pharmaceutical Companies' methods, which may give them a competitive advantage in developing potential products. The Pharmaceutical Companies' competitors may also obtain marketing approval from the FDA or other regulatory authorities for their products more rapidly than the Pharmaceutical Companies may obtain approval, which could result in the Pharmaceutical Companies' competitors establishing a strong market position before they are able to enter the market.

Many of the Pharmaceutical Companies' competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than the Pharmaceutical Companies do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of the Pharmaceutical Companies' competitors. Smaller and other clinical stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with the Pharmaceutical Companies' in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the Pharmaceutical Companies' programs.

Even if the Pharmaceutical Companies or their collaborators are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm the Pharmaceutical Companies' business.

The commercial success of the Pharmaceutical Companies' product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of the Pharmaceutical Companies' product candidates will be paid by third-party payors, including government health administration authorities and private health coverage insurers. If coverage and reimbursement is not available, or reimbursement is available only to limited levels, the Pharmaceutical Companies, or any future collaborators, may not be able to successfully commercialize the Pharmaceutical Companies' product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or any future collaborators, to establish or maintain pricing sufficient to realize a sufficient return on the Pharmaceutical Companies' or their investments. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors, and coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require the Pharmaceutical Companies' to provide scientific and clinical support for the use of their products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, the Pharmaceutical Companies, or any future collaborators, might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenue the Pharmaceutical Companies are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder the Pharmaceutical Companies' ability or the ability of any future collaborators to recoup the Pharmaceutical Companies' or their investment in one or more product candidates, even if the Pharmaceutical Companies' product candidates obtain marketing approval.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, the Pharmaceutical Companies' ability, and the ability of any future collaborators, to commercialize any of the Pharmaceutical Companies' product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors. Third-party payors decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect the Pharmaceutical Companies' ability or that of any future collaborators to sell the Pharmaceutical Companies' product candidates profitably. These payors may not view the Pharmaceutical Companies' products, if any, as cost-effective, and coverage and reimbursement may not be available to the Pharmaceutical Companies' customers, or those of any future collaborators, or may not be sufficient to allow the Pharmaceutical Companies' products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us, or any future collaborators, to decrease the price the Pharmaceutical Companies, or they, might establish for products, which could result in lower than anticipated product revenue. If the prices for the Pharmaceutical Companies' products, if any, decrease or if governmental and other third-party payors do not provide coverage or adequate reimbursement, the Pharmaceutical Companies' prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers the Pharmaceutical Companies' costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. The Pharmaceutical Companies cannot be sure that coverage will be available for any product candidate that they, or any future collaborator, commercializes and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of the Pharmaceutical Companies' product candidates for which they, or any future collaborator, obtain marketing approval could significantly harm the Pharmaceutical Companies' operating results, the Pharmaceutical Companies' ability to raise capital needed to commercialize products and the Pharmaceutical Companies' overall financial condition.

Product liability lawsuits against the Pharmaceutical Companies or their collaborators could cause substantial liabilities and could limit commercialization of any medicines that the Pharmaceutical Companies or their collaborators may develop.

The Pharmaceutical Companies and their collaborators face an inherent risk of product liability exposure related to the testing of the Pharmaceutical Companies' product candidates in human clinical trials and will face an even greater risk if the Pharmaceutical Companies or they commercially sell any medicines that the Pharmaceutical Companies or they may develop. If the Pharmaceutical Companies or their collaborators cannot successfully defend themselves against claims that the Pharmaceutical Companies' product candidates or medicines caused injuries, the Pharmaceutical Companies could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or medicines that the Pharmaceutical Companies may develop;
- injury to the Pharmaceutical Companies' reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of the Pharmaceutical Companies' management to pursue the Pharmaceutical Companies' business strategy; and
- the inability to commercialize any medicines that the Pharmaceutical Companies may develop.

Although the Pharmaceutical Companies maintain product liability insurance coverage, it may not be adequate to cover all liabilities that the Pharmaceutical Companies may incur. We anticipate that the Pharmaceutical Companies will need to increase their insurance coverage as they continue to run clinical trials and if they successfully commercialize any medicine. Insurance coverage in this setting is increasingly expensive. The Pharmaceutical Companies may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. In addition, if one of their collaboration partners were to become subject to product liability claims or were unable to successfully defend themselves against such claims, any such collaboration partner could be more likely to terminate such relationships and therefore substantially limit the commercial potential of the Pharmaceutical Companies' products.

If the Pharmaceutical Companies fail to comply with environmental, health and safety laws and regulations, they could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of their businesses.

The Pharmaceutical Companies are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. The Pharmaceutical Companies' operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. The Pharmaceutical Companies' operations also produce hazardous waste products. The Pharmaceutical Companies generally contract with third parties for the disposal of these materials and wastes. The Pharmaceutical Companies cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from their use of hazardous materials, the Pharmaceutical Companies could be held liable for any resulting damages, and any liability could exceed their resources. The Pharmaceutical Companies also could incur significant costs associated with civil or criminal fines and penalties.

Although the Pharmaceutical Companies maintain workers' compensation insurance to cover them for costs and expenses they may incur due to injuries to their employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. The Pharmaceutical Companies may not maintain adequate insurance for environmental liability or toxic tort claims that may be asserted against them in connection with their storage or disposal of biological, hazardous or radioactive materials.

In addition, the Pharmaceutical Companies may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair the Pharmaceutical Companies' research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Current and future legislation may increase the difficulty and cost for the Pharmaceutical Companies and any future collaborators to obtain marketing approval of the Pharmaceutical Companies' other product candidates and affect the prices obtained.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of the Pharmaceutical Companies' other product candidates, restrict or regulate post-approval activities and affect the Pharmaceutical Companies' ability, or the ability of any future collaborators, to profitably sell any products for which the Pharmaceutical Companies, or they, obtain marketing approval. The Pharmaceutical Companies expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that the Pharmaceutical Companies, or any future collaborators, may receive for any approved products.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA, was signed into law. Among the provisions of the ACA of potential importance to the Pharmaceutical Companies' business and the Pharmaceutical Companies' product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, or MDRP;
- a new methodology by which rebates owed by manufacturers under the MDRP are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to now offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals for eventual publication;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians for eventual publication;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- a Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models.

Since enactment of the ACA, there have been numerous executive and legal challenges and Congressional actions to repeal and replace provisions of the law. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact the Pharmaceutical Companies' businesses.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for drug products.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for the Pharmaceutical Companies' products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for the Pharmaceutical Companies' product candidates, or additional pricing pressures.

We expect that healthcare reform measures that may be adopted in the future, could have a material adverse effect on the Pharmaceutical Companies industry generally and on our ability to maintain or increase sales of any of our product candidates that they successfully commercialize.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Risks Related to Reliance on Third Parties

The Pharmaceutical Companies currently rely, and plan to rely on in the future, third parties to conduct and support their preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, the Pharmaceutical Companies may not be able to obtain regulatory approval of or commercialize their product candidates.

The Pharmaceutical Companies have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners to conduct and support their preclinical studies and clinical trials under written agreements. The Pharmaceutical Companies will generally have to negotiate budgets and contracts with CROs, trial sites and CMOs and they may not be able to do so on favorable terms, which may result in delays to anticipated development timelines and increased costs.

We expect that the Pharmaceutical Companies will rely heavily on these third parties over the course of their preclinical studies and clinical trials, and they will control only certain aspects of their activities. As a result, the Pharmaceutical Companies will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if they were relying entirely upon their own staff. Nevertheless, the Pharmaceutical Companies are responsible for ensuring that each of their studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. The Pharmaceutical Companies and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections, both announced and unannounced, of trial sponsors, principal investigators and trial sites, and the corresponding books and records of such parties.

If the Pharmaceutical Companies or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in their clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require them to perform additional clinical trials before approving any marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of the Pharmaceutical Companies' clinical trials comply with the GCP regulations. In addition, such clinical trials must be conducted with pharmaceutical product produced under cGMP regulations and will require a large number of test patients. The Pharmaceutical Companies' failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us or them to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting the Pharmaceutical Companies' clinical trials will not be their employees and, except for remedies available to them under our agreements with such third parties, the Pharmaceutical Companies cannot control whether or not any third-party personnel will devote sufficient time and resources to the Pharmaceutical Companies' product candidates. These third parties may also have relationships with other commercial entities, including competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to clinical protocols or regulatory requirements or for other reasons, the Pharmaceutical Companies' clinical trials may be extended, delayed or terminated and they may not be able to complete development of, obtain regulatory approval of or successfully commercialize their product candidates. As a result, our financial results and the commercial prospects would be adversely affected, our costs could increase and our ability to generate revenue could be delayed.

The Pharmaceutical Companies currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or on third parties to manufacture our product candidates, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.

We do not currently own any facility that may be used as a clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture the Pharmaceutical Companies' product candidates. The Pharmaceutical Companies have not yet caused their product candidates to be manufactured on a commercial scale and may not be able to do so. We expect that our Pharmaceutical Companies will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates and they may not be able to do so on favorable terms.

The facilities used by contract manufacturers to manufacture approved products must also be approved by the FDA or other comparable foreign regulatory authorities following inspections that will be conducted after the Pharmaceutical Companies submit an application to the FDA or other comparable foreign regulatory authorities. The Pharmaceutical Companies may not control the manufacturing process of, and may be completely dependent on, contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of products and product candidates. Beyond periodic audits, the Pharmaceutical Companies have no control over the ability of their contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of any approved products or if it withdraws any approval in the future, the Pharmaceutical Companies may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially adversely affect the ability to develop, obtain regulatory approval for or market any product candidates, if approved. Similarly, if any third-party manufacturers on which the Pharmaceutical Companies will rely fail to manufacture quantities of their product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows them to achieve profitability, our business, financial condition and prospects could be materially and adversely affected.

The anticipated reliance on a limited number of third-party manufacturers exposes us to a number of risks, including the following:

- the Pharmaceutical Companies may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must inspect any manufacturers for cGMP compliance as part of our marketing application;
- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of the Pharmaceutical Companies' product candidates;
- third-party manufacturers might be unable to timely manufacture Pharmaceutical Companies' product candidates or produce the quantity and quality required to meet their clinical and commercial needs, if any;
- contract manufacturers may not be able to execute the Pharmaceutical Companies' manufacturing procedures and other logistical support requirements appropriately;
- future contract manufacturers may not perform as agreed, may not devote sufficient resources to the Pharmaceutical Companies product candidates or may not remain in the contract manufacturing business for the time required to supply clinical trials or to successfully produce, store and distribute approved products, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards and the Pharmaceutical Companies have no control over third-party manufacturers' compliance with these regulations and standards;
- the Pharmaceutical Companies may not own, or may have to share, the intellectual property rights to any improvements made by any third-party manufacturers in the manufacturing process for the Pharmaceutical Companies' product candidates;

- third-party manufacturers could breach or terminate their agreements with us or the Pharmaceutical Companies;
- raw materials and components used in the manufacturing process, particularly those for which the Pharmaceutical Companies have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and
- contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and the Pharmaceutical Companies will have no direct control over contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel.

Our business could be materially adversely affected by business disruptions caused by third-party providers that could materially adversely affect our potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of the Pharmaceutical Companies' clinical trials or the approval of any of the Pharmaceutical Companies' product candidates by the FDA, result in higher costs or adversely impact commercialization of any product candidates.

We may, in the future, form or seek collaborations or strategic alliances or enter into licensing arrangements, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We may, in the future, form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to the Pharmaceutical Companies' product candidates and any future product candidates that we or they may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view such product candidates as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with the Pharmaceutical Companies' product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;

- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of a product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into future collaboration agreements and strategic partnerships or out-license the Pharmaceutical Companies' product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Furthermore, if conflicts arise between our future corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Any delays in entering into future collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

The Pharmaceutical Companies' relationships with customers, physicians and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If they or their respective employees, independent contractors, consultants, commercial partners, or vendors violate these laws, they could face substantial penalties.

The Pharmaceutical Companies' relationships with customers, physicians, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. These laws may impact, among other things, our clinical research program, as well as our proposed and future sales, marketing, and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations designed to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive, and other business arrangements. The Pharmaceutical Companies may also be subject to federal, state and foreign laws governing the privacy and security of identifiable patient information. The U.S. healthcare laws and regulations that may affect their ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully, offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchasing, leasing, ordering or arranging for the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that may be alleged to be intended to induce prescribing, purchases or recommendations, include any payments of more than fair market value, and may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;

- federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal government programs that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government, including federal healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act and the civil monetary penalties statute;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal civil and criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, which impose requirements on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors; and

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, such reporting obligations will include payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, and certified nurse-midwives.

The Pharmaceutical Companies may also be subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope. For example, we may be subject to the following: state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, or that apply regardless of payor; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing; state and local laws requiring the registration of pharmaceutical sales and medical representatives; and state and foreign laws, such as the European Union General Data Protection Regulation, or GDPR, governing 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. Additionally, we may be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, or our arrangements with physicians, could be subject to challenge under one or more of such laws. It is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to

ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If the Pharmaceutical Companies or their respective employees, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions and/or significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of the Pharmaceutical Companies' operations, any of which could adversely affect their ability to operate their business and their results of operations. In addition, the approval and commercialization of any of the Pharmaceutical Companies' product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Risks Related to our Commercial Real Estate Business

Economic, regulatory, and socio-economic changes that impact the real estate market generally, or that could affect patterns of use of commercial office space, may cause our operating results to suffer and decrease the value of our real estate properties.

If our properties do not generate income sufficient to meet operating expenses, and capital expenditures, it may cause our operating results to suffer and decrease the value of our real estate properties. The following factors, among others, may adversely affect the operating performance and long- or short-term value of our properties:

- changes in the national, regional, and local economic climates, particularly in markets in which we have our properties;
- changes in the national, regional, and local political climates which may influence the demand for office space;
- local office submarket conditions such as changes in the supply of, or demand for, space in properties similar to those that we own within a particular area;
- changes in the patterns of office use due to technological advances which may make telecommuting more prevalent;
- the attractiveness of our properties to potential tenants;
- changes in interest rates and availability of permanent mortgage funds that may render the sale of a property difficult or unattractive;
- the financial stability of our tenants, including bankruptcies, financial difficulties or lease defaults by our tenants;
- changes in operating costs and expenses, including costs for maintenance (planned and unplanned), insurance and real estate taxes, and our ability to control rents in light of such changes;
- the need to periodically fund the costs to repair, renovate and re-lease space;
- earthquakes, tornadoes, hurricanes, pandemics and other natural disasters, civil unrest, terrorist acts or acts of war, which may result in uninsured or underinsured losses, less demand for office space and financial health uncertainty of the building's tenancy;
- the current COVID-19 pandemic has had, and any future public health crises could have, serious adverse effects on leasing and on our tenant's operations and financial conditions;
- changes in, or increased costs of compliance with, governmental regulations, including those governing usage, zoning, the environment and taxes; and
- changes in accounting standards.

Any of these factors may prevent us from maintaining the value of our real estate properties.

The geography of our real estate holdings may make us particularly susceptible to adverse economic developments in the real estate markets of those areas.

In addition to general, regional and national economic conditions, our operating results are impacted by the economic conditions in New Jersey and Israel. Any adverse economic or real estate developments in New Jersey or Israel, such as business layoffs or downsizing, industry slowdowns, relocations of businesses, changing demographics and other factors, or any decrease in demand for office space resulting from the local business climate, could adversely affect our property revenue, and hence net operating income.

The cost of complying with environmental and other governmental laws and regulations may adversely affect us.

All real property and the operations conducted on real property are subject to federal, state and local laws and regulations (including those of foreign jurisdictions) relating to environmental protection and human health and safety. These laws and regulations generally govern wastewater discharges, air emissions, the operation and removal of underground and above-ground storage tanks, the use, storage, treatment, transportation and disposal of solid and hazardous materials, and the remediation of contamination associated with disposals. We also are required to comply with various local, state and federal fire, health, life-safety and similar regulations. Some of these laws and regulations may impose joint and several liability on tenants or owners for the costs of investigating or remediating contaminated properties. These laws and regulations often impose liability whether or not the owner knew of, or was responsible for, the presence of the hazardous or toxic substances. The cost of removing or remediating could be substantial. In addition, the presence of these substances, or the failure to properly remediate these substances, may adversely affect our ability to sell or rent a property or to use the property as collateral for borrowing.

Environmental laws and regulations also may impose restrictions on the manner in which properties may be used or businesses may be operated, and these restrictions may require substantial expenditures by us. Environmental laws and regulations provide for sanctions in the event of noncompliance and may be enforced by governmental agencies or, in certain circumstances, by private parties. Third parties may seek recovery from owners of real properties for personal injury or property damage associated with exposure to released hazardous substances. Compliance with new or more stringent laws or regulations or stricter interpretations of existing laws may require material expenditures by us. For example, various federal, regional and state laws and regulations have been implemented or are under consideration to mitigate the effects of climate change caused by greenhouse gas emissions. Among other things, "green" building codes may seek to reduce emissions through the imposition of standards for design, construction materials, water and energy usage and efficiency, and waste management. We are not aware of any such existing requirements that we believe will have a material impact on our current operations. However, future requirements could increase the costs of maintaining or improving our existing properties or developing new properties.

Our costs associated with complying with the Americans with Disabilities Act may affect cash available for our operations or to pay distributions or make additional investments.

Our real properties are generally subject to the Americans with Disabilities Act of 1990, as amended. Under this Act, all places of public accommodation are required to comply with federal requirements related to access and use by disabled persons. The Act has separate compliance requirements for "public accommodations" and "commercial facilities" generally requiring that buildings and services be made accessible and available to people with disabilities. The Act's requirements could require removal of access barriers and could result in the imposition of injunctive relief, monetary penalties or, in some cases, an award of damages. We attempt to acquire properties that comply with the Act or any relevant law or regulation of a foreign jurisdiction or place the burden on the seller or other third-party, such as a tenant, to ensure compliance with those laws or regulations. However, we cannot assure you that we will be able to acquire properties or allocate responsibilities in this manner.

We may be unable to renew leases or relet space as leases expire.

If tenants decide not to renew their leases upon expiration, we may not be able to relet the space. Even if tenants do renew or we can relet the space, the terms of a renewal or new lease, taking into account among other things, the cost of improvements to the property and leasing commissions, may be less favorable than the terms in the expired leases. In addition, changes in space utilization by tenants may impact our ability to renew or relet space without the need to incur substantial costs in renovating or redesigning the internal configuration of the relevant property. If we are unable to promptly renew the leases or relet the space at similar rates or if we incur substantial costs in renewing or reletting the space, our cash flow and ability to service debt obligations and pay dividends and distributions to security holders could be adversely affected.

We face significant competition for tenants.

The leasing of real estate is highly competitive. The principal competitive factors are rent, location, services provided and the nature and condition of the property to be leased. We directly compete with all owners, developers and operators of similar space in the areas in which our properties are located. Our commercial office properties are concentrated in New Jersey. There are number of competitive office properties in which our properties are located, which may be newer or better located than our properties and could have a material adverse effect on our ability to lease office space at our properties, and on the effective rents we are able to charge.

Risks Related to Intellectual Property

If we are unable to adequately protect our proprietary technology and product candidates, if the scope of the patent protection obtained is not sufficiently broad, or if the terms of our patents are insufficient to protect our product candidates for an adequate amount of time, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our product candidates may be materially impaired.

We rely primarily upon a combination of patents, trademarks, trade secret protection, and other intellectual property rights as well as nondisclosure, confidentiality and other contractual agreements to protect the intellectual property related to our brands, product candidates, and other proprietary technologies. Our success depends on our ability to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technologies without alleged or actual infringement, misappropriation or other violation of the patents and other intellectual property rights of third parties. There have been many lawsuits and other proceedings asserting patents and other intellectual property rights in the pharmaceutical and biotechnology industries. We cannot assure you that our product candidates will not infringe existing or future third-party patents. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be applications now pending of which we are unaware and which may later result in issued patents that we may infringe by commercializing our product candidates. There may also be issued patents or pending patent applications that we are aware of, but that we think are irrelevant to our product candidates, which may ultimately be found to be infringed by the manufacture, sale, or use of our product candidates. Moreover, we may face claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. In addition, many of our product candidates have a complex structure that makes it difficult to conduct a thorough search and review of all potentially relevant third-party patents. Because we have not yet conducted a formal freedom to operate analysis for patents related to our product candidates, we may not be aware of issued patents that a third party might assert are infringed by one of our current or future product candidates, which could materially impair our ability to commercialize our product candidates. Even if we diligently search third-party patents for potential infringement by our products or product candidate, we may not successfully find patents that our products or product candidates may infringe. If we are unable to secure and maintain freedom to operate, others could preclude us from commercializing our product candidates.

The process of obtaining patent protection is expensive and time-consuming, and we may not be able to prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations or products and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. As a result, in some jurisdictions some of our products currently or in the future may not be, protected by patents. We generally apply for patents in those countries where we intend to make, have made, use, offer for sale, or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities. In addition, the actual protection afforded by a patent varies on a product-by-product basis, from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Furthermore, we cannot guarantee that any patents will be issued from any pending or future owned or licensed patent applications, or that any current or future patents will provide us with any meaningful protection or competitive advantage. Even if issued, existing or future patents may be challenged, including with respect to ownership, narrowed, invalidated, held unenforceable or circumvented, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of terms of patent protection we may have for our product candidates. Moreover, should we be unable to obtain meaningful patent coverage for clinically relevant infusion rates in jurisdictions with commercially significant markets, our ability to extend and reinforce patent protection for these product candidates in those jurisdictions may be adversely impacted, which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of terms of patent protection we may have for those product candidates. Other companies may also design around technologies we have patented, licensed or developed. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our products or practicing our own patented technology.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights may be uncertain. The standards that the United States Patent and Trademark Office, or the USPTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly. Changes in either the patent laws, implementing regulations or the interpretation of patent laws may diminish the value of our rights. The legal systems of certain countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does. In addition, many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to "work" the invention in that country, or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement.

Because patent applications in the United States, Europe and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to conceive or reduce to practice the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or pending patent applications. We can give no assurance that all of the potentially relevant art relating to our patents and patent applications has been found; overlooked prior art could be used by a third party to challenge the validity, enforceability and scope of our patents or prevent a patent from issuing from a pending patent application. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the validity, enforceability and scope of our patents in the United States, Europe and in other countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against our competitors.

Third parties may challenge any existing patent or future patent we own or license through adversarial proceedings in the issuing offices or in court proceedings, including as a response to any assertion of our patents against them. In any of these proceedings, a court or agency with jurisdiction may find our patents invalid and/or unenforceable, or even if valid and enforceable, insufficient to provide protection against competing products and services sufficient to achieve our business objectives. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or reexamination by the USPTO if a third party asserts a substantial question of patentability against any claim of a U.S. patent we own or license. The adoption of the Leahy-Smith America Invents Act, or the Leahy-Smith Act, in September 2011 established additional opportunities for third parties to invalidate U.S. patent claims, including inter partes review and post-grant review proceedings. Outside of the United States, patents we own or license may become subject to patent opposition or similar proceedings, which may result in loss of scope of some claims or the entire patent. In addition, such proceedings are very complex and expensive, and may divert our management's attention from our core business. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise

limited or expire prior to the commercialization of our products, and if we do not own or have exclusive rights to other enforceable patents protecting our products or other technologies, competitors and other third parties could market products and use processes that are substantially similar to, or superior to, ours and our business would suffer.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage. For example:

- others may be able to develop products that are similar to, or better than, ours in a way that is not covered by the claims of our patents;
- we might not have been the first to conceive or reduce to practice the inventions covered by our patents or pending patent applications;
- we might not have been the first to file patent applications for our inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own. We currently in-license certain intellectual property from third parties to be able to use such intellectual property in our products and product candidates and to aid in our research activities. In the future, we may in-license intellectual property from additional licensors. We may rely on certain of these licensors to file and prosecute patent applications and maintain, or assist us in the maintenance of, patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted diligently or in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate, or support our efforts to initiate, an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

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

Competitors may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights, trade secrets or other intellectual property, or those of our licensors. To counter infringement, misappropriation, unauthorized use or other violations, we may be required to file legal claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

We may not be able to prevent, alone or with our licensees or any future licensors, infringement, misappropriation or other violations of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party or a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from exploiting the claimed subject matter at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from exploiting its technology on the grounds that our patents do not cover such technology. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our

ability to exclude third parties from making, using, importing and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement, misappropriation or other intellectual property litigation, any award of monetary damages we receive may not be commercially valuable. 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 litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. We may not be able to detect or prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Our commercial success depends significantly on our ability to operate without infringing upon the intellectual property rights of third parties.

The biotechnology and pharmaceutical industries are subject to rapid technological change and substantial litigation regarding patent and other intellectual property rights. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates and services. Numerous third-party patents exist in the fields relating to our products and services, and it is difficult for industry participants, including us, to identify all third-party patent rights relevant to our product candidates, services and technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, because some patent applications are maintained as confidential for a certain period of time, we cannot be certain that third parties have not filed patent applications that cover our product candidates, services and technologies. Therefore, it is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies for our product candidates, or processes, or to obtain licenses or cease certain activities.

Patents could be issued to third parties that we may ultimately be found to infringe. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing products using our technology. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are determined to be held invalid or unenforceable. Our failure to obtain or maintain a license to any technology that we require to develop or commercialize our current and future product candidates, may materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

From time to time, we may be party to, or threatened with, litigation or other proceedings with third parties, including non-practicing entities, who allege that our product candidates, components of our product candidates, services, and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our product candidates, or processes do not infringe those third parties' patents;
- we or our collaborators may participate at substantial cost in International Trade Commission proceedings to abate importation of third-party products that would compete unfairly with our products;

- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or product candidates, infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings;
- if third parties initiate litigation or other proceedings, including inter partes reviews, oppositions or other similar agency proceedings, seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their products, services, or technologies do not infringe our patents or patents licensed to us, we will need to defend against such proceedings;
- we may be subject to ownership disputes relating to intellectual property, including disputes arising from conflicting obligations of consultants or others who are involved in developing our product candidate; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or product candidates infringe or misappropriate its patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

These lawsuits and proceedings, regardless of merit, are time-consuming and expensive to initiate, maintain, defend or settle, and could divert the time and attention of managerial and technical personnel, which could materially adversely affect our business. Any such claim could also force use to do one or more of the following:

- incur substantial monetary liability for infringement or other violations of intellectual property rights, which we may have to pay if a court decides that the product candidate, service, or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay up to treble damages and the third party's attorneys' fees;
- pay substantial damages to our customers or end users to discontinue use or replace infringing technology with non-infringing technology;
- stop manufacturing, offering for sale, selling, using, importing, exporting or licensing the product or technology incorporating the allegedly infringing technology or stop incorporating the allegedly infringing technology into such product, service, or technology;
- obtain from the owner of the infringed intellectual property right a license, which may require us to pay substantial upfront fees or royalties to sell or use the relevant technology and which may not be available on commercially reasonable terms, or at all;
- redesign our product candidates, services, and technology so they do not infringe or violate the third party's intellectual property rights, which may not be possible or may require substantial monetary expenditures and time;
- enter into cross-licenses with our competitors, which could weaken our overall intellectual property position;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others;
- find alternative suppliers for non-infringing products and technologies, which could be costly and create significant delay; or
- relinquish rights associated with one or more of our patent claims, if our claims are held invalid or otherwise unenforceable.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology.

Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows.

In addition, we may indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our product candidates. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors, or may be required to obtain licenses for the product candidates, or services they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products or services.

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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a material adverse effect on the price of our common stock. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. The occurrence of any of these events may have a material adverse effect on our business, results of operation, financial condition or cash flows.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Because we expect to rely on third parties to manufacture our product candidates, and we expect to continue to collaborate with third parties on the development of our product candidates, we must, at times, share trade secrets with them. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them prior to disclosing our proprietary information, such as our consultants and vendors, or our former or current employees. These agreements typically limit the rights of third parties to use or disclose our confidential information, including our trade secrets. We also enter into confidentiality and invention assignment agreements with our employees and consultants. Despite these efforts, however, any of these parties may breach the agreements and disclose our trade secrets and other unpatented or unregistered proprietary information, and once disclosed, we are likely to lose trade secret protection. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to enforce trade secret protection. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business, operating results and financial condition. Additionally, we cannot be certain that competitors will not gain access to our trade secrets and other proprietary confidential information or independently develop substantially equivalent information and techniques.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future product candidates and processes.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries involves both technological and legal complexity, and is therefore costly, time consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith Act was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switched the United States patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had

conceived or reduced to practice the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

The United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. We partner with a number of universities, including the University of Iowa and the University of Texas Southwestern Medical Center, with respect to certain of our research, development and manufacturing. While it is our policy to avoid engaging our university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

If we do not obtain patent term extensions in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation with respect to our product candidates, thereby potentially extending the term of marketing exclusivity for such product candidates, our business may be harmed.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, which permits a patent term extension of up to a maximum of five years beyond the normal expiration of the patent if the patent is eligible for such an extension under the Hatch-Waxman Act as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request.

We may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request and the patent term may still expire before or shortly after we receive FDA marketing approval. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We have not yet registered trademarks for a commercial trade name for our product candidate(s), including in the United States or elsewhere. During trademark registration proceedings, our trademark application(s) may be rejected. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties can oppose pending trademark applications and seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our product candidate(s) in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential partners or customers in our markets of interest. In addition, third parties have used trademarks similar and identical to our trademarks in foreign jurisdictions, and have filed or may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

We may not be able to adequately protect our intellectual property rights throughout the world.

Certain of our key patent families have been filed in the United States, as well as in numerous jurisdictions outside the United States. However, our intellectual property rights in certain jurisdictions outside the United States may be less robust. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. For example, the requirements for patentability may differ in certain countries, particularly developing countries, and we may be unable to obtain issued patents that contain claims that adequately cover or protect our current or future product candidates. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market current or future product candidates. Consequently, we may not be able to prevent third parties from practicing our technology in all countries outside the United States, or from selling or importing products made using our technology in and into those other jurisdictions where we do not have intellectual property rights. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our technology.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our products. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates, and services. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates, and services.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign products, product candidates, or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan, and the protection patents afford is limited. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Even if patents covering our product candidates are obtained, once the patent life has expired for patents covering a product or product candidate, we may be open to competition from competitive products and services. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

While we seek broad coverage under our existing patent applications, there is always a risk that an alteration to products or processes may provide sufficient basis for a competitor to avoid infringing our patent claims. In addition, patents, if granted, expire and we cannot provide any assurance that any potentially issued patents will adequately protect our product candidates. Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether.

In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology, but that are not covered by the claims of the patents that we own or control, assuming such patents have issued or do issue;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensors or any future 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 advantage, 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;
- third parties performing manufacturing or testing for us using our product candidates, including technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We do and may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our licensors, competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims.

Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or product candidates. Such a license may not be available on commercially reasonable terms or at all. 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, and could result in customers seeking other sources for the technology, or in ceasing from doing business with us.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while we typically require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. To the extent that we fail to obtain such assignments, such assignments do not contain a self-executing assignment of intellectual property rights or such assignment agreements are breached, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property and this may interfere with our ability to capture the commercial value of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. We may be subject to claims that former collaborators or other third parties have an ownership interest in our patents or other intellectual property. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time-consuming. If we are unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

We may not be successful in obtaining necessary intellectual property rights to future products through acquisitions and in-licenses.

Although we intend to develop products and technology through our own internal research, we may also seek to acquire or in-license technologies to grow our product offerings and technology portfolio. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any such products or technology from third parties on commercially reasonable terms or at all. In that event, we may be unable to develop or commercialize such products or technology. We may also be unable to identify products or technology that we believe are an appropriate strategic fit for our Company and protect intellectual property relating to, or necessary for, such products and technology.

The in-licensing and acquisition of third-party intellectual property rights for product candidates is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for products that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to additional technologies or products, our business, financial condition, results of operations and prospects for growth could suffer.

In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for products and technologies that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for products or technology on terms that would allow us to make an appropriate return on our investment.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

Public health threats could have an adverse effect on the Company's operations and financial results.

In 2020, a strain of novel coronavirus disease, COVID-19, was declared a pandemic and spread across the world, including throughout the United States, Europe and Asia. The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended.

The impacts on the operations and specifically the ongoing clinical trials of the Pharmaceutical Companies have been actively managed by respective pharmaceutical management teams who have worked closely with the appropriate regulatory agencies to continue clinical trial activities with as minimal impact as possible, including receiving waivers for certain clinical trial activities from the respective regulatory agencies to continue the studies.

In the earlier days of the pandemic's impact, Rafael Pharmaceuticals experienced certain delays in enrollment in certain of clinical trials. We believe, however, that those trials' enrollment goals were ultimately attained in a timely manner.

We have implemented a number of measures to protect the health and safety of our workforce including a mandatory work-from-home policy for our workforce who can perform their jobs from home as well as restrictions on business travel and workplace and in-person meetings.

As a result of the COVID-19 pandemic, we may experience further disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- risk that participants enrolled in our clinical trials or related staff will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA, which may impact approval timelines;

- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing or supply shortages, production slowdowns, global shipping delays or stoppages and disruptions in delivery systems;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.
- refusal of the FDA to accept data from clinical trials in affected geographies;
- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our business continuity plans; and
- delays or difficulties with equity offerings due to disruptions and uncertainties in the securities market

The COVID-19 pandemic could also negatively impact our real estate business in a number of ways, including:

- the financial condition of our tenants and their ability or willingness to pay rent in full on a timely basis;
- the impact on rents and demand for office and retail space;
- a complete or partial closure of operations resulting from government action;
- the impact of new regulations or norms on physical space needs and expectations;
- the effectiveness of governmental measures aimed at slowing and containing the spread;
- the extent and terms associated with governmental relief programs;
- the ability of debt and equity markets to function and provide liquidity;
- the ability to avoid delays or cost increases associated with building materials or construction services necessary for development, redevelopment and tenant improvements; and
- our tenants' ability to ensure business continuity in the event a continuity of operations plan is not effective or improperly implemented.

Due to both known and unknown risks, including quarantines, closures and other restrictions resulting from the outbreak, our operations and those of our holdings may be adversely impacted. Additionally, as there is an evolving nature to the COVID-19 situation, we cannot reasonably assess or predict at this time the full extent of the negative impact that the COVID-19 pandemic may have on our business, financial condition, results of operations and cash flows. The impact will depend on future developments such as the ultimate duration and the severity of the spread of the COVID-19 pandemic in the U.S. and globally, the effectiveness of federal, state, local and foreign government actions on mitigation and spread of COVID-19, the pandemic's impact on the U.S. and global economies, changes in our customers' behavior emanating from the pandemic and how quickly we can resume our normal operations, among others. For all these reasons, we may incur expenses or delays relating to such events outside of our control, which could have a material adverse impact on our business.

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

The requirements of being a public company may strain our resources, result in more litigation and divert management's attention.

As a public company, we are and will continue to be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of Nasdaq and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control over financial reporting on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We have invested and intend to continue to invest in resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers. By disclosing information in filings required of us as a public company, our business and financial condition will continue to become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

If we fail to implement and maintain an effective system of internal controls, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, or any subsequent testing by our independent registered public accounting firm, may

reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an emerging growth company until the end of the fiscal year ending after the fifth anniversary of our initial registration statement filed related to our Spin-Off from IDT, or such earlier time that we are no longer an emerging growth company and, if we do, the information that we provide stockholders may be different than you might receive from other public companies in which you hold equity. We would cease to be an emerging growth company if we have more than $1.07 billion in annual revenue, have more than $700 million in market value of our shares of common stock held by non-affiliates, or issue more than $1.0 billion of non-convertible debt over a three-year period.

An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential delisting from the stock exchange on which we list, regulatory investigations and civil or criminal sanctions.

The relationships between Howard S. Jonas and IDT Corporation, Genie Energy and Rafael Pharmaceuticals, Inc. could conflict with our stockholders' interests.

Howard S. Jonas, Chairman of our Board of Directors and our former Chief Executive Officer is also the chairman of IDT Corporation and Chairman of the Board of Genie and holds certain direct and indirect interests in Rafael Pharmaceuticals in addition to his interests through ownership of our common stock. These relationships may cause a conflict of interest with our stockholders.

Insurance policies are expensive and protect us only from some business risks, which leaves us exposed to uninsured liabilities.

Some of the insurance policies we currently maintain include general liability, employment practices liability, property, product liability, workers' compensation, umbrella, and directors' and officers' insurance. These policies may not adequately cover all categories of risk that our business may encounter.

Any additional product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any of the Pharmaceutical Companies' product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of any product candidates we develop. We may not carry adequate specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do

not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our and the Pharmaceutical Companies' businesses effectively.

Despite the implementation of security measures, our and the Pharmaceutical Companies' internal computer systems and those of third parties with which we and the Pharmaceutical Companies contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our and the Pharmaceutical Companies' operations, and could result in a material disruption of their clinical and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our and the Pharmaceutical Companies' regulatory approval efforts and significantly increase their 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 or the Pharmaceutical Companies' data or applications, or inappropriate disclosure of confidential or proprietary information, we and the Pharmaceutical Companies could incur liability and their product research, development and commercialization efforts could be delayed.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

Risks Related to the Merger

The parties may not realize the anticipated benefits and cost savings of the Merger.

While we and Rafael Pharmaceuticals will continue to operate independently until the completion of the Merger, the success of the Merger will depend, in part, on our and Rafael Pharmaceuticals' ability to realize the anticipated benefits and cost savings from combining our and Rafael Pharmaceutical's businesses. The parties' ability to realize these anticipated benefits and cost savings is subject to certain risks, including, among others:

- the parties' ability to successfully combine their respective businesses;
- the risk that the combined businesses will not perform as expected;
- the extent to which the parties will be able to realize the expected synergies, which include realizing potential savings from re-assessing priority assets and aligning investments, eliminating duplication and redundancy, adopting an optimized operating model between both companies and leveraging scale, and creating value resulting from the combination of our and Rafael Pharmaceuticals' businesses;
- the possibility that the combined company will not achieve the free cash flow that the parties have projected;
- the reduction of cash available for operations and other uses and the incurrence of indebtedness to finance the Merger;
- the assumption of our known and unknown liabilities, including potential tax and employee-related liabilities; and
- the possibility of costly litigation challenging the Merger.

If we and Rafael Pharmaceuticals are not able to successfully integrate their businesses within the anticipated time frame, or at all, the anticipated cost savings, synergies operational efficiencies and other benefits of the Merger may not be realized fully or may take longer to realize than expected, and the combined company may not perform as expected.

Failure to complete the Merger could negatively impact our stock price and the future business and financial results.

The parties' respective obligations to complete the Merger are subject to the satisfaction or waiver of a number of conditions set forth in the Merger Agreement. There can be no assurance that the conditions to completion of the Merger will be satisfied or waived or that the Mergers will be completed. If the Merger is not completed for any reason, our and Rafael Pharmaceuticals' ongoing businesses may be materially and adversely affected and, without realizing any of the benefits of having completed the Merger, we and Rafael Pharmaceuticals would be subject to a number of risks, including the following:

- we may experience negative reactions from the financial markets, including negative impacts on trading prices of our Class B Common Stock and from its customers, vendors, regulators and employees;
- we may be required to pay certain expenses incurred in connection with the Merger, whether or not the Merger is completed;
- the Merger Agreement places certain restrictions on the operation of our business prior to the closing of the Merger, and such restrictions, the waiver of which is subject to the consent of the other parties, may prevent us from making certain acquisitions, taking certain other specified actions or otherwise pursuing business opportunities during the pendency of the Merger that we would have made, taken or pursued if these restrictions were not in place; and
- matters relating to the Merger (including integration planning) will require substantial commitments of time and resources by our management and the expenditure of significant funds in the form of fees and expenses, which would otherwise have been devoted to day-to-day operations and other opportunities that may have been beneficial to us as an independent company.

In addition, each of us and Rafael Pharmaceuticals could be subject to litigation related to any failure to complete the Merger or related to any proceeding to specifically enforce our or Rafael Pharmaceuticals' obligations under the Merger Agreement. If any of these risks materialize, they may materially and adversely affect our business, financial condition, financial results and stock prices.

For additional risk factors related to the Merger, please see the Risk Factors section of our Registration Statement on Form S-4 (File No. 333-259524) filed with the SEC on September 14, 2021.

Risks Related to Ownership of our Common Stock

We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock.

We have never declared or paid any cash dividends on our equity securities. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of our common stock, which is not certain.

Eight trusts for the benefit of sons and daughters of Howard S. Jonas, our former Chief Executive Officer and Chairman of the Board of Directors, hold shares that, in the aggregate, represent more than a majority of the combined voting power of our outstanding capital stock, which may limit the ability of other stockholders to affect our management.

Eight trusts for the benefit of sons and daughters of Howard S. Jonas, or the Trusts, our former Chief Executive Officer and Chairman of the Board, collectively have voting power over 5,126,612 shares of our common stock (which includes 787,163 shares of our Class A common stock, which are convertible into shares of our Class B common stock on a 1-for-1 basis, and 4,339,449 shares of our Class B common stock), representing approximately 69% of the combined voting power of our outstanding capital stock, as of July 31, 2021. In addition, as of July 31, 2021, Howard S. Jonas holds 101,254 shares of our Class B common stock. Each of the Trusts has a different, independent trustee. We are not aware of any voting agreement between or among any of the Trusts and/or Howard S. Jonas, but if such a voting agreement or other similar arrangement exists or were to be consummated, or if all or several or all of the Trusts

were to act in concert, certain or all of the Trusts and/or Howard S. Jonas would be able to control matters requiring approval by our stockholders, including the election of all of the directors and the approval of significant corporate matters, including any merger, consolidation or sale of all or substantially all of our assets. As a result, the ability of any of our other stockholders to influence our management may be limited.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Outstanding shares of our common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act, or to the extent that such shares have already been registered under the Securities Act and are held by non-affiliates of ours. Moreover, holders of a substantial number of shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also have registered all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (a) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (b) the last day of the fiscal year following the fifth anniversary of the date of the completion of our Spin-Off (July 31, 2023), (c) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years, or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404;
- an exemption from compliance with the requirement of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. In particular, we have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our shares price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We intend to take advantage of the extended transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are considered a "smaller reporting company." We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced 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 our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock prices may be more volatile.

General Risk Factors

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisition opportunities and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. In addition, if we undertake acquisitions or pursue collaborations in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Investors may suffer dilution.

We may engage in equity financing to fund our future operations and growth or issue equity securities in commercial or other transactions. If we raise additional funds by issuing equity securities, or issue equity securities for other purposes, stockholders may experience significant dilution of their ownership interest (both with respect to the percentage of total securities held, and with respect to the book value of their securities) and such securities may have rights senior to those of the holders of our common stock. In addition. if we do not provide our Pharmaceutical Companies with the capital they require, they may seek capital from other sources, which would result in dilution and possible subordination or other diminution in value of our interests in those companies.

The trading price of the shares of our Class B common stock is likely to remain volatile, and purchasers of our Class B common stock could incur substantial losses.

Our stock price is likely to remain volatile. The stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their Class B common stock at or above the price paid for the shares. The market price for our Class B common stock may be influenced by many factors, including:

- actual or anticipated variations in quarterly operating results;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- stock market price and volume fluctuations of other publicly traded companies and, in particular, those that operate in the real estate or pharmaceutical industries;
- announcements by us or our competitors of the results of clinical trials, new product or service offerings, or significant acquisitions;
- strategic collaborations or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- additions or departures of key personnel; and
- sales of our common stock, including sales by our directors and officers or specific stockholders. In addition, in the past, stockholders have initiated class action lawsuits against companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will rely in part on the research and reports that equity research analysts may publish about us and our business. We do not currently have analyst coverage and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts or others downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal executive office is located in 520 Broad Street, Newark, New Jersey.

Barer Institute's total annual rent at 3675 Market Street in Philadelphia, Pennsylvania, is approximately $193,000 for a private lab and office.

LipoMedix has a Research and Services Agreement with Shaare Zedek Scientific Ltd. by which laboratory space at Shaare Zedek Medical Center is used for R&D activities. This agreement is conditioned to grant support for the Shaare Zedek Nano-Oncology research center either directly from LipoMedix or indirectly through the Israel Innovation Authority Fund (Israel Chief Scientist Office). This arrangement has been in place since 2012, and the grant support is negotiable and renewed on an annual basis. However, there can be no guarantees that Shaare Zedek will continue this agreement in the future.

LipoMedix leases an Administrative Office in Giv'at Ram Hi-Tech Park from the Hebrew University. Rent is $3,600, annually, and the lease agreement runs through 2021.

Levco has a Sponsored Research Agreement with Shaare Zedek Scientific Ltd. by which laboratory space at Shaare Zedek Medical Center is used for R&D activities. Levco shall fund the research program in exchange for a license to the results thereof and all intellectual property arising in connection with the research.

See Item 1 — "Real Estate" for a discussion of properties held by the Company for investment purposes and Item 8 — "Financial Statements and Supplemental Data," for a detailed listing of such facilities.

Item 3. Legal Proceedings.

On December 31, 2019, an employee of the Company filed a complaint in connection with the incident that led to the OSHA inspection noted above for personal injuries against the Company and other parties in the New Jersey Supreme Court for an incident that took place on January 31, 2019 at 520 Broad Street, Newark, New Jersey. The Company intends to vigorously defend this matter. The loss is considered remote and no accrual has been recorded.

The Company may from time to time be subject to legal proceedings that may arise in the ordinary course of business. Although there can be no assurance in this regard, other than noted above, the Company does not expect any of those legal proceedings to have a material adverse effect on the Company's results of operations, cash flows or financial condition.

Item 4. Mine Safety Disclosures.

Not applicable.

Part II

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

PRICE RANGE OF COMMON STOCK

Our Class B common stock trades on the New York Stock Exchange under the symbol "RFL." Trading commenced on the NYSE American on March 27, 2018 and on November 21, 2019, the Company commenced trading on the New York Stock Exchange.

On October 11, 2021, there were 300 holders of record of our Class B common stock and eight holders of record of our Class A common stock. All shares of Class A common stock are beneficially owned by Howard Jonas. The number of holders of record of our Class B common stock does not include the number of persons whose shares are in nominee or in "street name" accounts through brokers. On October 15, 2021, the last sales price reported on the NYSE for the Class B common stock was $30.54 per share.

We do not anticipate paying dividends on our common stock until we achieve sustainable profitability (after satisfying all of our operational needs) and retain certain minimum cash reserves. Distributions will be subject to the need to retain earnings for investment in growth opportunities or the acquisition of complementary assets. The payment of dividends in any specific period will be at the sole discretion of our Board of Directors.

The information required by Item 201(d) of Regulation S-K will be contained in our Proxy Statement for our Annual Stockholders Meeting, which we will file with the Securities and Exchange Commission within 120 days after July 31, 2021, and which is incorporated by reference herein.

Performance Graph of Stock

We are a smaller reporting company as defined by Rule 12b-2 of the Securities and Exchange Act of 1934 and are not required to provide the information under this item.

Issuer Repurchases of Equity Securities

None.

Item 6. [Reserved].

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including statements that contain the words "believes," "anticipates," "expects," "plans," "intends" and similar words and phrases. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from the results projected in any forward-looking statement. In addition to the factors specifically noted in the forward-looking statements, other important factors, risks and uncertainties that could result in those differences include, but are not limited to, those discussed under Item 1A to Part I "Risk Factors" in this Annual Report. The forward-looking statements are made as of the date of this Annual Report, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements. Investors should consult all of the information set forth in this report and the other information set forth from time to time in our reports filed with the Securities and Exchange Commission pursuant to the Securities Act of 1933 and the Securities Exchange Act of 1934, including our reports on Forms 10-Q and 8-K.

The following discussion should be read in conjunction with the Consolidated Financial Statements and Notes thereto included in Item 8 of this Annual Report.

Overview

Rafael Holdings, Inc. (NYSE:RFL), ("Rafael Holdings", "we" or the "Company"), a Delaware corporation, holds interests in clinical and early stage pharmaceutical companies, including an investment in Rafael Pharmaceuticals, Inc., or Rafael Pharmaceuticals, a late-stage cancer metabolism-based therapeutics company, its preclinical cancer metabolism research institute, the Barer Institute ("Barer"), and commercial real estate assets. The Company focuses its efforts on funding, discovering and developing novel cancer therapies through its continued investment in Rafael Pharmaceuticals, the creation of the Barer Institute in 2019 and continued investments in advancing its preclinical portfolio as well as investments in other early-stage oncology companies with a goal of building a focused cancer metabolism therapeutics company with the potential to improve and extend the lives of patients. On June 17, 2021, the Company entered into a merger agreement to acquire full ownership of Rafael Pharmaceuticals in exchange for issuing Company Class B common stock to the other stockholders of Rafael Pharmaceuticals. We expect to bring the merger to a vote of our stockholders this calendar year.

The Company's investment in Rafael Pharmaceuticals includes preferred and common equity interests and a warrant to purchase additional equity (the "Warrant"). In 2019, the Company established Barer, as an early-stage small molecule research institute focused on developing a pipeline of novel therapeutic compounds, including compounds to regulate cancer metabolism with potentially broader application in other indications beyond cancer. Barer is led by a team of scientists and academic advisors considered to be among the leading experts in cancer metabolism, chemistry, and drug development. In addition to its own internal discovery efforts, Barer is pursuing collaborative research agreements and in-licensing opportunities with leading scientists from top academic institutions. Farber Partners, LLC ("Farber"), was formed around one such agreement with Princeton University's Office of Technology Licensing for technology from the laboratory of Professor Joshua Rabinowitz, in the Department of Chemistry, Princeton University, for an exclusive worldwide license to its SHMT (serine hydroxymethyltransferase) inhibitor program. The Company also holds a majority equity interest in LipoMedix Pharmaceuticals Ltd. ("LipoMedix"), a clinical stage oncological pharmaceutical company based in Israel. In addition, the Company has recently initiated efforts to develop other early stage pharmaceutical ventures including Levco Pharmaceuticals Ltd. ("Levco"), an Israeli company, established to partner with Dr. Alberto Gabizon and a leading institution in Israel on the development of novel compounds for cancer.

The Company's commercial real estate holdings consist of a building at 520 Broad Street in Newark, New Jersey that serves as headquarters for the Company and certain other entities and tenants and an associated 800-car public garage, and a portion of a building in Israel. The Company sold other real estate holdings in 2020.

On June 17, 2021, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with RH Merger I, Inc., a Delaware corporation and a wholly-owned subsidiary of Holdings, RH Merger II, LLC, a Delaware limited liability company and a wholly-owned subsidiary of Holdings and Rafael Pharmaceuticals, Inc., a Delaware corporation ("Rafael Pharmaceuticals" or "Pharma"), whereby Pharma will become our wholly-owned limited liability subsidiary.

We filed a preliminary proxy statement/prospectus with the SEC on September 14, 2021.

Business Update — COVID-19

In December 2019, a new coronavirus, now known as COVID-19, which has proved to be highly contagious, has since spread around the globe. We actively monitor the outbreak and its potential impact on our operations and those of our holdings.

The impacts on our and our affiliates' operations and specifically the ongoing clinical trials of our pharmaceutical holdings have been actively managed by respective pharmaceutical management teams who have worked closely with the appropriate regulatory agencies to continue clinical trial activities with as minimal impact as possible including receiving waivers for certain clinical trial activities from the respective regulatory agencies to continue the studies.

Although partially mitigated recently, there remains a general degree of uncertainty in the national commercial real estate market based on the COVID-19 pandemic and as a result there is a potential impact to the value of our real estate portfolio as well as efforts to monetize those assets.

We have implemented a number of measures to protect the health and safety of our workforce, including a voluntary work-from-home policy for our workforce who can perform their jobs from home, as well as restrictions on business travel.

Due to both known and unknown risks, including quarantines, closures and other restrictions resulting from the outbreak, operations and those of our holdings may be adversely impacted. Additionally, as there is an evolving nature to the COVID-19 situation, we cannot reasonably assess or predict at this time the full extent of the negative impact that the COVID-19 pandemic may have on our business, financial condition, results of operations and cash flows. The impact will depend on future developments such as the ultimate duration and the severity of the spread of the COVID-19 pandemic in the U.S. and globally, the effectiveness of federal, state, local and foreign government actions on mitigation and spread of COVID-19, the pandemic's impact on the U.S. and global economies, changes in our customers' behavior emanating from the pandemic and how quickly we can resume our normal operations, among others. For all these reasons, we may incur expenses or delays relating to such events outside of our control, which could have a material adverse impact on our business.

Results of Operations

Our business consists of two reportable segments — Pharmaceuticals and Real Estate. We evaluate the performance of our Pharmaceuticals segment based primarily on research and development efforts and results of clinical trials and our Real Estate segment based primarily on results of operations. Accordingly, the income and expense line items below loss from operations are only included in the discussion of consolidated results of operations.

Pharmaceuticals Segment

Our consolidated expenses for our Pharmaceuticals segment were as follows:

	Year Ended July 31,		Change	
	2021	2020	$	%
		(in thousands)		
Selling, general and administrative	$ (8,153)	$ (419)	$ (7,734)	(1,846)%
Research and development	(4,907)	(2,391)	(2,516)	105%
Depreciation and amortization	(1)	(1)	—	—%
Impairment – Altira	(7,000)	—	(7,000)	(100)%
Loss From Operations	$ (20,061)	$ (2,811)	$ (17,250)	614%

To date, the Pharmaceuticals segment has not generated any revenues. The entirety of the expenses in the Pharmaceuticals segment relates to the activities of LipoMedix, Barer, Levco, Farber, and Rafael Medical Devices. For the years ended July 31, 2021 and 2020, we held a 100% interest in Barer, a 68% and 67% interest, respectively, in LipoMedix, a 95% and 0% interest in Levco, respectively, and a 93% and 0% interest in Farber, respectively. Rafael Medical Devices is a newly created entity during the year ended July 31, 2021, in which we have a 100% interest.

Selling, general and administrative expenses. Selling, general and administrative expenses consist mainly of payroll, benefits, facilities, consulting and professional fees. The increase in selling, general and administrative expenses in the fiscal year ended July 31, 2021 compared to the fiscal year ended July 31, 2020 is primarily due to non-cash share-based compensation expense of approximately $5.5 million for awards issued to our newly hired CEO and Chief Commercial Officer ("CCO") and payroll of approximately $2.4 million pertaining to our newly hired CEO and CCO, partially offset by the expenses incurred to the founders of LipoMedix in 2020.

Research and development expenses. Research and development increased for the fiscal year ended July 31, 2021, due to increased activity at Barer, Levco, Farber, and Rafael Medical Devices.

Impairment expense — Altira. The Company recorded an impairment loss of $7 million related to the Company's additional investment in 33.333% of Altira for the year ended July 31, 2021.

Real Estate Segment

Our consolidated income and expenses for our Real Estate segment were as follows:

	Year Ended July 31,		Change	
	2021	2020	$	%
	(in thousands)			
Rental – Third Party	$ 890	$ 1,516	$ (626)	(41)%
Rental – Related Party	2,099	2,082	17	1%
Parking	502	832	(330)	(40)%
Other – Related Party	480	480	—	—%
Selling, general and administrative	(12,263)	(8,699)	(3,564)	(41)%
Depreciation and amortization	(1,459)	(1,865)	406	22%
Loss From Operations	$ (9,751)	$ (5,654)	$ (4,097)	72%

Revenues. Rental and Parking revenues decreased by approximately $0.9 million in the fiscal year ended July 31, 2021, compared to the prior fiscal year, primarily due to the sale of the building in Piscataway and the related reduced rental income, as well as a decrease in parking as many customers who were utilizing the parking garage are now working from home due to COVID-19.

Selling, general and administrative expenses. Selling, general and administrative expenses consist mainly of payroll, benefits, facilities, consulting and professional fees. The increase in selling, general and administrative expenses in the fiscal year ended July 31, 2021 compared to the fiscal year ended July 31, 2020 is primarily due to increased legal and professional fees of approximately $1.6 million, increased real estate tax costs of approximately $0.7 million, an approximate $0.5 million increase in directors and officers liability insurance, and an increase in non-cash share-based compensation expense of approximately $0.4 million for awards issued to Management level employees.

Depreciation and amortization expenses. Depreciation and amortization expenses decreased in the fiscal year ended July 31, 2021 compared to the prior fiscal year due to the sale of the building in Piscataway, New Jersey.

Consolidated Operations

Our consolidated income and expense line items below income from operations were as follows:

	Year Ended July 31,		Change	
	2021	2020	$	%
	(in thousands)			
Loss from operations	$ (29,812)	$ (8,465)	$ (21,347)	252%
Interest expense, net	(102)	(32)	(70)	219%
Net loss resulting from foreign exchange transactions	—	(5)	5	(100)%
Gain on sale of building	749	—	749	100%
Impairment of investments – Other Pharmaceuticals	(724)	(799)	75	(9)%
Unrealized gain on investments – Hedge Funds	4,758	2,385	2,373	99%
Loss before income taxes	(25,131)	(6,916)	(18,215)	(263)%
Provision for income taxes	(18)	(29)	11	(38)%
Impairment of equity method investment in Altira	—	(4,000)	4,000	(100)%
Equity in earnings of RP Finance	383	192	191	99%
Consolidated net loss	(24,766)	(10,753)	(14,013)	130%
Net loss attributable to noncontrolling interests	(222)	(338)	116	(34)%
Net loss attributable to Rafael Holdings, Inc.	$ (24,544)	$ (10,415)	$ (14,129)	136%

Interest expense, net. Interest (expense), net for the year ended July 31, 2021 totaled approximately $2 thousand of interest income and $104 thousand of interest expense. Interest (expense) income, net for the year ended July 31, 2020 totaled approximately $52 thousand of interest income and $84 thousand of interest expense. Interest expense of $104 is primarily related to $64 thousand of accrued interest and $28 thousand of amortization of debt issuance costs related to the Note Payable entered into in July 2021. The increase of interest (expense) income, net is due to interest incurred on the $15,000,000 Note Payable entered into in July 2021.

Net loss resulting from foreign exchange transactions. Net loss resulting from foreign exchange transactions is comprised entirely from changes in movements in New Israeli Shekels relative to the U.S. Dollar.

Gain on sale of building. In August 2020, we sold a building located in Piscataway, New Jersey, and recognized a gain on the sale of approximately $749 thousand.

Impairment of investments — Other Pharmaceuticals. We recorded an impairment loss of $724 thousand related to our investment using the measurement alternative for the year ended July 31, 2021.

Impairment of equity method investment of Altira. The Company recorded an impairment loss of $0 and $4 million related to the Company's initial investment in 33.333% of Altira for the years ended July 31, 2021 and 2020, respectively.

Unrealized gain on investments — Hedge Funds. We recorded unrealized gains of approximately $4.8 million and $2.4 million for the years ended July 31, 2021 and 2020, respectively, due to gains on our Hedge Funds portfolio.

Provision for income taxes. During the years ended July 31, 2021 and 2020, there was a provision for income taxes for $18 thousand and $29 thousand, respectively.

Equity in earnings of RP Finance. We recognized approximately $383 thousand and $192 thousand in income from our ownership interests of 37.5% in RP Finance for the years ended July 31, 2021 and 2020, respectively, related to our equity method investment in RP Finance.

Net loss attributable to noncontrolling interests. The change in the net loss attributable to noncontrolling interests was due to the losses related to noncontrolling interests held in LipoMedix, Farber, and Levco for the year ended July 31, 2021.

Liquidity and Capital Resources

General

As of July 31, 2021, we had cash and cash equivalents of $7.9 million in addition to our investment in a hedge fund valued at $5.3 million.

In August 2021, we completed a securities purchase agreement and in which we sold 2,945,986 shares of Class B Common Stock for aggregate net proceeds of $97.8 million, after deducting transaction costs of $6.4 million.

We expect that the balance of our cash and cash equivalents as of July 31, 2021, in addition to our balance in Investments — Hedge Funds and the proceeds of the August 2021 financing, to be sufficient to meet Rafael Holdings' obligations for at least the next 12 months from the issuance of these consolidated financial statements.

On July 9, 2021, the Company, as guarantor, Rafael Holdings Realty, Inc., a wholly-owned subsidiary of the Registrant ("Realty"), as pledgor, and Broad-Atlantic Associates, LLC, a wholly-owned subsidiary of Realty (the "Borrower," and together with the Company and Realty, the "Borrower Parties"), as borrower, entered into a loan agreement (the "Loan Agreement") with 520 Broad Street LLC, a third-party lender (the "Lender"). The Loan Agreement provides for a loan in the amount of $15 million (the "Note Payable") from Lender to Borrower secured by (i) a first mortgage on 520 Broad Street, Newark, New Jersey 07102; and (ii) a first priority security interest in the equity of the Borrower as set forth in the Pledge and Security Agreement between Realty and Lender.

The Note Payable bears interest at a rate per annum equal to seven and one-quarter percent (7.25%) and thereafter at an interest rate per annum equal to the 30-day LIBOR Rate, as published in *The Wall Street Journal*, plus 6.90% per annum, but in no event less than seven and one-quarter percent (7.25%) per annum. The Note Payable is due on August 1, 2022, subject to the Company's option to extend the maturity date until August 1, 2023 for a fee equal to three-quarters of one percent (0.75%) of the Note Payable.

Effective September 24, 2021, we entered into a line of credit agreement with Rafael Pharmaceuticals (the "Debtor"), which provides for loan commitments in the amount of $25,000,000. The funds loaned under the Line of Credit Agreement are to be used by the Debtor in accordance with the budget that has been approved by the Company. Of the aggregate amount, $1.9 million was advanced on September 24, 2021 and the remaining amount was funded

on October 1, 2021. Our cash balance is sufficient to meet our currently anticipated working capital, research and development, and capital expenditure requirements during the next 12 months from the issuance of these consolidated financial statements.

	July 31,	
	2021	2020
Cash flows (used in) provided by	*(in thousands)*	
Operating activities	$ (15,601)	$ (4,666)
Investing activities	(8,171)	(1,034)
Financing activities	30,298	(96)
Effect of exchange rates on cash, cash equivalents and restricted cash	122	(22)
Increase (decrease) in cash, cash equivalents and restricted cash	$ 6,648	$ (5,818)

Operating Activities

The increase in cash used in operating activities for the year ended July 31, 2021 as compared to the year ended July 31, 2020 was primarily related to the net loss, and impact from noncash items, primarily the unrealized gain on investment — Hedge Funds of $4.8 million, the gain on the sale of the office building in Piscataway, New Jersey of $749 thousand offset by the impairment expense related to the investment in Altira of $7 million, stock based compensation of $6.6 million, depreciation of $1.5 million, the impairment of investment — Other Pharmaceuticals of $724 thousand, and other changes in assets and liabilities.

Investing Activities

Cash used in investing activities for the year ended July 31, 2021 was primarily related to the purchase of 7.3 million shares of Rafael Pharmaceuticals' Series D Preferred Stock for $9.1 million, the payments to fund our portion of advances under the line of credit between RP Finance and Rafael Pharmaceuticals for $7.5 million, the payments of an aggregate of $2 million towards the acquisition of a second 33.333% membership interest in Altira, and purchases of property and equipment of $206 thousand, offset by the proceeds of $7 million from the liquidation of the hedge funds and $3.7 million from the sale of the building in Piscataway, New Jersey in August 2020.

Cash used in investing activities for the year ended July 31, 2020 related to the initial payments of $0.5 million towards the acquisition of 33.333% membership interest in Altira for a product-in development, and $0.5 million related to building improvements made to our real estate holdings.

Financing Activities

Cash provided by financing activities for the year ended July 31, 2021 was primarily related to proceeds from the issuance of a note payable in the amount of $15.0 million, proceeds of $13 million for the sale of 567,437 shares of our Class B common stock and warrants to purchase an additional 113,487 shares of Class B common stock. Additionally, there were approximately $2 million in proceeds provided by the exercise of warrants to purchase 87,298 shares of Class B common stock by two holders of the warrants.

Cash used in financing activities for the year ended July 31, 2020 was related to payments for taxes related to shares withheld for employee taxes, offset by proceeds from the exercise of options.

We do not anticipate paying dividends on our common stock until we achieve sustainable profitability and retain certain minimum cash reserves. The payment of dividends in any specific period will be at the sole discretion of our Board of Directors.

Trends and Uncertainties — COVID-19

In December 2019, a novel strain of COVID-19 emerged and has subsequently expanded to a pandemic resulting in significant risks and disruptions to the health and welfare of the global population and economy. For the year ended July 31, 2021, COVID-19 has not had a material impact on our operations.

We actively monitor the outbreak and its potential impact on our operations and those of our holdings. Although our operations are mainly in the United States, we have assets outside of the United States, and some of our pharmaceutical holdings conduct operations, manufacturing and clinical trial activities in Europe and Asia.

The impacts on our and our affiliates' operations and specifically the ongoing clinical trials of our pharmaceutical holdings have been actively managed by respective pharmaceutical management teams who have worked closely with the appropriate regulatory agencies to continue clinical trial activities with as minimal impact as possible including receiving waivers for certain clinical trial activities from the respective regulatory agencies to continue the studies.

Although partially mitigated recently, there remains a general degree of uncertainty in the national commercial real estate market based on the COVID-19 pandemic and as a result there is a potential impact to the value of our real estate portfolio as well as efforts to monetize those assets.

We have implemented a number of measures to protect the health and safety of our workforce, including a voluntary work-from-home policy for our workforce who can perform their jobs from home, as well as restrictions on business travel.

Due to both known and unknown risks, including quarantines, closures and other restrictions resulting from the outbreak, operations and those of our holdings may be adversely impacted. Additionally, as there is an evolving nature to the COVID-19 situation, we cannot reasonably assess or predict at this time the full extent of the negative impact that the COVID-19 pandemic may have on our business, financial condition, results of operations and cash flows. The impact will depend on future developments such as the ultimate duration and the severity of the spread of the COVID-19 pandemic in the U.S. and globally, the effectiveness of federal, state, local and foreign government actions on mitigation and spread of COVID-19, the pandemic's impact on the U.S. and global economies, changes in our customers' behavior emanating from the pandemic and how quickly we can resume our normal operations, among others. For all these reasons, we may incur expenses or delays relating to such events outside of our control, which could have a material adverse impact on our business.

Critical Accounting Policies and Estimates

Our financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses as well as the disclosure of contingent assets and liabilities. Critical accounting policies are those that require application of management's most subjective or complex judgments, often as a result of matters that are inherently uncertain and may change in subsequent periods. Our critical accounting policies include those related to revenue recognition, allowance for doubtful accounts, income taxes and valuation of investments and long-lived assets. Management bases its estimates and judgments on historical experience and other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. See Note 1 to the Consolidated Financial Statements in this Annual Report for a complete discussion of our significant accounting policies. For more information on recent accounting standards, see Note 1 to the Consolidated Financial Statements in this Annual Report.

Off-Balance Sheet Arrangements

We do not have any "off-balance sheet arrangements," as defined in relevant SEC regulations that are reasonably likely to have a current or future effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks.

FOREIGN CURRENCY RISK

Revenue from tenants located in Israel represented 7% and 6% of our consolidated revenues in the fiscal years ended July 31, 2021 and 2020, respectively. The entirety of these revenues is in currencies other than the U.S. Dollar. Our foreign currency exchange risk is somewhat mitigated by our ability to offset a portion of these non-U.S. Dollar-denominated revenues with operating expenses that are paid in the same currencies. While the impact from fluctuations in foreign exchange rates affects our revenues and expenses denominated in foreign currencies, the net amount of our exposure to foreign currency exchange rate changes at the end of each reporting period is generally not material.

INVESTMENT RISK

In addition to, but separate from our primary business, we will hold a portion of our assets in hedge funds and a passive investment in another entity. Investments in hedge funds carry a degree of risk and depend to a great extent on correct assessments of the future course of price movements of securities and other instruments. There can be no assurance that our investment managers will be able to accurately predict these price movements. The securities markets have in recent years been characterized by great volatility and unpredictability. Our passive interests in other entities are not currently liquid and we cannot assure that we will be able to liquidate them when we desire, or ever. Accordingly, the value of our investments may go down as well as up and we may not receive the amounts originally invested upon redemption.

Item 8. Financial Statements and Supplementary Data.

The Consolidated Financial Statements of the Company and the report of the independent registered public accounting firm thereon starting on page F-1 are included herein.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

An evaluation was performed under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) promulgated under the Securities and Exchange Act of 1934, as amended) as of July 31, 2021. Based on that evaluation, the Company's management, including the President and Chief Executive Officer and Chief Financial Officer, concluded that the Company's disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting. The internal control process has been designed under management's supervision to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external reporting purposes in accordance with U.S. GAAP.

Management conducted an assessment of the effectiveness of the Company's internal control over financial reporting as of July 31, 2021 utilizing the framework established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has determined that the Company's internal control over financial reporting as of July 31, 2021 is effective.

The Company's internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that accurately and fairly reflect, in reasonable detail, transactions and dispositions of assets; and provide reasonable assurances that: (1) transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP; (2) receipts and expenditures are being made only in accordance with authorizations of management and the directors of the Company; and (3) unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the Company's financial statements are prevented or timely detected.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There were no significant changes made in the Company's internal control over financial reporting during the fourth quarter of the year ended July 31, 2021 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance.

The following is a list of our directors and executive officers as of October 1, 2021, along with the specific information required by Rule 14a-3 of the Securities Exchange Act of 1934:

Executive Officers

Howard S. Jonas — Chairman of the Board
Ameet Mallik — Chief Executive Officer
Patrick Fabbio — Chief Financial Officer
William Conkling — Chief Commercial Officer
Ashok Marin — Chief Legal Officer

Directors

Howard S. Jonas — Chairman of the Board

Stephen Greenberg
Rachel Jonas
Shannon Klinger
Mark McCamish
Dr. Boris C. Pasche
Dr. Michael J. Weiss

The remaining information required by this Item will be contained in our Proxy Statement for our Annual Stockholders Meeting, which will be filed with the Securities and Exchange Commission within 120 days after July 31, 2021, and which is incorporated by reference herein.

Corporate Governance

We have included as exhibits to this Annual Report on Form 10-K certificates of our Chief Executive Officer and Chief Financial Officer certifying the quality of our public disclosure.

We make available free of charge through the investor relations page of our web site (*http://rafaelholdings.irpass.com/*) our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, and all beneficial ownership reports on Forms 3, 4 and 5 filed by directors, officers and beneficial owners of more than 10% of our equity, as soon as reasonably practicable after such reports are electronically filed with the Securities and Exchange Commission. We have adopted codes of business conduct and ethics for all of our employees, including our principal executive officer, principal financial officer and principal accounting officer. Copies of the codes of business conduct and ethics are available on our web site.

Our web site and the information contained therein or incorporated therein are not intended to be incorporated into this Annual Report on Form 10-K or our other filings with the Securities and Exchange Commission.

Item 11. Executive Compensation.

The information required by this Item will be contained in our Proxy Statement for our Annual Stockholders Meeting, which will be filed with the Securities and Exchange Commission within 120 days after July 31, 2021, and which is incorporated by reference herein.

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

The information required by this Item will be contained in our Proxy Statement for our Annual Stockholders Meeting, which will be filed with the Securities and Exchange Commission within 120 days after July 31, 2021, and which is incorporated by reference herein.

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

The information required by this Item will be contained in our Proxy Statement for our Annual Stockholders Meeting, which will be filed with the Securities and Exchange Commission within 120 days after July 31, 2021, and which is incorporated by reference herein.

Item 14. Principal Accounting Fees and Services.

The information required by this Item will be contained in our Proxy Statement for our Annual Stockholders Meeting, which will be filed with the Securities and Exchange Commission within 120 days after July 31, 2021, and which is incorporated by reference herein.

Part IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Report:

1 Report of Independent Registered Public Accounting Firm on Consolidated Financial Statements.

Consolidated Financial Statements covered by Report of Independent Registered Public Accounting Firm.

2 Financial Statement Schedules.

All schedules have been omitted since they are either included in the Notes to Consolidated Financial Statements or not required or not applicable.

3 Exhibits. The exhibits listed in paragraph (b) of this item are filed, furnished, or incorporated by reference as part of this Form 10-K.

Certain of the agreements filed as exhibits to this Form 10-K contain representations and warranties by the parties to the agreements that have been made solely for the benefit of the parties to the agreement. These representations and warranties:

- may have been qualified by disclosures that were made to the other parties in connection with the negotiation of the agreements, which disclosures are not necessarily reflected in the agreements;
- may apply standards of materiality that differ from those of a reasonable investor; and
- were made only as of specified dates contained in the agreements and are subject to subsequent developments and changed circumstances.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date that these representations and warranties were made or at any other time. Investors should not rely on them as statements of fact.

(b) Exhibits.

Exhibit Number	Description of Exhibits
2.01[(1)]	Agreement and Plan of Merger, dated as of June 17, 2021, by and among Rafael Holdings, Inc. Merger Sub I, Merger Sub II and Pharma
3.1[(2)]	Amended and Restated Certificate of Incorporation of Rafael Holdings, Inc.
3.2[(3)]	Amended and Restated By-Laws of Rafael Holdings, Inc.
4.2*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
10.1[(2)]	2018 Equity Incentive Plan
10.2[(4)]	Employment Agreement dated as of March 5, 2021, between the Company and Ameet Mallik.
10.3[(5)]	Letter Agreement dated September 10, 2021, between the Company and Patrick Fabbio.
10.4[(6)]	Securities Purchase Agreement, dated August 19, 2021, by and among Rafael Holdings, Inc. and the Investors named therein.
10.5[(6)]	Securities Purchase Agreement, dated August 19, 2021, by and among Rafael Holdings, Inc. and I9Plus, LLC.
10.6[(6)]	Registration Rights Agreement, dated August 19, 2021, by and among Rafael Holdings, Inc. and the Investors named therein.
10.7[(7)]	Loan Agreement by and between the Registrant, Rafael Holdings Realty, Inc., Broad-Atlantic Associates, LLC and 520 Broad Street LLC, dated July 9, 2021.
21.01*	Subsidiaries of the Registrant
23.1*	Consent of CohnReznick LLP, Independent Registered Public Accounting Firm
31.01*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.02*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.01*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.02*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* filed herewith.
(1) Incorporated by reference to Form 8-K, filed June 21, 2021.
(2) Incorporated by reference to Form 10-12G/A, filed March 26, 2018.
(3) Incorporated by reference to Form 8-K, filed September 26, 2019.
(4) Incorporated by reference to Form 8-K, filed March 11, 2021.
(5) Incorporated by reference to Form 8-K, filed September 14, 2021.
(6) Incorporated by reference to Form 8-K, filed August 24, 2021.
(7) Incorporated by reference to Form 8-K, filed July 15, 2021.

Item 16. Form 10-K Summary

None.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

RAFAEL HOLDINGS, INC.

By: /s/ Ameet Mallik
Ameet Mallik
Chief Executive Officer
(Principal Executive Officer)

Date: October 18, 2021

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Titles	Date
/s/ Ameet Mallik **Ameet Mallik**	Chief Executive Officer (Principal Executive Officer)	October 18, 2021
/s/ Patrick Fabbio **Patrick Fabbio**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	October 18, 2021
/s/ Howard S. Jonas **Howard S. Jonas**	Director and Chairman of the Board	October 18, 2021
/s/ Stephen Greenberg **Stephen Greenberg**	Director	October 18, 2021
/s/ Rachel Jonas **Rachael Jonas**	Director	October 18, 2021
/s/ Shannon Klinger **Shannon Klinger**	Director	October 18, 2021
/s/ Mark McCamish **Mark McCamish**	Director	October 18, 2021
/s/ Boris C. Pasche **Dr. Boris C. Pasche**	Director	October 18, 2021
/s/ Michael J. Weiss **Dr. Michael J. Weiss**	Director	October 18, 2021

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Rafael Holdings, Inc.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Rafael Holdings, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Rafael Holdings, Inc. (the "Company") as of July 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, equity and cash flows for the years then ended, and the related notes (collectively referred to as "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 July 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 audits 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.

/s/ CohnReznick LLP

We have served as the Company's auditor since 2019.

New York, New York

October 18, 2021

RAFAEL HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	July 31, 2021	July 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 7,854	$ 6,206
Restricted cash	5,000	—
Trade accounts receivable, net of allowance for doubtful accounts of $193 and $218 at July 31, 2021 and 2020, respectively	235	267
Due from Rafael Pharmaceuticals	600	118
Prepaid expenses and other current assets	1,075	273
Assets held for sale	—	2,968
Total current assets	14,764	9,832
Property and equipment, net	43,238	44,433
Equity investment – RP Finance	575	192
Due from RP Finance LLC	7,500	—
Investments – Rafael Pharmaceuticals	79,141	70,018
Investments – Other Pharmaceuticals	477	1,201
Investments – Hedge Funds	5,268	7,510
Deferred income tax assets, net	—	6
In-process research and development and patents	1,575	1,575
Other assets	1,517	1,580
TOTAL ASSETS	$ 154,055	$ 136,347
LIABILITIES AND EQUITY		
CURRENT LIABILITIES		
Trade accounts payable	$ 1,160	$ 921
Accrued expenses	1,227	1,191
Amount due for purchase of membership interest	—	3,500
Due to related parties	136	—
Note payable, net of debt issuance costs	14,528	—
Other current liabilities	252	115
Total current liabilities	17,303	5,727
Other liabilities	48	92
TOTAL LIABILITIES	17,351	5,819
COMMITMENTS AND CONTINGENCIES		
EQUITY		
Class A common stock, $0.01 par value; 35,000,000 shares authorized, 787,163 shares issued and outstanding as of July 31, 2021 and 2020	8	8
Class B common stock, $0.01 par value; 200,000,000 shares authorized, 16,947,066 issued and 16,936,864 outstanding as of July 31, 2021, and 15,034,598 issued and 15,028,536 outstanding as of July 31, 2020	169	149
Additional paid-in capital	159,136	129,136
Accumulated deficit	(40,799)	(16,255)
Accumulated other comprehensive income related to foreign currency translation adjustment	3,772	3,762
Total equity attributable to Rafael Holdings, Inc.	122,286	116,800
Noncontrolling interests	14,418	13,728
TOTAL EQUITY	136,704	130,528
TOTAL LIABILITIES AND EQUITY	$ 154,055	$ 136,347

See accompanying notes to consolidated financial statements.

RAFAEL HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Year Ended July 31,	
	2021	**2020**
REVENUES		
Rental – Third Party	$ 890	$ 1,516
Rental – Related Party	2,099	2,082
Parking	502	832
Other – Related Party	480	480
Total Revenue	3,971	4,910
COSTS AND EXPENSES		
Selling, general and administrative	20,416	9,118
Research and development	4,907	2,391
Depreciation and amortization	1,460	1,866
Impairment – Altira	7,000	—
Loss from operations	(29,812)	(8,465)
Interest expense, net	(102)	(32)
Net loss resulting from foreign exchange transactions	—	(5)
Gain on sale of building	749	—
Impairment of investments – Other Pharmaceuticals	(724)	(799)
Unrealized gain on investments – Hedge Funds	4,758	2,385
Loss before income taxes	(25,131)	(6,916)
Provision for income taxes	(18)	(29)
Impairment of equity method investment in Altira	—	(4,000)
Equity in earnings of RP Finance	383	192
Consolidated net loss	(24,766)	(10,753)
Net loss attributable to noncontrolling interests	(222)	(338)
Net loss attributable to Rafael Holdings, Inc.	$ (24,544)	$ (10,415)
OTHER COMPREHENSIVE LOSS		
Consolidated Net Loss	$ (24,766)	$ (10,753)
Foreign Currency Translation Adjustment	10	(22)
Total Comprehensive Loss	(24,756)	(10,775)
Comprehensive loss attributable to noncontrolling interests	(37)	(9)
Total Comprehensive loss attributable to Rafael Holdings, Inc.	$ (24,793)	$ (10,784)
Loss per share		
Basic and Diluted	$ (1.49)	$ (0.66)
Weighted average number of shares used in calculation of loss per share		
Basic and Diluted	16,522,686	15,764,829

See accompanying notes to consolidated financial statements.

RAFAEL HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF EQUITY FOR THE YEARS ENDED JULY 31, 2021 AND 2020
(in thousands, except share data)

	Year Ended July 31, 2021								
	Common Stock, Series A		Common Stock, Series B		Additional Paid-in Capital	Accumulated Deficit	Accumulated other comprehensive income	Noncontrolling interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance at August 1, 2020	787,163	$ 8	15,028,536	$ 149	$ 129,136	$ (16,255)	$ 3,762	$ 13,728	$ 130,528
Net loss for the year ended July 31, 2021	—	—	—	—	—	(24,544)	—	(222)	(24,766)
Stock-based compensation	—	—	953,329	10	6,337	—	—	—	6,347
Stock-based compensation to Board of Directors	—	—	12,609	—	286	—	—	—	286
Shares issued – Investment in Altira	—	—	280,323	3	8,498	—	—	—	8,501
Shares issued – Securities Purchase Agreements	—	—	567,437	6	12,994	—	—	—	13,000
Shares withheld for payroll taxes	—	—	(7,214)	—	(185)	—	—	—	(185)
Warrants exercised	—	—	87,298	1	1,999	—	—	—	2,000
Stock options exercised	—	—	14,546	—	71	—	—	—	71
Capital contribution for noncontrolling interest	—	—	—	—	—	—	—	912	912
Foreign currency translation adjustment	—	—	—	—	—	—	10	—	10
Balance at July 31, 2021	787,163	$ 8	16,936,864	$ 169	$ 159,136	$ (40,799)	$ 3,772	$ 14,418	$ 136,704

RAFAEL HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF EQUITY FOR THE YEARS ENDED JULY 31, 2021 AND 2020
(in thousands, except share data)

	Year Ended July 31, 2020								
	Common Stock, Series A		Common Stock, Series B		Additional Paid-in Capital	Accumulated Deficit	Accumulated other comprehensive income	Noncontrolling interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance at August 1, 2019	787,163	$ 8	13,142,502	$ 131	$ 112,898	$ (5,840)	$ 3,784	$ 13,783	$ 124,764
Net loss for the year ended July 31, 2020	—	—	—	—	—	(10,415)	—	(338)	(10,753)
Stock-based compensation	—	—	23,738	—	476	—	—	—	476
Stock-based compensation to Board of Directors	—	—	12,609	—	208	—	—	—	208
Shares issued for convertible debt	—	—	1,849,749	18	15,650	—	—	—	15,668
Shares withheld for payroll taxes	—	—	(6,062)	—	(125)	—	—	—	(125)
Stock options exercised	—	—	6,000	—	29	—	—	—	29
Conversion of LipoMedix Bridge Notes	—	—	—	—	—	—	—	283	283
Foreign currency translation adjustment	—	—	—	—	—	—	(22)	—	(22)
Balance at July 31, 2020	787,163	$ 8	15,028,536	$ 149	$ 129,136	$ (16,255)	$ 3,762	$ 13,728	$ 130,528

See accompanying notes to consolidated financial statements.

RAFAEL HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended July 31,	
	2021	**2020**
Operating activities		
Consolidated net loss	$ (24,766)	$ (10,753)
Adjustments to reconcile consolidated net loss to net cash used in operating activities		
Depreciation and amortization	1,460	1,866
Deferred income taxes	6	13
Net unrealized gain on investments – Hedge Funds	(4,758)	(2,385)
Impairment of equity method investment of Altira	7,000	4,000
Impairment of investments – Other Pharmaceuticals	724	799
Equity in earnings of RP Finance	(383)	(192)
Provision for doubtful accounts	193	96
Noncash compensation	6,633	684
Amortization of debt issuance costs	28	—
Amortization of debt discount	—	54
Gain on sale of building	(749)	—
Change in assets and liabilities:		
Trade accounts receivable	(161)	87
Prepaid expenses and other current assets	(802)	234
Other assets	63	(168)
Accounts payable and accrued expenses	164	713
Other current liabilities	137	88
Due to related parties	136	(65)
Due from related parties	(482)	162
Accrued interest – Related Party	—	19
Other liabilities	(44)	82
Net cash used in operating activities	(15,601)	(4,666)
Investing activities		
Purchases of property and equipment	(206)	(534)
Proceeds from the sale of building	3,658	—
Proceeds from sale of hedge funds	7,000	—
Payment to fund RP Finance Line of Credit	(7,500)	—
Investment in Altira	(2,000)	(500)
Investment in Rafael Pharmaceuticals	(9,123)	—
Net cash used in investing activities	(8,171)	(1,034)
Financing activities		
Contribution from noncontrolling interest of consolidated entity	912	—
Proceeds from issuance of shares	13,000	—
Proceeds from exercise of options	71	29
Payments for taxes related to shares withheld for employee taxes	(185)	(125)
Proceeds from exercise of warrants	2,000	—
Proceeds from issuance of note payable	15,000	—
Payment of debt issuance costs	(500)	—
Net cash provided by (used in) financing activities	30,298	(96)

RAFAEL HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS — (Continued)
(in thousands)

	Year Ended July 31,	
	2021	**2020**
Effect of exchange rate changes on cash, cash equivalents and restricted cash	122	(22)
Net increase (decrease) in cash, cash equivalents and restricted cash	6,648	(5,818)
Cash, cash equivalents and restricted cash, beginning of year	6,206	12,024
Cash, cash equivalents and restricted cash, end of year	$ 12,854	$ 6,206
Supplemental Schedule of Noncash Investing and Financing Activities		
Issuance of shares to Altira for payment of membership interest	$ 8,501	$ —
Amount due for purchase of membership interest	$ —	$ 3,500
Transfer of asset held for sale	$ —	$ 2,968
Conversion of LipoMedix Bridge Notes	$ —	$ 283
Conversions of related party convertible notes payable and accrued interest	$ —	$ 15,668
Reconciliation of cash and restricted cash		
Cash and cash equivalents	$ 7,854	$ 6,206
Restricted cash	5,000	—
Total cash, cash equivalents and restricted cash shown in statement of cash flows	$ 12,854	$ 6,206

See accompanying notes to consolidated financial statements.

NOTE 1 — DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Rafael Holdings, Inc. (NYSE-RFL), ("Rafael Holdings" or the "Company"), a Delaware corporation, holds interests in clinical and early stage pharmaceutical companies, including an investment in Rafael Pharmaceuticals, Inc. or Rafael Pharmaceuticals, a late-stage cancer metabolism--based therapeutics company, its preclinical cancer metabolism research institute, the Barer Institute ("Barer"), and commercial real estate assets. The Company focuses its efforts on funding, discovering and developing novel cancer therapies through its continued investment in Rafael Pharmaceuticals, the creation of the Barer Institute in 2019 and continued investments in advancing its preclinical portfolio as well as investments in other early-stage oncology companies with a goal of building a focused cancer metabolism therapeutics company with the potential to improve and extend the lives of patients. On June 17, 2021, the Company entered into a merger agreement to acquire full ownership of Rafael Pharmaceuticals in exchange for issuing Company Class B common stock to the other stockholders of Rafael Pharmaceuticals. We expect to bring the merger to a vote of our stockholders this calendar year. The assets are operated as two separate lines of business.

The Company's investment in Rafael Pharmaceuticals includes preferred and common equity interests and a warrant to purchase additional equity. In 2019, the Company established Barer, as an early-stage small molecule research institute focused on developing a pipeline of novel therapeutic compounds, including compounds to regulate cancer metabolism with potentially broader application in other indications beyond cancer. Barer is led by a team of scientists and academic advisors considered to be among the leading experts in cancer metabolism, chemistry, and drug development. In addition to its own internal discovery efforts, Barer is pursuing collaborative research agreements and in-licensing opportunities with leading scientists from top academic institutions. Farber Partners, LLC ("Farber") was formed around one such agreement with Princeton University's Office of Technology Licensing for technology from the laboratory of Professor Joshua Rabinowitz, in the Department of Chemistry, Princeton University, for an exclusive worldwide license to its SHMT (serine hydroxymethyltransferase) inhibitor program. The Company also holds a majority equity interest in LipoMedix Pharmaceuticals Ltd. ("LipoMedix"), a clinical stage oncological pharmaceutical company based in Israel. In addition, the Company has recently initiated efforts to develop other early stage pharmaceutical ventures including Levco Pharmaceuticals Ltd. ("Levco"), an Israeli company, established to partner with Dr. Alberto Gabizon and a leading institution in Israel on the development of novel compounds for cancer.

The Company's commercial real estate holdings consist of a building at 520 Broad Street in Newark, New Jersey that serves as headquarters for the Company and certain other entities and tenants and an associated 800-car public garage, and a portion of a building in Israel. The Company sold other real estate holdings in 2020.

Basis of Presentation

The "Company" in these consolidated financial statements refers to Rafael Holdings and its subsidiaries on a consolidated basis. All significant intercompany accounts and transactions have been eliminated in consolidation.

The Company's fiscal year ends on July 31 of each calendar year. Each reference below to a fiscal year refers to the fiscal year ending in the calendar year indicated (e.g., fiscal year 2021 refers to the fiscal year ended July 31, 2021).

The accompanying consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

NOTE 1 — DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

All majority-owned subsidiaries are consolidated with all intercompany transactions and balances eliminated in consolidation or combination. The entities included in these consolidated financial statements are as follows:

Company	Country of Incorporation	Percentage Owned
Rafael Holdings, Inc.	United States – Delaware	100%
Broad Atlantic Associates, LLC	United States – Delaware	100%
IDT 225 Old NB Road, LLC	United States – Delaware	100%
IDT R.E. Holdings Ltd.	Israel	100%
Rafael Holdings Realty, Inc.	United States – Delaware	100%
Barer Institute, Inc.	United States – Delaware	100%
The Barer Institute, LLC	United States – Delaware	100%
Hillview Avenue Realty, JV	United States – Delaware	100%
Hillview Avenue Realty, LLC	United States – Delaware	100%
Rafael Medical Devices, LLC	United States – Delaware	100%
Levco Pharmaceuticals Ltd.	Israel	95%
Farber Partners, LLC	United States – Delaware	93%
Pharma Holdings, LLC	United States – Delaware	90%
LipoMedix Pharmaceuticals Ltd.	Israel	68%
Altira Capital & Consulting, LLC	United States – Delaware	67%
CS Pharma Holdings, LLC	United States – Delaware	45%*

* 50% of CS Pharma Holdings, LLC is owned by Pharma Holdings, LLC. We have a 90% ownership in Pharma Holdings, LLC and, therefore, an effective 45% interest in CS Pharma Holdings, LLC.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the balance sheet and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ significantly from those estimates.

Liquidity

As of July 31, 2021, the Company had cash and cash equivalents of $7.9 million in addition to the Company's investment in a hedge fund valued at $5.3 million.

In August 2021, the Company completed a securities purchase agreement and in which 2,945,986 shares of Class B Common Stock were sold for an aggregate net proceeds of $97.8 million, after deducting transaction costs of $6.4 million.

Management expects that the balance of the Company's cash and cash equivalents as of July 31, 2021, in addition to the balance in Investments — Hedge Funds, and the proceeds of the August 2021 financing to be sufficient to meet Rafael Holdings' obligations for at least the next 12 months from the issuance of these consolidated financial statements.

On September 23, 2021, the Company entered into a line of credit agreement with Rafael Pharmaceuticals (the "Debtor") in which the Debtor may borrow up to an aggregate amount of $25,000,000. The first advance made to the Debtor was in the amount of $1,900,000 on September 24, 2021. On October 1, 2021, a second advance was made to the Debtor in the amount of $23,100,000. The Company's cash balance is sufficient to meet the Company's currently anticipated working capital, research and development, and capital expenditure requirements during the next 12 months from the issuance of these consolidated financial statements.

NOTE 1 — DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

Risks and Uncertainties — COVID-19

In December 2019, a new coronavirus, now known as COVID-19, which has proved to be highly contagious, has since spread around the globe. The Company actively monitors the outbreak and its potential impact on its operations and those of the Company's holdings.

The impacts on the Company's and its affiliates' operations and specifically the ongoing clinical trials of the Company's pharmaceutical holdings have been actively managed by respective pharmaceutical management teams who have worked closely with the appropriate regulatory agencies to continue clinical trial activities with as minimal impact as possible including receiving waivers for certain clinical trial activities from the respective regulatory agencies to continue the studies.

Although partially mitigated recently, there remains a general degree of uncertainty in the national commercial real estate market based on the COVID-19 pandemic and as a result there remains a potential impact to the value of the Company's real estate portfolio as well as efforts to monetize those assets.

The Company has implemented a number of measures to protect the health and safety of the Company's workforce, including a voluntary work-from-home policy for the Company's workforce who can perform their jobs from home, as well as restrictions on business travel.

Due to both known and unknown risks, including quarantines, closures and other restrictions resulting from the outbreak, operations and those of the Company's holdings may be adversely impacted. Additionally, as there is an evolving nature to the COVID-19 situation, the Company cannot reasonably assess or predict at this time the full extent of the negative impact that the COVID-19 pandemic may have on the Company's business, financial condition, results of operations and cash flows. The impact will depend on future developments such as the ultimate duration and the severity of the spread of the COVID-19 pandemic in the U.S. and globally, the effectiveness of federal, state, local and foreign government actions on mitigation and spread of COVID-19, the pandemic's impact on the U.S. and global economies, changes in the Company's customers' behavior emanating from the pandemic and how quickly the Company can resume our normal operations, among others. For all these reasons, the Company may incur expenses or delays relating to such events outside of the Company's control, which could have a material adverse impact on the Company's business.

Cash and Cash Equivalents

The Company considers all liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

Restricted Cash

Restricted cash represents escrow funds held in bank accounts owned by the Company to be used to pay the severance due to the chief executive officer for termination without cause, pursuant to his employment agreement. The Company does not have the right to use this cash balance for any other purpose.

Concentration of Credit Risk and Significant Customers

The Company routinely assesses the financial strength of its customers. As a result, the Company believes that its accounts receivable credit risk exposure is limited. For the year ended July 31, 2021, related parties represented 65% of the Company's revenue, and as of July 31, 2021, two customers represented 45% and 33% of the Company's accounts receivable balance, respectively. For the year ended July 31, 2020, related parties represented 52% of the Company's revenue, and as of July 31, 2020, three customers represented 11%, 10%, and 10% of the Company's accounts receivable balance, respectively.

NOTE 1 — DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

Allowance for Doubtful Accounts

The allowance for doubtful accounts reflects the Company's best estimate of probable losses inherent in the accounts receivable balance. The allowance is determined based on known troubled accounts, historical experience and other currently available evidence. Doubtful accounts are written off upon final determination that the trade accounts will not be collected. The computation of this allowance is based on the tenants' or parking customers' payment histories, as well as certain industry or geographic specific credit considerations. If the Company's estimates of collectability differ from the cash received, then the timing and amount of the Company's reported revenue could be impacted. The credit risk is mitigated by the high quality of the Company's existing tenant base, inclusive of related parties, which represented 65% and 52% of the Company's total revenue for the years ended July 31, 2021 and 2020, respectively. The Company recorded bad debt expense of approximately $193,000 and $96,000 for the years ended July 31, 2021 and 2020, respectively.

Investments

The method of accounting applied to long-term investments, whether consolidated, equity or cost, involves an evaluation of the significant terms of each investment that explicitly grant or suggest evidence of control or influence over the operations of the investee and also includes the identification of any variable interests in which the Company is the primary beneficiary. The consolidated financial statements include the Company's controlled affiliates. All significant intercompany accounts and transactions between the consolidated affiliates are eliminated.

Investments in businesses that the Company does not control, but in which the Company has the ability to exercise significant influence over operating and financial matters, are accounted for using the equity method. Investments in which the Company does not have the ability to exercise significant influence over operating and financial matters are accounted for using the cost method. The Company periodically evaluates its investments for impairment due to declines considered to be other than temporary. If the Company determines that a decline in fair value is other than temporary, then a charge to earnings is recorded in the accompanying consolidated statements of operations and comprehensive loss, and a new basis in the investment is established.

Variable Interest Entities

In accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 810, *Consolidation* ("ASC 810"), the Company assesses whether it has a variable interest in legal entities in which it has a financial relationship and, if so, whether or not those entities are variable interest entities ("VIEs"). For those entities that qualify as VIEs, ASC 810 requires the Company to determine if the Company is the primary beneficiary of the VIE, and if so, to consolidate the VIE.

If an entity is determined to be a VIE, the Company evaluates whether the Company is the primary beneficiary. The primary beneficiary analysis is a qualitative analysis based on power and economics. The Company consolidates a VIE if both power and benefits belong to the Company — that is, the Company (i) has the power to direct the activities of a VIE that most significantly influence the VIE's economic performance (power), and (ii) has the obligation to absorb losses of, or the right to receive benefits from, the VIE that could potentially be significant to the VIE (benefits). The Company consolidates VIEs whenever it is determined that the Company is the primary beneficiary.

Cost Method Investments — Rafael Pharmaceuticals (see Note 2) is a VIE; however, the Company has determined that it is not the primary beneficiary as the Company does not have the power to direct the activities of Rafael Pharmaceuticals that most significantly impact Rafael Pharmaceuticals' economic performance. Cost method investments are presented as "Investments — Rafael Pharmaceuticals."

NOTE 1 — DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

Equity Method Investments — RP Finance, LLC ("RP Finance") (see Note 4) has been identified as a VIE; however, the Company has determined that it is not the primary beneficiary as the Company does not have the power to direct the activities of RP Finance that most significantly impact RP Finance's economic performance and, therefore, is not required to consolidate RP Finance. The Company accounts for its investment in RP Finance using the equity method of accounting.

Long-Lived Assets

Equipment, buildings, leasehold improvements, and furniture and fixtures are recorded at cost and are depreciated on a straight-line basis over their estimated useful lives, which range as follows:

Classification	Years
Building and improvements	40
Tenant improvements	7 – 15
Other (primarily equipment and furniture and fixtures)	5

Long-lived assets are reviewed for impairment when circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the future net cash flows estimated by the Company to be generated by such assets. If such assets are considered to be impaired, the impairment to be recognized is the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of by sale are recorded as held for sale at the lower of carrying value or estimated net realizable value. Tests for impairment or recoverability are performed at least annually and require significant management judgment and the use of estimates which the Company believes are reasonable and appropriate at the time of the impairment test. Future unanticipated events affecting cash flows and changes in market conditions could affect such estimates and result in the need for an impairment charge. The Company also re-evaluates the periods of amortization to determine whether circumstances warrant revised estimates of current useful lives. No impairment losses were identified or recorded in the fiscal years ended July 30, 2021 and 2020 on the Company's other intangible assets.

Properties

The Company owns commercial real estate located at 520 Broad Street in Newark, New Jersey, and a related 800-car public parking garage across the street. Additionally, the Company owns a portion of the 6th floor of a building located at 5 Shlomo Halevi Street, in Jerusalem, Israel.

Assets Held for Sale

The Company classifies assets held for sale if all held for sale criteria is met pursuant to ASC 360-10. Assets classified as held for sale are not depreciated and are measured at the lower of their carrying amount or fair value less cost to sell. Further, assets held for sale are presented as current assets on the consolidated balance sheet.

Debt Issuance Costs

Debt issuance costs are recorded net against the related debt and amortized to interest expense over the life of the related debt. During the years ended July 31, 2021 and 2020, amortized debt issuance costs of $27,776 and $0, respectively, were recorded as a component of interest expense.

NOTE 1 — DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

Revenue Recognition

The Company applies the five-step approach as described in ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), which consists of the following: (i) identifying the contract with a customer, (ii) identifying the performance obligations in the contract, (iii) determining the transaction price, (iv) allocating the transaction price to the performance obligations in the contract and (v) recognizing revenue when (or as) the entity satisfies a performance obligation.

The Company disaggregates its revenue by source within its consolidated statements of operations and comprehensive loss. As an owner and operator of real estate, the Company derives the majority of its revenue from leasing office and parking space to tenants at its properties. In addition, the Company earns revenue from recoveries from tenants, consisting of amounts due from tenants for common area maintenance, real estate taxes and other recoverable costs. Revenue from recoveries from tenants is recorded together with rental income on the consolidated statements of operations and comprehensive loss which is also consistent with the guidance under ASC 842, *Leases*.

Contractual rental revenue is reported on a straight-line basis over the terms of the respective leases. Accrued rental income, included within other assets on the consolidated balance sheets, represents cumulative rental income earned in excess of rent payments received pursuant to the terms of the individual lease agreements.

The Company also earns revenue from parking which is derived primarily from monthly and transient daily parking. The monthly and transient daily parking revenue falls within the scope of ASC 606 and is accounted for at the point in time when control of the goods or services transfers to the customer and the Company's performance obligation is satisfied, consistent with the Company's previous accounting.

The Company maintains an allowance for doubtful accounts for estimated losses resulting from the inability of tenants to make required rent payments or parking customers to pay amounts due.

Research and Development Costs

Research and development costs and expenses consist primarily of salaries and related personnel expenses, stock-based compensation, fees paid to external service providers, laboratory supplies, costs for facilities and equipment, license costs, and other costs for research and development activities. Research and development expenses are recorded in operating expenses in the period in which they are incurred. Estimates have been used in determining the liability for certain costs where services have been performed but not yet invoiced. The Company monitors levels of performance under each significant contract for external service providers, including the extent of patient enrollment and other activities through communications with the service providers to reflect the actual amount expended.

Contingent milestone payments associated with acquiring rights to intellectual property are recognized when probable and estimable. These amounts are expensed to research and development when there is no alternative future use associated with the intellectual property.

Repairs and Maintenance

The Company charges the cost of repairs and maintenance, including the cost of replacing minor items not constituting substantial betterment, to selling, general and administrative expenses as these costs are incurred.

Stock-Based Compensation

The Company accounts for stock-based compensation using the provisions of ASC 718, *Stock Based Compensation*, which requires the recognition of the fair value of stock-based compensation. Stock-based compensation is estimated at the grant date based on the fair value of the awards. The Company accounts for forfeitures as they occur. Compensation cost for awards is recognized using the straight-line method over the vesting period. Stock-based compensation is included in selling, general and administrative expense in the consolidated statements of operations and comprehensive loss.

NOTE 1 — DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

Income Taxes

The Company recognizes deferred tax assets and liabilities for the future tax consequences attributable to temporary differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets depends on the generation of future taxable income during the period in which related temporary differences become deductible. The Company considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in its assessment of a valuation allowance. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date of such change.

The Company uses a two-step approach for recognizing and measuring tax benefits taken or expected to be taken in a tax return. The Company determines whether it is more-likely-than-not that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. In evaluating whether a tax position has met the more-likely-than-not recognition threshold, the Company presumes that the position will be examined by the appropriate taxing authority that has full knowledge of all relevant information. Tax positions that meet the more-likely-than-not recognition threshold are measured to determine the amount of tax benefit to recognize in the financial statements. The tax position is measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. Differences between tax positions taken in a tax return and amounts recognized in the financial statements will generally result in one or more of the following: an increase in a liability for income taxes payable, a reduction of an income tax refund receivable, a reduction in a deferred tax asset, or an increase in a deferred tax liability.

The Company classifies interest and penalties on income taxes as a component of income tax expense, if any.

Contingencies

The Company accrues for loss contingencies when both (a) information available prior to issuance of the financial statements indicates that it is probable that a liability had been incurred at the date of the financial statements and (b) the amount of loss can reasonably be estimated. When the Company accrues for loss contingencies and the reasonable estimate of the loss is within a range, the Company records its best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company accrues the minimum amount in the range. The Company discloses an estimated possible loss or a range of loss when it is at least reasonably possible that a loss may have been incurred.

Leases

The Company adopted FASB ASC Topic 842, *Leases*, ("ASC 842") on August 1, 2019. The Company categorizes leases at their inception as either operating or finance leases. On certain lease agreements, the Company may receive rent holidays and other incentives. The Company recognizes lease costs on a straight-line basis without regard to deferred payment terms, such as rent holidays, that defer the commencement date of required payments. As of July 31, 2021 and 2020, the Company was not a lessee under any leasing arrangements.

As a lessor, the Company presents all rental revenue and reimbursements from tenants as a single line item rental income within the consolidated statements of operations and comprehensive loss.

NOTE 1 — DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

Fair Value Measurements

Fair value of financial and non-financial assets and liabilities is defined as an exit price, which is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The three-tier hierarchy for inputs used to measure fair value, which prioritizes the inputs to valuation techniques used to measure fair value, is as follows:

Level 1 — quoted prices in active markets for identical assets or liabilities;

Level 2 — quoted prices in active markets for similar assets and liabilities and inputs that are observable for the asset or liability; or

Level 3 — unobservable inputs for the asset or liability, such as discounted cash flow models or valuations.

A financial asset's or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. The assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of the assets and liabilities being measured and their placement within the fair value hierarchy.

Functional Currency

The U.S. Dollar is the functional currency of our entities operating in the United States. The functional currency for our subsidiaries operating outside of the United States is the New Israeli Shekel, the currency of the primary economic environment in which such subsidiaries primarily expend cash. The Company translates those subsidiaries' financial statements into U.S. Dollars. The Company translates assets and liabilities at the exchange rate in effect as of the consolidated financial statement date, and translates accounts from the statements of operations and comprehensive loss using the weighted average exchange rate for the period. The Company reports gains and losses from currency exchange rate changes related to intercompany receivables and payables, currently in non-operating expenses.

Loss Per Share

Basic loss per share is computed by dividing net loss attributable to all classes of common stockholders of the Company by the weighted average number of shares of all classes of common stock outstanding during the applicable period. Diluted loss per share is determined in the same manner as basic loss per share, except that the number of shares is increased to include restricted stock still subject to risk of forfeiture and to assume exercise of potentially dilutive stock options using the treasury stock method, unless the effect of such increase would be anti-dilutive.

Recently Issued Accounting Standards Not Yet Adopted

In June 2016, the FASB issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, that changes the impairment model for most financial assets and certain other instruments. For receivables, loans and other instruments, entities will be required to use a new forward-looking "expected loss" model that generally will result in the earlier recognition of allowance for losses. For available-for-sale debt securities with unrealized losses, entities will measure credit losses in a manner similar to current practice, except the losses will be recognized as allowances instead of reductions in the amortized cost of the securities. In addition, an entity will have to disclose significantly more information about allowances, credit quality indicators and past due securities. The new standard is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, and will be applied as a cumulative-effect adjustment to retained earnings. The Company is currently evaluating the impact of the pending adoption of the new standard on its consolidated financial statements and intends to adopt the standard on August 1, 2023.

NOTE 1 — DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

In August 2020, the FASB issued ASU No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), which simplifies an issuer's accounting for convertible instruments by reducing the number of accounting models that require separate accounting for embedded conversion features. ASU 2020-06 also simplifies the settlement assessment that entities are required to perform to determine whether a contract qualifies for equity classification and makes targeted improvements to the disclosures for convertible instruments and earnings-per-share (EPS) guidance. This update will be effective for the Company's fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. Entities can elect to adopt the new guidance through either a modified retrospective method of transition or a fully retrospective method of transition. The Company is currently evaluating the impact of the pending adoption of the new standard on its financial statements and intends to adopt the standard as of August 1, 2024.

NOTE 2 — INVESTMENT IN RAFAEL PHARMACEUTICALS

Rafael Pharmaceuticals is a clinical stage, oncology-focused pharmaceutical company committed to the development and commercialization of therapies that exploit the metabolic differences between normal cells and cancer cells.

The Company owns equity interests and rights in Rafael Pharmaceuticals through a 90%-owned non-operating subsidiary, Pharma Holdings, LLC, or Pharma Holdings.

Pharma Holdings owns 50% of CS Pharma Holdings, LLC ("CS Pharma"), a non-operating entity that owns equity interests in Rafael Pharmaceuticals. Accordingly, the Company holds an effective 45% indirect interest in the assets held by CS Pharma.

A trust for the benefit of the children of Howard Jonas (Chairman of the Board and former Chief Executive Officer of the Company and former Chairman of the Board of Rafael Pharmaceuticals) holds a financial instrument (the "Instrument") that owns 10% of Pharma Holdings.

Pharma Holdings holds 44.0 million shares of Rafael Pharmaceuticals Series D Convertible Preferred Stock and a warrant to increase ownership to up to 56% of the fully diluted equity interests in Rafael Pharmaceuticals (the "Warrant"). The Warrant is exercisable at the lower of 70% of the price sold in an equity financing, or $1.25 per share, subject to certain adjustments.

On March 25, 2020, the Board of Directors of Rafael Pharmaceuticals extended the expiration date of the Warrant held by Pharma Holdings to purchase shares of the Warrant from December 31, 2020 to June 30, 2021, and on August 31, 2020 the Board of Directors of Rafael Pharmaceuticals further extended the expiration date of the Warrant held by Pharma Holdings, LLC to purchase shares of the Warrant to August 15, 2021. In connection with the Merger Agreement, the Warrant expiration was extended and will expire upon the earlier of (i) upon the occurrence of the effective time of the Merger (the "Effective Time"), or (ii) if the Effective Time does not occur, the date that is calculated by adding (A) the number of calendar days the Merger Agreement has been in effect prior to its termination in accordance with its terms, to (B) August 15, 2021. Accordingly, the Company holds an effective 90% interest in the Rafael Pharmaceuticals interests held by Pharma Holdings directly, and an effective 45% indirect interest in the assets held by CS Pharma.

Pharma Holdings also holds certain governance rights in Rafael Pharmaceuticals including appointment of directors. Pharma Holdings is not the primary beneficiary of Rafael Pharmaceuticals as it does not control or direct the activities of Rafael Pharmaceuticals that most significantly impact Rafael Pharmaceuticals' economic performance.

CS Pharma holds 16.7 million shares of Rafael Pharmaceuticals Series D Convertible Preferred Stock. CS Pharma owned a $10 million Series D Convertible Note, with 3.5% interest, in Rafael Pharmaceuticals which was converted to shares of Series D Preferred Stock in January 2019.

NOTE 2 — INVESTMENT IN RAFAEL PHARMACEUTICALS (cont.)

The Company and its subsidiaries collectively own securities representing 51% of the outstanding capital stock of Rafael Pharmaceuticals and 41% of the capital stock on a fully diluted basis (excluding the remainder of the Warrant).

The Series D Convertible Preferred Stock has a stated value of $1.25 per share (subject to appropriate adjustment to reflect any stock split, combination, reclassification or reorganization of the Series D Preferred Stock or any dilutive issuances, as described below). Holders of Series D Stock are entitled to receive non-cumulative dividends when, as and if declared by the Board of Rafael Pharmaceuticals, prior to any dividends to any other class of capital stock of Rafael Pharmaceuticals. In the event of any liquidation, dissolution or winding up of the Company, or in the event of any deemed liquidation, proceeds from such liquidation, dissolution or winding up shall be distributed first to the holders of Series D Stock. Except with respect to certain major decisions, or as required by law, holders of Series D Stock vote together with the holders of the other preferred stock and common stock and not as a separate class.

The Company serves as the managing member of Pharma Holdings, and Pharma Holdings serves as the managing member of CS Pharma, with broad authority to make all key decisions regarding their respective holdings. Any distributions that are made to CS Pharma from Rafael Pharmaceuticals that are in turn distributed by CS Pharma, will need to be made pro rata to all members, which would entitle Pharma Holdings to 50% (based on current ownership) of such distributions. Similarly, if Pharma Holdings were to distribute proceeds it receives from CS Pharma, it would do so on a pro rata basis, entitling the Company to 90% (based on current ownership) of such distributions.

The Company evaluated its investments in Rafael Pharmaceuticals in accordance with ASC 323, *Investments — Equity Method and Joint Ventures,* to establish the appropriate accounting treatment for its investment and has concluded that its investment did not meet the criteria for the equity method of accounting or consolidation and is carried at cost.

Rafael Pharmaceuticals is a VIE; however, the Company has determined that it is not the primary beneficiary as it does not have the power to direct the activities of Rafael Pharmaceuticals that most significantly impact Rafael Pharmaceuticals' economic performance. In addition, the interests held in Rafael Pharmaceuticals are Series D Convertible Preferred Stock and do not represent in-substance common stock.

The Instrument holds a contractual right to receive additional shares of Rafael Pharmaceuticals capital stock equal to 10% of the fully diluted capital stock of Rafael Pharmaceuticals (the "Bonus Shares") upon the achievement of certain milestones. The Merger Agreement provides that such events will be deemed satisfied in connection with the Mergers. The Instrument will receive 2,021,802 shares of the Company's Class B Common Stock in respect of the Bonus Shares. The additional 10% is based on the fully diluted capital stock of Rafael Pharmaceuticals, excluding the remainder for the Warrant, at the time of issuance. If any of the milestones are met, the Bonus Shares are to be issued without any additional payment.

Pharma Holdings holds the Warrant to purchase a significant stake in Rafael Pharmaceuticals, as well as other equity and governance rights in Rafael Pharmaceuticals. The Company currently owns 51% of the issued and outstanding equity in Rafael Pharmaceuticals. Approximately 8% of the issued and outstanding equity is owned by the Company's subsidiary CS Pharma and 43% is held by the Company's subsidiary Pharma Holdings. The Company's subsidiary Pharma Holdings holds the Warrant, which is non-dilutable and provides for the Company to increase its (via Pharma Holdings and CS Pharma and inclusive of the interests held by the other owners of those entities) total ownership to 56%. Based on the current shares issued and outstanding of Rafael Pharmaceuticals as of July 31, 2021, the Company, and the Company's affiliates, would need to pay approximately $17 million to exercise the Warrant in full to 56%. On an as-converted fully diluted basis (for all convertible securities of Rafael Pharmaceuticals outstanding), the Company and the Company's affiliates would need to pay approximately $126 million to exercise the Warrant in full (including to offset the impact of additional issuances of Rafael Pharmaceuticals equity under the Line of Credit). The Instrument holds 10% of the interest in Pharma Holdings and would need to contribute 10% of any cash necessary to exercise any portion of the Warrant. Following any exercise, a portion of the Company's interest in Rafael Pharmaceuticals would continue to be held for the benefit of the other equity holders in Pharma Holdings and CS Pharma. Given the Company's anticipated available cash, the Company would not be able to exercise the Warrant in its entirety and the Company may never be able to exercise the Warrant in full. Rafael Pharmaceuticals may also issue additional equity interests, such as employee stock options, which will require the Company to pay additional cash to maintain the Company's ownership percentage or exercise the Warrant in full.

NOTE 2 — INVESTMENT IN RAFAEL PHARMACEUTICALS (cont.)

On January 28, 2021, Pharma Holdings partially exercised the Warrant to maintain the 51% ownership percentage and purchased 7.3 million shares of Rafael Pharmaceuticals' Series D Preferred Stock for $9.1 million, of which $0.9 million was contributed by the holder of a minority interest in Pharma Holdings.

On June 17, 2021, the Company entered into a merger agreement with Rafael Pharmaceuticals. Upon closing of the merger, each outstanding share of each class of Rafael Pharmaceuticals capital stock will be automatically cancelled and will entitle a holder of shares of a given class of Rafael Pharmaceuticals capital stock to receive 0.12045 shares of Holdings' Class B Common Stock. Pursuant to the Transactions, an aggregate of 17,145,038 shares of the Company's Class B Common Stock are expected to be issued to holders of outstanding shares of Rafael Pharmaceuticals capital stock.

The Company filed a preliminary proxy statement/prospectus related to the Merger and the issuance of shares to interest holders of Rafael Pharmaceuticals thereunder with the SEC on September 14, 2021.

NOTE 3 — INVESTMENT IN ALTIRA

The Company entered into a Membership Interest Purchase Agreement (the "Purchase Agreement") on May 13, 2020 with a member (the "First Seller") of Altira Capital & Consulting, LLC ("Altira"). Pursuant to the Purchase Agreement, on May 13, 2020, the First Seller sold the economic rights related to a 33.333% membership interest in Altira to the Company and in effect the Company purchased the potential right to receive a 1% royalty on Net Sales (as defined in the Royalty Agreement between Altira and Rafael Pharmaceuticals) on sales of certain Rafael Pharmaceuticals' products. The purchase consideration for the purchase of the membership interest consisted of 1) $1,000,000 that was payable monthly in four equal monthly installments of $250,000 each; 2) $3,000,000 payable on January 3, 2021; 3) $3,000,000 due within fifteen (15) days of interim data analysis in Rafael Pharmaceutical's Phase 3 pivotal trial (AVENGER 500®) of CPI-613® (devimistat); and 4) $3,000,000 which is due within one-hundred and twenty (120) days from the date that Rafael Pharmaceuticals files a new drug application with the U.S. Food and Drug Administration for approval of devimistat (CPI-613) as a first in-line therapy for pancreatic cancer, as defined in the Purchase Agreement. The post-closing payments are to be made to the First Seller, at the Company's discretion, in cash or shares of the Company's Class B common stock based on the ten-day average share price of the Company's Class B common stock prior to the date of payment or any combination thereof.

The Company has accounted for the purchase of the initial 33.333% membership interest in Altira as an equity method investment in accordance with the guidance in ASC 323, *Investments — Equity Method and Joint Ventures*. The Company determined that a 33.333% membership interest in Altira indicates that the Company is able to exercise significant influence over Altira, and the Company's membership interest is considered to be "more than minor" in accordance with the guidance. The cost of the investment was determined to be $4,000,000 pursuant to the terms of the Purchase Agreement. The contingent consideration, as described within the Purchase Agreement, in the amount of $6,000,000, will be recognized when the payments are considered probable.

For the fiscal year ended July 31, 2020, the Company determined that the investment in Altira was fully impaired as of the acquisition date as there were no probable cash flows, and accordingly, the investment had no value. The Company recorded an impairment charge of $4,000,000, which was the total amount of the Company's investment recognized for the Purchase Agreement as of July 31, 2020.

On December 7, 2020, the Company purchased an additional 33.333% of membership interests in Altira, pursuant to a Membership Interest Purchase Agreement (the "Second Altira Agreement") between the Company and another Altira member, (the "Second Seller"). With this transaction, the Company now owns a right to an aggregate 66.666% of the membership interests in Altira. Pursuant to the Second Altira Agreement, on December 7, 2020, the Second Seller sold his economic rights related to a 33.333% membership interest in Altira to the Company and in effect the Company purchased the potential right to receive an additional 1% royalty on Net Sales (as defined in the Royalty Agreement between Altira and Rafael Pharmaceuticals) on sales of certain Rafael Pharmaceuticals' products. The purchase consideration for the purchase of the Membership Interest consists of 1) $1,000,000 that was payable monthly in four equal monthly installments of $250,000 each, commencing on January 4, 2021; 2) $3,000,000 payable on

NOTE 3 — INVESTMENT IN ALTIRA (cont.)

January 4, 2021; 3) $3,000,000 due within fifteen (15) days of the earlier to occur of either the completion of Rafael Pharmaceuticals' Phase III pivotal trial (AVENGER 500®) of CPI-613® (devimistat) or May 31, 2021 and not before January 4, 2021; and 4) $3,000,000 which is due within one-hundred and twenty (120) days from the date that Rafael Pharmaceuticals files a new drug application with the U.S. Food and Drug Administration for approval of devimistat (CPI-613) as a first in-line therapy for pancreatic cancer, as defined in the Purchase Agreement.

Certain of the post-closing payments may be made, at the Company's discretion, in cash or shares of the Company's Class B common stock based on the ten-day average share price of the Company's Class B common stock prior to the date of payment or any combination thereof.

The purchase of the additional membership interests was accounted for as an asset acquisition, as Altira is not considered a business in accordance with the guidance in ASC 805, *Business Combinations.* The membership interests acquired do not consist of inputs, processes, and are not generating outputs, as required in ASC 805 to qualify as a business, and are therefore accounted for as an asset acquisition. Although this transaction is considered an asset acquisition, there are no assets or liabilities to be recorded as of the acquisition date as Altira does not have any business operations. The cost of the investment was determined to be $7,000,000 pursuant to the terms of the Second Altira Agreement.

For the year ended July 31, 2021, the Company determined that the investment in Altira was fully impaired as of the acquisition date as there were no probable cash flows, and accordingly, had no value. The Company recorded an impairment charge of $7,000,000, which was the total amount of the Company's investment recognized for the Second Altira Agreement as of July 31, 2021.

During the year ended July 31, 2021, the Company issued 129,620 shares of Class B Common Stock with a value of $3.5 million to the First Seller under the Purchase Agreement.

Additionally, the Company issued 150,703 shares of Class B Common Stock with a value of $5 million to the Altira Second Seller, and cash payments totaling $2 million to satisfy the remaining non-contingent obligation due to the Altira Second Seller during the year ended July 31, 2021.

Upon the December 2020 acquisition of the additional 33% membership interest, the Company had a majority interest in Altira, which would require consolidation. However, the assets and operations of Altira are not significant to the Company as a whole. The Company has identified the investment in Altira as a related party transaction (see Note 13).

NOTE 4 — INVESTMENT IN RP FINANCE, LLC

On February 3, 2020, Rafael Pharmaceuticals entered into a Line of Credit Loan Agreement ("Line of Credit Agreement") with RP Finance which provides a revolving commitment of up to $50,000,000 to fund clinical trials and other capital needs.

The Company owns 37.5% of the equity interests in RP Finance and is required to fund 37.5% of funding requests from Rafael Pharmaceuticals under the Line of Credit Agreement. Howard Jonas owns 37.5% of the equity interests in RP Finance, and is required to fund 37.5% of funding requests from Rafael Pharmaceuticals under the Line of Credit Agreement. The remaining 25% equity interests in RP Finance is owned by other shareholders of Rafael Pharmaceuticals.

Under the Line of Credit Agreement, all funds borrowed will bear interest at the mid-term Applicable Federal Rate published by the U.S. Internal Revenue Service. The maturity date is the earlier of February 3, 2025, upon a change of control of Rafael Pharmaceuticals or a sale of Rafael Pharmaceuticals or its assets. Rafael Pharmaceuticals can draw on the facility on 60 days' notice. The funds borrowed under the Line of Credit Agreement must be repaid out of certain proceeds from equity sales by Rafael Pharmaceuticals.

NOTE 4 — INVESTMENT IN RP FINANCE, LLC (cont.)

In connection with entering into the Line of Credit Agreement, Rafael Pharmaceuticals agreed to issue to RP Finance shares of its common stock representing 12% of the issued and outstanding shares of Rafael Pharmaceuticals common stock, with such interest subject to anti-dilution protection as set forth in the Line of Credit Agreement.

RP Finance has been identified as a VIE; however, the Company has determined that it is not the primary beneficiary as the Company does not have the power to direct the activities of RP Finance that most significantly impact RP Finance's economic performance and, therefore, is not required to consolidate RP Finance. Therefore, the Company will use the equity method of accounting to record its investment in RP Finance. The Company has recognized approximately $383 thousand and $192 thousand in income from its ownership interests of 37.5% in RP Finance for the years ended July 31, 2021 and 2020, respectively. The assets and operations of RP Finance are not significant and the Company has identified the equity investment in RP Finance as a related party transaction (see Note 13).

In August 2020, Rafael Pharmaceuticals called for a $5 million draw on the line of credit facility and the facility was funded by RP Finance LLC in the amount of $5 million, paid in parts in August and September 2020. In November 2020, Rafael Pharmaceuticals called for a second $5 million draw on the line of credit facility and the facility was funded by RP Finance in the amount of $5 million. In June 2021 and July 2021, Rafael Pharmaceuticals called for a total aggregate $10 million draw on the line of credit facility and was funded by RP Finance in the amount of $10 million.

As of July 31, 2021, the Company has funded a total of $7.5 million in accordance with its 37.5% ownership interests in RP Finance.

In September 2021, Rafael Pharmaceuticals called for a $5 million draw on the line of credit facility and the Company has funded an additional $1.875 million in accordance with its 37.5% ownership interests in RP Finance.

NOTE 5 — INVESTMENT IN LIPOMEDIX PHARMACEUTICALS LTD.

LipoMedix is a clinical-stage, privately held Israeli company focused on the development of an innovative, safe and effective cancer therapy based on liposome delivery.

As of July 31, 2021, the Company held 68% of the issued and outstanding ordinary shares of LipoMedix and has consolidated this investment from the second quarter of fiscal 2018.

Between July 2018 and April 2019, the Company issued three bridge notes totaling $1,125,000 to LipoMedix. These bridge notes were converted into 2,122,641 shares of LipoMedix prior to December 31, 2019.

In November 2019, the Company provided bridge financing in the principal amount of $100,000 to LipoMedix with a maturity date of May 3, 2020 and an interest rate of 6%. Under the terms of the note, as long as it remains outstanding, LipoMedix may not incur any additional debt, make any shareholder distributions, or assume any liens on property or assets.

In January 2020, the Company provided bridge financing in the principal amount of $125,000 to LipoMedix with a maturity date of May 3, 2020 and an interest rate of 6%. Under the terms of the note, as long as it remains outstanding, LipoMedix may not incur any additional debt, make any shareholder distributions, or assume any liens on property or assets.

In March 2020, the Company provided bridge financing in the principal amount of $75,000 to LipoMedix with a maturity date of April 20, 2020 and an interest rate of 10%. Under the terms of the note, as long as it remains outstanding, LipoMedix may not incur any additional debt, make any shareholder distributions, or assume any liens on property or assets.

NOTE 5 — INVESTMENT IN LIPOMEDIX PHARMACEUTICALS LTD. (cont.)

In May 2020, the Company entered into a Share Purchase Agreement with LipoMedix to purchase 4,000,000 ordinary shares of LipoMedix for an aggregate purchase price of $1,000,000. The purchase consideration consisted of the outstanding Promissory Notes between the Company and LipoMedix dated November 13, 2019, January 21, 2020 and March 27, 2020 in the total principal amount of $300,000 plus accrued interest, for an aggregate amount of $306,737, and $693,263 of cash, thereby increasing the Company's ownership in LipoMedix from 58% to 68%.

In March 2021, the Company provided bridge financing in the principal amount of up to $400,000 to LipoMedix with a maturity date of September 1, 2021, and an interest rate of 8% per annum. As of July 31, 2021, the Company has provided $400,000 of funding to LipoMedix. As of July 31, 2021, accrued and unpaid interest on the bridge financing amounted to $10,290. If the note is not repaid or extended by the maturity, the interest rate will increase to 15% per annum. Under the terms of the note, as long as it remains outstanding, LipoMedix may not incur any additional debt, make any shareholder distributions, or assume any liens on property or assets. As of September 1, 2021, LipoMedix was in default on the terms of the loan and as such, the interest rate has increased to 15% per annum.

NOTE 6 — FAIR VALUE MEASUREMENTS

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability of fair value measures, the following hierarchy prioritizes the inputs to valuation methodologies used to measure fair value:

Level 1 — quoted prices in active markets for identical assets or liabilities;

Level 2 — quoted prices in active markets for similar assets and liabilities and inputs that are observable for the asset or liability; or

Level 3 — unobservable inputs for the asset or liability, such as discounted cash flow models or valuations.

The determination of where assets and liabilities fall within this hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The following is a listing of the Company's assets required to be measured at fair value on a recurring basis and where they are classified within the fair value hierarchy as of July 31, 2021 and July 31, 2020:

	July 31, 2021			
	Level 1	Level 2	Level 3	Total
		(in thousands)		
Assets:				
Hedge Funds	$ —	$ —	$ 5,268	$ 5,268
Total	$ —	$ —	$ 5,268	$ 5,268

	July 31, 2020			
	Level 1	Level 2	Level 3	Total
		(in thousands)		
Assets:				
Hedge Funds	$ —	$ —	$ 7,510	$ 7,510
Total	$ —	$ —	$ 7,510	$ 7,510

At July 31, 2021 and July 31, 2020, the Company did not have any liabilities measured at fair value on a recurring basis.

NOTE 6 — FAIR VALUE MEASUREMENTS (cont.)

The following table summarizes the change in the balance of the Company's assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3):

	July 31,	
	2021	2020
Balance, beginning of period	$ 7,510	$ 5,125
Liquidation of Hedge Fund Investments	(7,000)	—
Total gain included in earnings	4,758	2,385
Balance, end of period	$ 5,268	$ 7,510

Hedge funds classified as Level 3 include investments and securities which may not be based on readily observable data inputs. The availability of observable inputs can vary from security to security and are affected by a wide variety of factors, including, for example, the type of security, whether the security is new and not yet established in the marketplace, the liquidity of markets, and other characteristics particular to the security. The fair value of these assets is estimated based on information provided by the fund managers or the general partners. Therefore, these assets are classified as Level 3.

The Company received proceeds from the sale of a portion of the Company's investments in Hedge Funds in October 2020 and May 2021 of approximately $2 million and $5 million, respectively.

The Company holds $0.5 million in investments in securities in another entity that are not liquid, which were included in Investments — Other Pharmaceuticals in the accompanying consolidated balance sheets. The investments are accounted for under ASC 321, *Investments — Equity Securities*, using the measurement alternative as defined within the guidance, and the Company recorded impairment losses of $0.7 million and $0.8 million for the years ended July 31, 2021 and 2020, respectively.

Fair Value of Other Financial Instruments

The estimated fair value of the Company's other financial instruments was determined using available market information or other appropriate valuation methodologies. However, considerable judgment is required in interpreting these data to develop estimates of fair value. Consequently, the estimates are not necessarily indicative of the amounts that could be realized or would be paid in a current market exchange.

Cash and cash equivalents, prepaid expense and other current assets, and accounts payable. At July 31, 2021 and July 31, 2020, the carrying amount of these assets and liabilities approximated fair value because of the short period of time to maturity. The fair value estimates for cash and cash equivalents were classified as Level 1 and other current assets, and other current liabilities were classified as Level 2 of the fair value hierarchy.

Other assets and other liabilities. At July 31, 2021 and July 31, 2020, the carrying amount of these assets and liabilities approximated fair value. The fair values were estimated based on the Company's assumptions, which were classified as Level 3 of the fair value hierarchy.

The Company's financial instruments include trade accounts receivable, trade accounts payable, and due from related parties. The recorded carrying amounts of trade accounts receivable, trade accounts payable and due from related parties approximate their fair value due to their short-term nature. Other than noted above, the Company did not have any other assets or liabilities that were measured at fair value on a recurring basis as of July 31, 2021 or July 31, 2020.

NOTE 7 — TRADE ACCOUNTS RECEIVABLE

Trade Accounts Receivable consisted of the following:

	July 31, 2021	July 31, 2020
	(in thousands)	
Trade Accounts Receivable	$ 315	$ 364
Accounts Receivable – Related Party	113	121
Less Allowance for Doubtful Accounts	(193)	(218)
Trade Accounts Receivable, net	$ 235	$ 267

The current portion of deferred rental income included in prepaid expenses and other current assets was approximately $111 thousand and $11 thousand as of July 31, 2021 and July 31, 2020, respectively.

The noncurrent portion of deferred rental income included in Other Assets was approximately $1.5 million and $1.5 million as of July 31, 2021 and July 31, 2020, respectively.

NOTE 8 — PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	At July 31, 2021	At July 31, 2020
	(in thousands)	
Building and Improvements	$ 47,841	$ 47,591
Land	10,412	10,412
Furniture and Fixtures	1,145	1,145
Other	271	256
	59,669	59,404
Less Accumulated Depreciation	(16,431)	(14,971)
Total	$ 43,238	$ 44,433

Other property and equipment consist of other equipment and miscellaneous computer hardware.

Depreciation expense pertaining to property and equipment was approximately $1.5 million and $1.9 million for the years ended July 31, 2021 and 2020, respectively.

The Company's headquarters are located at 520 Broad Street in Newark, New Jersey, where it occupies office space in the building owned by its subsidiary.

In August 2020, the Company sold an office/data center building in Piscataway, New Jersey, which was classified as held for sale at July 31, 2020.

NOTE 9 — INCOME TAXES

At July 31, 2021, the Company has federal net operating loss ("NOL") carryforwards from domestic operations of approximately $47.0 million, to offset future taxable income. The Company has state NOLs of $27.8 million. The Company has NOLs from foreign operations of $2.9 million. As part of the Tax Act, federal NOLs generated in 2018 and later are not subject to an expiration period and are available to offset 80% of taxable income in the year in which they are utilized. The federal NOL carryforwards generated prior to 2018 will begin to expire in 2026. The state NOLs will begin to expire in 2038 and foreign NOLs do not expire.

NOTE 9 — INCOME TAXES (cont.)

The components of loss before income taxes are as follows:

	For the Year Ended July 31,	
	2021	2020
	(in thousands)	
Domestic	$ (24,251)	$ (6,212)
Foreign	(880)	(704)
Loss before income taxes	$ (25,131)	$ (6,916)

(Provision for) benefit from income taxes as presented in the consolidated statements of operations and comprehensive loss consisted of the following:

	For the Year Ended July 31,	
	2021	2020
	(in thousands)	
Current:		
Foreign	$ (19)	$ (2)
Federal	—	(9)
State	1	—
Total current expense	(18)	(11)
Deferred:		
Foreign	—	(18)
Total deferred expense	—	(18)
Provision for income taxes	$ (18)	$ (29)

The differences between income taxes expected at the U.S. federal statutory income tax rate and income taxes are reported as follows:

	At July 31,	
	2021	2020
	(in thousands)	
U.S. federal income tax at statutory rate	$ 5,278	$ 2,298
State income tax	1,724	662
Valuation allowance	(7,039)	(3,007)
Foreign tax rate differential	203	11
Permanent differences	—	(2)
Other	(184)	9
Provision for income taxes	$ (18)	$ (29)

The Company has not recorded U.S. income tax expense for foreign earnings because it has not generated any foreign earnings.

NOTE 9 — INCOME TAXES (cont.)

Significant components of the Company's deferred tax assets and deferred tax liabilities are as follows:

	At July 31,	
	2021	2020
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 12,495	$ 8,395
Unrealized gain/loss	968	—
Depreciation	2,583	2,660
Reserves and accruals	54	61
Stock-based compensation	2,096	312
Gross deferred tax assets	18,196	11,428
Less valuation allowance	(18,196)	(11,422)
Total deferred tax assets	—	6
Total deferred tax liabilities	—	—
Deferred tax assets, net	$ —	$ 6

Net deferred tax assets are included in deferred income tax assets, net in the consolidated balance sheets.

NOTE 10 — NOTE PAYABLE

On July 9, 2021, the Company, as guarantor, Rafael Holdings Realty, Inc., a wholly-owned subsidiary of the Company ("Realty"), as pledgor, and Broad-Atlantic Associates, LLC, a wholly-owned subsidiary of Realty (the "Borrower," and together with the Company and Realty, the "Borrower Parties"), as borrower, entered into a loan agreement (the "Loan Agreement") with 520 Broad Street LLC, a third-party lender (the "Lender"). The Loan Agreement provides for a loan in the amount of $15 million (the "Note Payable") from Lender to Borrower secured by (i) a first mortgage on 520 Broad Street, Newark, New Jersey 07102; and (ii) a first priority security interest in the equity of the Borrower as set forth in the Pledge and Security Agreement between Realty and Lender.

The Note Payable bears interest at a rate per annum equal to seven and one-quarter percent (7.25%) and thereafter at an interest rate per annum equal to the 30-day LIBOR Rate, as published in *The Wall Street Journal*, plus 6.90% per annum, but in no event less than seven and one-quarter percent (7.25%) per annum. The Note Payable is due on August 1, 2022, subject to the Company's option to extend the maturity date until August 1, 2023 for a fee equal to three-quarters of one percent (0.75%) of the Note Payable.

The Loan Agreement contains customary affirmative covenants, negative covenants and events of default, as defined in the Loan Agreement, including covenants and restrictions that, among other things, restrict the Borrower's ability to incur liens, or transfer, lease or sell the collateral as defined in the Loan Agreement. A failure to comply with these covenants could permit the Lender to declare the Borrower's obligations under the Loan Agreement, together with accrued interest and fees, to be immediately due and payable.

Interest expense under the Note Payable amounted to $64,315 and $0 for the years ended July 31, 2021 and 2020, respectively.

Unamortized debt issuance costs on the Note Payable totaled $472,184 and $0 for the years ended July 31, 2021 and 2020, respectively. Amortization of the debt discount on the Note Payable totaled approximately $27,776 and $0 for the years ended July 31, 2021 and 2020, respectively.

NOTE 11 — LEASES

The Company is the lessor of certain properties which are leased to tenants under net operating leases with initial term expiration dates ranging from 2021 to 2029. Lease income included on the consolidated statements of operations and comprehensive loss for the years ended July 31, 2021 and 2020 was $3.0 million and $3.6 million, respectively.

The future contractual minimum lease payments to be received (excluding operating expense reimbursements) by the Company as of July 31, 2021, under non-cancellable operating leases which expire on various dates through 2028 are as follows:

Year ending July 31,	Related Parties	Other	Total
		(in thousands)	
2022	$ 2,078	$ 782	$ 2,860
2023	2,117	592	2,709
2024	2,155	538	2,693
2025	1,659	550	2,209
Thereafter	—	1,948	1,948
Total Minimum Future Rental Income	$ 8,009	$ 4,410	$ 12,419

The Company has related party leases that expire in April 2025 for (i) an aggregate of 88,631 square feet, which includes two parking spots per thousand square feet of space leased at 520 Broad Street, Newark, New Jersey, and (ii) 3,595 square feet in Israel. The annual rent is approximately $2.0 million in the aggregate. The related parties have the right to terminate the domestic leases upon four months' notice, and upon early termination will pay a termination penalty equal to 25% of the portion of the rent due over the course of the remaining term. A related party has the right to terminate the Israeli lease upon four months' notice. IDT has the right to lease an additional 50,000 square feet, in 25,000-foot increments, in the building located at 520 Broad Street, Newark, New Jersey on the same terms as their base lease, and other rights should 25,000 square feet or less remain available to lessees in the building (see Note 13). Upon expiration of the lease, related parties have the right to renew the leases for another five years.

NOTE 12 — COMMITMENTS AND CONTINGENCIES

Legal Proceedings

On July 12, 2019, the Company received a Citation and Notification of Penalty from the Occupational Safety and Health Administration of the U.S. Department of Labor, or OSHA, related to an OSHA inspection of 520 Broad Street, Newark, New Jersey. The citation seeks to impose penalties related to alleged violations of the Occupation Safety and Health Act of 1970 at 520 Broad Street. On July 31, 2019, the Company filed a Notice of Contest with OSHA contesting the citation in its entirety. On February 14, 2020, the Company entered into a Settlement Agreement with OSHA, as related to the citation received on July 12, 2019. As part of the Settlement Agreement, the Company agreed to pay a penalty of $127,294 in eight quarterly installment payments through November 2021, which the Company accrued for and has an outstanding balance of approximately $32,000 as of July 31, 2021. The penalty was recorded to accrued expenses within the Consolidated Balance Sheets. As the Company accounts for contingencies when a loss is considered probable and can be reasonably estimated, the accrued balance is for legal fees and losses believed to be both probable and reasonably estimable, but an exposure to additional loss may exist in excess of the amount accrued.

On December 31, 2019, an employee of the Company filed a complaint in connection with the incident that led to the OSHA inspection noted above for personal injuries against the Company and other parties in the New Jersey Supreme Court for an incident that took place on January 31, 2019 at 520 Broad Street, Newark, New Jersey. The Company intends to vigorously defend this matter. The loss is considered remote and no accrual has been recorded.

The Company may from time to time be subject to legal proceedings that may arise in the ordinary course of business. Although there can be no assurance in this regard, other than noted above, the Company does not expect any of those legal proceedings to have a material adverse effect on the Company's results of operations, cash flows or financial condition.

NOTE 13 — RELATED PARTY TRANSACTIONS

IDT Corporation

The Company has historically maintained an intercompany balance due to/from related parties that relates to cash advances for investments, loan repayments, charges for services provided to the Company by IDT Corporation, or IDT, and payroll costs for the Company's personnel that were paid by IDT. The Company also receives rental income from various companies under common control to IDT. The Company recorded expense of approximately $322 thousand and $309 thousand in related party services to IDT for the years ended July 31, 2021 and 2020, respectively, of which approximately $136 thousand and $0 is included in Due to Related Parties at July 31, 2021 and 2020, respectively.

IDT leases approximately 80,000 square feet of office space plus parking occupied by IDT at 520 Broad Street, Newark, NJ and approximately 3,600 square feet of office space in Jerusalem, Israel. IDT paid the Company approximately $1.8 million for office rent and parking during both fiscal 2021and 2020. As of July 31, 2021 and 2020, IDT owed the Company approximately $168 thousand and $9 thousand, respectively, for office rent and parking.

During the year ended July 31, 2021, IDT exercised 43,649 warrants to purchase shares of Class B Common Stock.

Rafael Pharmaceuticals

The Company provides Rafael Pharmaceuticals with administrative, finance, accounting, tax and legal services. Howard S. Jonas served as the former Chairman of the Board of Rafael Pharmaceuticals and owns an equity interest in Rafael Pharmaceuticals. The Company billed Rafael Pharmaceuticals $480 thousand for each of the years ended July 31, 2021 and 2020. As of July 31, 2021 and 2020, Rafael Pharmaceuticals owed the Company $600 thousand and $118 thousand, respectively, included in Due from Rafael Pharmaceuticals.

Levco Pharmaceuticals Ltd

On September 8, 2020, Levco Pharmaceuticals Ltd ("Levco") entered into a research and development consulting agreement with Dr. Alberto Gabizon for a two-year period. Under the agreement, in exchange for the services provided, Levco will pay Dr. Gabizon $3,000 per month and issue to him common shares representing up to 5% of common stock outstanding. Additionally, Levco will provide a lab grant in the amount of $120,000 to support the project.

On September 8, 2020, Levco entered into a Sponsored Research Agreement with a company for a research program related to patent applications with payments totaling $120,000 plus value-added tax. The research period is over 13 months, with two additional 12-month options to extend.

During the year ended July 31, 2021, the Company funded approximately $657,000 to Levco.

Farber Partners, LLC

On December 10, 2020, a controlled subsidiary of the Company, Farber, reached an agreement with Princeton University to in-license certain patents and related information related to the serine hydroxymethyltransferase (SHMT) inhibitor program developed by the laboratory of Dr. Joshua D. Rabinowitz at Princeton. Farber will pay Princeton a minimum annual royalty payment of $50 thousand, in addition to percentage royalties and a percentage of any sublicense revenue. Additionally, there are development milestone payments which Farber will pay Princeton for the first three products developed by Farber, or any sublicensees or affiliates.

Pharma Holdings

On January 28, 2021, Pharma Holdings partially exercised the Warrant and purchased 7.3 million shares of Rafael Pharmaceuticals' Series D Preferred Stock for $9.1 million, of which $0.9 million was contributed by the holder of a minority interest in Pharma Holdings.

NOTE 13 — RELATED PARTY TRANSACTIONS (cont.)

Related Party Rental Income

The Company leases space to related parties which represented approximately 65% and 52% of the Company's total revenue for the years ended July 31, 2021 and 2020, respectively. See Note 11 for future minimum rent payments from related parties and other tenants.

Investment in Altira

In May 2020, the Company acquired its first membership interest of 33.333% in Altira, a related party. In December 2020, the Company acquired an additional 33.333% membership interest in Altira, for an aggregate of a 66.666% membership interest (see Note 3).

RP Finance LLC

For the years ended July 31, 2021 and 2020, respectively, the Company recognized approximately $383 thousand and $192 thousand in income from its ownership interests of 37.5% in RP Finance, respectively.

Howard Jonas, Chairman of the Board and Former Chief Executive Officer

In December 2020, two entities, on whose Boards of Directors Howard Jonas, the Registrant's Chairman of the Board and former Chief Executive Officer serves, each purchased 218,245 shares of Class B common stock for consideration of $5 million each. In connection with the purchases, each purchaser was granted warrants (the "Issued Warrants") to purchase twenty percent (20%) of the shares of Class B common stock purchased by such purchaser. The Issued Warrants have an exercise price of $22.91 per share and expire on June 6, 2022. The shares and Issued Warrants were issued in reliance on the exemption from registration provided for under Section 4(a)(2) of the Securities Act of 1933, as amended.

NOTE 14 — EQUITY

Class A Common Stock and Class B Common Stock

The rights of holders of Class A common stock and Class B common stock are identical except for certain voting and conversion rights and restrictions on transferability. The holders of Class A common stock and Class B common stock receive identical dividends per share when and if declared by the Company's Board of Directors. In addition, the holders of Class A common stock and Class B common stock have identical and equal priority rights per share in liquidation. The Class A common stock and Class B common stock do not have any other contractual participation rights. The holders of Class A common stock are entitled to three votes per share and the holders of Class B common stock are entitled to one-tenth of a vote per share. Each share of Class A common stock may be converted into one share of Class B common stock, at any time, at the option of the holder. Shares of Class A common stock are subject to certain limitations on transferability that do not apply to shares of Class B common stock.

On May 27, 2021, the Company filed a Registration Statement on Form S-3, whereby the Company may sell up to $250 million of Class B common stock. This registration was declared effective on June 7, 2021.

On June 1, 2021, the Company filed a Registration Statement on Form S-3 and issued 48,859 shares of Class B common stock to the Altira Second Seller totaling $2.25 million to satisfy a portion of the remaining non-contingent obligation due to the Altira Second Seller.

Stock-Based Compensation

The Rafael Holdings, Inc. 2018 Equity Incentive Plan (the "Plan") was created and adopted by the Company in March 2018. The Plan allows for the issuance of up to 2,090,954 shares which may be awarded in the form of incentive stock options or restricted shares. During fiscal 2021 the Plan was amended for additional shares to be issued to certain employees of the Company. There are 83,484 shares available for issuance under the Plan as of July 31, 2021.

NOTE 14 — EQUITY (cont.)

A summary of stock option activity for the Company is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at July 31, 2019	587,133	$ 4.90	3.66	$ 2,877
Granted	—	—		
Exercised	(6,000)	4.90		
Cancelled/Forfeited	(259)	4.90		
Outstanding at July 31, 2020	580,874	$ 4.90	2.65	$ 2,846
Granted	118,409	40.85		
Exercised	(14,546)	4.90		
Cancelled/Forfeited	(1,323)	4.90		
OUTSTANDING AT JULY 31, 2021	**683,414**	**$ 11.13**	3.05	**$ 26,982**
EXERCISABLE AT JULY 31, 2021	**565,005**	**$ 4.90**	1.65	**$ 25,826**

The value of option grants is calculated using the Black-Scholes option pricing model with the following assumptions for options granted during the fiscal year ended July 31, 2021:

Risk-free interest rate	1%
Expected term (in years)	6.04
Expected volatility	75%
Expected dividend yield	—%

There were no options granted during the fiscal year ended July 31, 2020.

During the year ended July 31, 2021, 118,409 options were granted to one individual, resulting in $0.5 million in stock-based compensation expense for the year ended July 31, 2021. These options are subject to graded vesting extending through April 15, 2025.

During the year ended July 31, 2021, 14,546 options were exercised. At July 31, 2021, there was unrecognized compensation cost related to non-vested stock options of $2.5 million, which is expected to be recognized over the next 1.86 years.

Restricted Stock Units

The fair value of restricted shares of the Company's Class B common stock is determined based on the closing price of the Company's Class B common stock on the grant date. Share awards generally vest on a graded basis over three years of service.

On May 27, 2021, the Company granted 908,497 restricted shares of Class B common stock of the Company to the Chief Executive Officer, which will vest over approximately four years. The aggregate fair value of the grants in fiscal 2021 was approximately $45.1 million, which is being charged to expense on a straight-line basis as the shares vest.

During fiscal 2021 and 2020, the Company granted employees and consultants 47,820 and 24,071 restricted shares of Class B Common Stock, respectively, which will vest over approximately three years. The aggregate fair value of the grants in fiscal 2021 and 2020 was approximately $1.1 million and $478 thousand, respectively, which is being charged to expense on a straight-line basis as the shares vest.

NOTE 14 — EQUITY (cont.)

A summary of the status of the Company's grants of restricted shares of Class B common stock is presented below:

	Number of Non-vested Shares	Weighted Average Grant Date Fair Value
Outstanding at July 31, 2019	156,426	$ 10.41
Granted	24,071	19.87
Vested	(57,060)	(8.17)
Cancelled/Forfeited	(333)	(4.90)
Outstanding at July 31, 2020	123,104	$ 10.80
Granted	956,317	48.34
Vested	(69,347)	(10.76)
Cancelled/Forfeited	(2,099)	(13.54)
NON-VESTED SHARES AT JULY 31, 2021	1,007,975	$ 46.77

At July 31, 2021, there was $41.5 million of total unrecognized compensation cost related to non-vested stock-based compensation arrangements, which is expected to be recognized over the next 9.09 years. The total grant date fair value of shares vested in fiscal 2021 and fiscal 2020, was approximately $746,000 and $466,000, respectively.

Securities Purchase Agreement

On December 7, 2020, Rafael Holdings entered into a Securities Purchase Agreement (the "SPA") for the sale of 567,437 shares of the Company's Class B common stock at a price per share of $22.91 (which was the closing price for the Class B common stock on the New York Stock Exchange on December 4, 2020 the trading day immediately preceding the date of the SPA) for an aggregate purchase price of $13 million.

Approximately $8.2 million of the proceeds received pursuant to the SPA were used by the Company to exercise an additional portion of the Warrant in order to maintain the Company's relative position in Rafael Pharmaceuticals in light of issuances of Rafael Pharmaceuticals equity securities to third-party shareholders of Rafael Pharmaceuticals, due to warrant exercises by these shareholders. The Company is using the remaining proceeds to fund the operations of its drug development programs including its Barer Institute subsidiary, and for general corporate purposes. Under the SPA, two entities, on whose Boards of Directors Howard Jonas, the Registrant's Chairman of the Board and former Chief Executive Officer serves, each purchased 218,245 shares of Class B common stock for consideration of $5 million each. The shares and warrants were issued in reliance on the exemption from registration provided for under Section 4(a)(2) of the Securities Act of 1933, as amended.

Equity-classified Warrants

In connection with the Share Purchase Agreement, each purchaser was granted warrants to purchase twenty percent (20%) of the shares of Class B common stock purchased by such purchaser. The Company issued warrants to purchase 113,487 shares of Class B common stock to the purchasers. The warrants are exercisable at a per share exercise price of $22.91, and are exercisable at any time on or after December 7, 2020 through June 6, 2022. The Company determined that these warrants are equity-classified.

During the year ended July 31, 2021, IDT and Genie each exercised 43,649 warrants, resulting in a total of 87,298 shares of Class B common stock issued for proceeds of approximately $2 million. At July 31, 2021, the Company had outstanding warrants to purchase 26,189 shares of common stock at an exercise price of $22.91 per share, all of which expire June 6, 2022.

NOTE 14 — EQUITY (cont.)

Conversion of Convertible Note

On November 15, 2018, Howard Jonas entered into an agreement to purchase a convertible note from the Company for $15.0 million that was convertible into shares of Class B common stock at $8.47 per share. The term of the note was three years with interest on the principal amount at a rate of 6% per annum, compounded quarterly. In August 2019, the note, including interest of approximately $667,000, was converted into 1,849,749 shares of Class B common stock.

Grant to Board of Directors

Pursuant to the Company's 2018 Equity Incentive Plan, three of our four non-employee directors of the Company were granted 4,203 restricted shares of our Class B common stock in January 2020 and 4,203 restricted shares of our Class B common stock in January 2021 which fully vested on the date of the grants. The fair value of the awards on the date of the grants were approximately $286,000 and $208,000 in January 2021 and January 2020, respectively, which was included in selling, general and administrative expense.

NOTE 15 — BUSINESS SEGMENT INFORMATION

The Company conducts business as two operating segments, Pharmaceuticals and Real Estate. The Company's reportable segments are distinguished by types of service, customers and methods used to provide their services. The operating results of these business segments are regularly reviewed by the Company's CEO and chief operating decision-maker.

The accounting policies of the segments are the same as the accounting policies of the Company as a whole. The Company evaluates the performance of its Pharmaceuticals segment based primarily on research and development efforts and results of clinical trials and the Real Estate segment based primarily on results of operations. All investments in Rafael Pharmaceuticals and assets and expenses associated with LipoMedix, Barer, Levco, Farber, and Rafael Medical Devices are tracked separately in the Pharmaceuticals segment. All corporate costs are allocated to the Real Estate segment.

The Pharmaceuticals segment is comprised of preferred and common equity interests and the Warrant to purchase equity interests in Rafael Pharmaceuticals, a majority equity interest in LipoMedix, Barer, Levco, Farber, and Rafael Medical Devices. To date, the Pharmaceuticals segment has not generated any revenues.

The Real Estate segment consists of the Company's real estate holdings, including a building at 520 Broad Street in Newark, New Jersey that houses headquarters for the Company and certain affiliates and its associated public garage, and a portion of an office building in Israel.

In August 2020, the Company sold a three-story, 65,253 square foot office building located at 225 Old New Brunswick Road in Piscataway, New Jersey to 225 ONBR, LLC, an entity unaffiliated with the Company. The purchase price was $3,875,000 and, after transfer taxes and broker's commission, the Company received net proceeds of $3,675,638 in cash. At July 31, 2020, the building was classified as held for sale on the consolidated balance sheet.

Operating results for the business segments of the Company are as follows:

(in thousands)	Pharmaceuticals	Real Estate	Total
At Year Ended July 31, 2021			
Revenues	$ —	$ 3,971	$ 3,971
Loss from operations	(20,061)	(9,751)	(29,812)
At Year Ended July 31, 2020			
Revenues	$ —	$ 4,910	$ 4,910
Loss from operations	(2,811)	(5,654)	(8,465)

NOTE 15 — BUSINESS SEGMENT INFORMATION (cont.)

Geographic Information

Revenues from tenants located outside of the United States were generated entirely from related parties located in Israel. Revenues from these non-United States customers as a percentage of total revenues were as follows (revenues by country are determined based on the location of the related facility):

Year Ended July 31,	2021	2020
Revenue from tenants located in Israel	7%	6%

Net long-lived assets and total assets held outside of the United States, which are located in Israel, were as follows:

(in thousands)	United States	Israel	Total
July 31, 2021			
Long-lived assets, net	$ 41,704	$ 1,534	$ 43,238
Total assets	150,847	3,208	154,055
July 31, 2020			
Long-lived assets, net	$ 42,840	$ 1,593	$ 44,433
Total assets	132,286	4,061	136,347

NOTE 16 — LOSS PER SHARE

Basic net loss per share is computed by dividing net loss attributable to all classes of common stockholders of the Company by the weighted average number of shares of all classes of common stock outstanding during the applicable period. Diluted loss per shares includes potentially dilutive securities such as stock options and other convertible instruments. For the years ended July 31, 2021 and 2020, these securities have been excluded from the calculation of diluted net loss per shares because all such securities are anti-dilutive for all periods presented.

The following table summarizes the Company's potentially dilutive securities, which have been excluded from the calculation of dilutive loss per share as their effect would be anti-dilutive:

	July 31,	
	2021	2020
Shares issuable upon exercise of stock options	683,414	580,874
Shares issuable upon exercise of warrants to purchase Class B common stock	26,189	—
Total	709,603	580,874

In the years ended July 31, 2021 and 2020, the diluted loss per share computation equals basic loss per share because the Company had a net loss and the impact of the assumed exercise of stock options and warrants would have been anti-dilutive.

NOTE 17 — SUBSEQUENT EVENTS

Share Purchase Agreement with Institutional Investors and I9Plus, LLC

On August 19, 2021, the Company entered into a Securities Purchase Agreement (the "Institutional Purchase Agreement") with institutional investors (the "Institutional Investors") and a Securities Purchase Agreement with I9Plus, LLC, (the "Jonas Purchase Agreement"), an entity affiliated with Howard S. Jonas, the Chairman of the Board of Directors of the Company. On August 24, 2021, the Company issued 2,833,425 shares of Class B common stock (the "Institutional Shares"), par value $0.01 per share, to the Institutional Investors, at a purchase price equal to $35.00 per share, for aggregate gross proceeds of approximately $99.2 million, before deducting placement agent fees and other offering expenses. Additionally, pursuant to the Jonas Purchase Agreement, the Company issued 112,561 shares of Class B common stock to I9Plus, LLC, at a purchase price equal to $44.42 per share, which was equal to the closing

NOTE 17 — SUBSEQUENT EVENTS (cont.)

price of a share of the Class B common stock on the New York Stock Exchange on August 19, 2021 (the "Jonas Offering"). The Jonas Offering resulted in additional aggregate gross proceeds of approximately $5.0 million. The total net proceeds from the issuance of shares was $97.8 million after deducting transaction costs of $6.4 million.

On August 19, 2021, in connection with the Institutional Purchase Agreement, the Company entered into a Registration Rights Agreement with the Institutional Investors whereby the Company agreed to prepare and file a registration statement with the SEC within 30 days after the earlier of (i) the date of the closing of the Merger Agreement, and (ii) the date the Merger Agreement is terminated in accordance with its terms, for purposes of registering the resale of the Institutional Shares and any shares of Class B common stock issued as a dividend or other distribution with respect to the Institutional Shares.

Line of Credit to Rafael Pharmaceuticals

On September 23, 2021, the Company entered into a line of credit agreement with Rafael Pharmaceuticals (the "Debtor") in which the Debtor may borrow up to an aggregate amount of $25,000,000. The first advance made to the Debtor was in the amount of $1,900,000 on September 24, 2021. On October 1, 2021, a second advance was made to the Debtor in the amount of $23,100,000.

Investment in RP Finance, LLC

In September 2021, Rafael Pharmaceuticals called for a $5 million draw on the line of credit facility and the Company has funded an additional $1.875 million in accordance with its 37.5% ownership interests in RP Finance.