

RAFAEL HOLDINGS, INC.

RAFAEL
Holdings, Inc.

2019 ANNUAL REPORT

RAFAEL

Holdings, Inc.

Dear Fellow Stockholders:

Since our spinoff from IDT Corporation in March of 2018, our Board, management and employees have been working diligently to generate shareholder value from our investments in commercial real estate and cancer therapeutics. They have done an outstanding job and I am pleased to have this opportunity to highlight some of their most significant achievements and works in progress.

Let's start with our real estate:

Rafael's Holdings' marquee property at 520 Broad Street in Newark, NJ is well positioned to benefit from Newark's revival as well as from positive trends in the broader real estate market. We have engaged a highly regarded team of real estate professionals to help us realize this property's full potential. They are pursuing several opportunities including a potential sale. We are also exploring monetization strategies for our industrial property in Piscataway, NJ. Our third property, an office condominium in Jerusalem, is now fully leased.

Turning to our pharmaceutical investments:

We are developing multiple, uniquely promising opportunities to significantly advance mankind's ability to treat some of the most difficult to treat cancers in part through our stakes in Rafael Pharmaceuticals, LipoMedix and the recently launched Barer Institute.

Rafael Pharmaceuticals is evaluating its lead compound, CPI-613[®] (devimistat), in five clinical studies — three with patients suffering from solid tumors and two with patients suffering hematological malignancies. Rafael Pharma initiated global Phase 3, pivotal trials in pancreatic cancer (AVENGER 500) and acute myeloid leukemia (ARMADA 2000) during calendar year 2018. Interim results, which could form the basis of a new drug application, may be available for review and evaluation as early as the second half of calendar 2020.

Rafael Pharmaceuticals achieved a significant business development milestone this summer by entering into a licensing agreement with Ono Pharmaceutical Co., a highly regarded Japanese pharmaceutical company. The agreement provides Ono with the exclusive right to commercialize and sell CPI-613[®] (devimistat) in Japan and other ASEAN (Association of Southeast Asian Nations) countries. In return, Ono paid Rafael Pharmaceuticals an upfront payment of \$12.9 million with an additional up to \$150 million contingent on the achievement of certain development and commercial milestones. Rafael will also receive low-double digit royalties based on net sales of devimistat in these countries.

Rafael Holdings (and its affiliates) has partially exercised its warrant to purchase equity in Rafael Pharmaceuticals, and now owns 51% of its issued and outstanding stock.

We also hold a majority stake in LipoMedix Pharmaceuticals Ltd, a clinical-stage company developing Promitil[®] — a liposomal prodrug for targeted delivery of Mitomycin C. Based on its preclinical work, LipoMedix has received FDA permission to launch a randomized Phase 2b clinical trial of Promitil for the treatment of patients with previously treated metastatic colorectal cancer.

In addition to these two investments, we recently launched the Barer Institute, a research and drug development initiative. The Barer Institute is leveraging the pioneering work done by leading scientists in cancer metabolism at top universities to develop therapies.

These investments in cancer therapeutics underscore our abiding commitment to improve outcomes for cancer patients and particularly for those without effective treatment options.

We look forward to updating you in the coming year as our work progresses.

Sincerely,



Howard Jonas
Chairman and Chief Executive Officer

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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, 2019.

or

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

Commission File Number: 000-55863

R A F A E L
Holdings, Inc.

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	NYSE American

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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the 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 31, 2019 (the last business day of the registrant's most recently completed second fiscal quarter) of the Class B common stock of \$15.42 per share, as reported on the New York Stock Exchange, was approximately \$96 million.

The number of shares outstanding of the registrant's common stock as of October 2, 2019 was:

Class A common stock, par value \$0.01 per share: 787,163 shares

Class B common stock, par value \$0.01 per share: 14,997,251 shares

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant's Annual Meeting of Stockholders, to be held January 15, 2020, 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

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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 2019 refers to the fiscal year ended July 31, 2019).

Item 1. Business.

OVERVIEW

Rafael Holdings, Inc., (“Rafael Holdings” or “the Company”), a Delaware corporation, owns interests in commercial real estate assets and clinical stage pharmaceutical companies. The assets are operated as two separate lines of business. 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, and an associated 800-car public garage, an office/data center building in Piscataway, New Jersey and a portion of a building in Israel. The pharmaceutical holdings include preferred equity interests and a warrant to purchase additional equity interests in Rafael Pharmaceuticals, Inc., or Rafael Pharmaceuticals, which 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, and a majority equity interest in LipoMedix Pharmaceuticals Ltd., or LipoMedix, a clinical stage oncological pharmaceutical company based in Israel.

Financial information by segment is presented in Note 13 in the Notes to our Consolidated and Combined 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://rafaelholdings.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.

THE SPIN-OFF

On March 26, 2018, IDT Corporation, or IDT, the former parent corporation of the Company, completed a tax-free spinoff (the “Spin-Off”) of the Company’s capital stock, through a pro rata distribution of common stock to its stockholders of record as of the close of business on March 13, 2018.

RECENT DEVELOPMENTS

- During the year, subsidiaries of the Company converted notes and exercised a portion of their warrant to purchase Series D Convertible Preferred Stock of Rafael Pharmaceuticals. A total of 53.4 million shares, representing 51% of the outstanding capital stock of Rafael Pharmaceuticals, was purchased or obtained through conversion of notes. The Company’s subsidiary still maintains additional rights under the Warrant to maintain ownership regardless of additional equity instruments issued by Rafael Pharmaceuticals and maintains the rights to increase ownership to 56% of the capital stock of Rafael Pharmaceuticals.
- Rafael Pharmaceuticals reached an out-licensing agreement with Ono Pharmaceutical Co., Ltd. (“Ono”) of Japan. Ono gained exclusive rights to develop and commercialize the Rafael Pharmaceuticals’ lead drug candidate, CPI-613[®] (devimistat), and related compounds for all indications in certain Asia-Pacific region countries. Rafael Pharmaceuticals received an upfront payment of \$12.9 million, with the right to an additional \$150.3 million contingent on attainment of certain developmental and commercial milestones. Rafael Pharmaceuticals will also receive low-double digit royalties based on net sales.

- Rafael Pharmaceuticals continued to expand its pivotal Phase 3 trial of CPI-613[®] (devimistat) for patients with relapsed or refractory acute myeloid leukemia (AML) adding clinical trial sites in France, Austria, South Korea and Spain.
- Rafael Pharmaceuticals continued to expand its pivotal Phase 3 trial of CPI-613[®] (devimistat) in combination with modified FOLFIRINOX as a first-line treatment for patients with metastatic pancreatic cancer adding clinical trial sites in France, Korea and Israel.
- *Future Oncology*, a peer-reviewed medical journal, published two manuscripts about the details of ongoing Phase 2 and Phase 3 studies at Rafael Pharmaceuticals.
- LipoMedix was awarded a Horizon 2020 Phase 1 grant for the project: Promitil[®] — a new ‘smart’ nanomedicine for cancer chemo-radiotherapy. Horizon 2020 is a research and innovation program of the European Union.
- We have established a wholly owned venture to develop a pipeline of therapeutic compounds including compounds to regulate cancer metabolism. The venture is pursuing collaborative research agreements with scientists from top academic institutions.

BUSINESS DESCRIPTION

We own commercial real estate assets and interests in clinical pharmaceutical companies. The assets are operated as two separate lines of business and we are looking to increase the value of both of our holdings.

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, an office/data center building in Piscataway, New Jersey 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. We have retained a leading real estate brokerage firm to market the building for potential sale while we continue to attempt to maximize the value of our holdings by leasing activity and improvements. 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 providing additional upside to potential purchasers.

The building serves as the headquarters of Rafael Holdings, IDT, and Genie Energy, Ltd. (“Genie”), who occupy the second through fourth floors. Currently, approximately 30% 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% 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 \$200,000. 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% 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, 2019 and July 31, 2018, the carrying value of the land, building and improvements at 520 Broad Street was \$43.8 million and \$45.2 million, respectively.

The building in Piscataway is located at 225 Old New Brunswick Road. It is a three-story commercial office building containing approximately 65,000 square feet. The building was completed in 1978. Since its completion, the building has been leased as data space and therefore has ample power, diverse paths of fiber, back-up generators and dedicated HVAC units. Currently, approximately 28% of the building is leased to two data users. Both leases are to tenants who each occupy a portion of the first floor. One lease expires at the end of 2020 and the other lease expires at the end of October 2022. We have commenced efforts to upgrade the building's aesthetics and infrastructure and initiated a lobby upgrade. We have retained Colliers International to market the building for potential sale. The marketing efforts were initiated in the first quarter of fiscal 2019 and are ongoing. We are also marketing the space for lease to the office and data center market.

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, 2019, the space is fully leased to 2 tenants; one is IDT and another third-party tenant.

Depreciation and amortization expense of property, plant and equipment was \$1.8 million and \$1.7 million in fiscal 2019 and fiscal 2018, respectively.

Pharmaceuticals

Overview

We have investments in Rafael Pharmaceuticals, 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. We also have an investment in LipoMedix, which is based in Israel, and is a clinical stage oncology company. In addition to our investments in Rafael Pharmaceuticals and LipoMedix, we have established a wholly owned venture to develop a pipeline of therapeutic compounds including compounds to regulate cancer metabolism. The venture is pursuing collaborative research agreements with scientists from top academic institutions.

Rafael Pharmaceuticals

We own interests/rights in Rafael Pharmaceuticals through a 90%-owned non-operating subsidiary, IDT-Rafael Holdings, LLC, or IDT-Rafael Holdings. IDT-Rafael Holdings holds 36.7 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, and will expire upon the earlier of December 31, 2020, a qualified initial public offering, or liquidation event of Rafael Pharmaceuticals.

IDT-Rafael Holdings also owns 50% of CS Pharma Holdings, LLC ("CS Pharma"), a non-operating entity that holds 16.7 million shares of Rafael Pharmaceuticals Series D Convertible Preferred Stock. Accordingly, the Company holds an effective 45% indirect interest in the assets held by CS Pharma.

Howard Jonas, Chairman of the Board and Chief Executive Officer of the Company, and Chairman of the Board of Rafael Pharmaceuticals owns 10% of IDT-Rafael Holdings.

IDT-Rafael Holdings also holds certain governance rights in Rafael Pharmaceuticals including appointment of directors.

We and our subsidiaries collectively own securities representing 51% of the outstanding capital stock of Rafael Pharmaceuticals and 38% 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, 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.

We serve as the managing member of IDT-Rafael Holdings and IDT-Rafael 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 IDT-Rafael Holdings to 50% (based on current ownership) of such distributions. Similarly, if IDT-Rafael Holdings were to distribute proceeds it receives from CS Pharma, it would do so on a pro rata basis, entitled the Company to 90% (based on current ownership) of such distributions.

Separately, Howard Jonas and Deborah Jonas jointly own \$525,000 of Series C Convertible Notes of Rafael Pharmaceuticals, and The Howard S. and Deborah Jonas Foundation owns \$525,000 of Series C Notes of Rafael Pharmaceuticals.

On September 19, 2017, IDT approved a compensatory arrangement with Howard Jonas related to the right held by IDT-Rafael Holdings to receive additional Rafael Pharmaceutical shares (“Bonus Shares”) upon the achievement of certain milestones. Under that arrangement, IDT transferred to Howard Jonas 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 that was previously held by IDT-Rafael Holdings, which is contingent upon achieving certain milestones. This right was previously held by IDT-Rafael Holdings, subject to its right to transfer to recipients that IDT-Rafael Holdings, in its sole discretion, felt merit because of special efforts by such persons in assisting Rafael Pharmaceuticals and its products. IDT-Rafael Holdings distributed the rights to its members and transferred the portion it received to Howard Jonas. If any of the milestones are met, the Bonus Shares are to be issued without any additional payment. Howard Jonas has the right to transfer the Bonus Shares, in his discretion, to others, including those who are instrumental to the future success of Rafael Pharmaceuticals. These milestones have not yet been met and no bonus shares have been issued.

Science and Preclinical:

Rafael Pharmaceuticals is developing its lead product CPI-613[®] (devimistat), an investigational new drug for the treatment of solid tumors and hematologic malignancies. This molecule has been developed based on Altered Metabolism Directed (AMD) platform. It is a small molecule and suitable for intravenous (IV) administration.

In the 1920's, Nobel Prize winner Dr. Otto Warburg observed that cancer cells metabolize glucose differently than normal cells. More recently it has been recognized that tumor-specific alteration of metabolism is pervasive, affecting all metabolic processes. Both cytosolic and mitochondrial processes are crucially transformed during the evolution of metastatic disease. This profoundly altered metabolism of cancer cells has recently emerged as one of the most promising new domains for therapeutic targeting of cancer. In most cancer cells, uptake of glucose is substantially increased. Glucose is metabolized to pyruvate which then is either reduced to lactate by lactate dehydrogenase (LDH) or oxidized to acetyl coenzyme A (Acetyl-CoA) by pyruvate dehydrogenase (PDH) for introduction into the mitochondrial tricarboxylic acid (TCA) cycle. The Acetyl-CoA then can be used for either energy generation or biosynthetic intermediate production, both crucial to tumor cell survival. Glutamine is an additional carbon source, also essential for sustaining the TCA cycle in tumor cells. Glutamine transport and metabolism are also upregulated in many tumor types. Glutamine is converted to glutamate and then to α -ketoglutarate (α -KG). α -KG is then converted to succinyl-CoA by α -ketoglutarate dehydrogenase (KGDH) for subsequent processing through the TCA cycle. The regulation of this metabolism of pyruvate and α -ketoglutarate is profoundly altered in tumor cells, presenting potential clinical targets, as discussed immediately below.

CPI-613[®] (devimistat) is a stable analog of normally transient, acylated catalytic intermediates of lipoate. These intermediates normally serve as signals to the PDH and KGDH regulatory systems altered in cancer; thus, CPI-613[®] (devimistat) misinforms these tumor systems, selectively turning off the cancer cell TCA cycle. CPI-613[®] (devimistat) tumor selectivity is further enhanced because cancer cells take up the drug preferentially. More specifically, CPI-613[®] (devimistat) selectively inactivates PDH in tumor cells by hyper-activating the corresponding tumor-specific configuration of regulatory Pyruvate dehydrogenase kinase (PDKs). PDKs phosphorylate and inactivate PDH. As well, CPI-613[®] (devimistat) simultaneously inactivates KGDH by hyper-activating a redox feedback loop normally

controlling the enzyme's activity and reconfigured in tumors. The simultaneous inhibition of these two TCA cycle enzymes dramatically compromises mitochondrial metabolic flows, triggering multiple, redundant apoptotic and necrotic cell death pathways selectively in tumor cells [Zachar et al., J Mol Med (Berl). 2011 Nov;89(11):1137-48; Stuart et al., Cancer Metab. 2014 Mar 10;2(1): reviewed in Bingham et al., Expert Rev Clin Pharmacol. 2014 Nov;7(6):837-46 and Hammoudi et al., Chin J Cancer. 2011 Aug;30(8):508-25]. Rafael Pharmaceuticals also continues to develop extensive insight into this drug family.

There are many potential advantages of CPI-613[®] (devimistat) over alternative anti-metabolism and anti-cancer drugs. It is believed to selectively targets altered metabolism in cancer cells. Therefore, CPI-613[®] (devimistat) is expected to be minimally toxic to healthy cells (i.e. safe and well tolerated), allows extended treatment courses (reducing likelihood of relapse). Moreover, its low side-effect toxicity allows CPI-613[®] (devimistat) to be used in combination with other drugs, including established standards of care for major malignancies and allows to treat surgically unresectable cancers. Further, this benevolent toxicity profile allows treatment of vulnerable, elderly patients. CPI-613[®] (devimistat) attacks multiple, individually essential targets (PDH, KGDH). So, we expect that it will be less susceptible to emergence of drug resistance. The redesign of metabolism is general to most or all cancers. Thus, it is also expected to have broad spectrum activity of CPI-613[®] (devimistat), i.e. the potential to treat different cancers including difficult-to-treat cancers, high risk cancers. and advanced stage cancers. By targeting metabolism, Rafael Pharmaceuticals expects the drug to be effective against formerly resistant tumor types and suppress metabolism-based drug-resistance.

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 in vitro and ex vivo studies, CPI-613[®] (devimistat) exhibited strong anticancer activities against an array (including solid tumors or hematologic malignancies) of tumor cell-lines and cells derived from patients (including patients with drug resistance). These anti-cancer activities were significantly higher compared to untreated cells or cells treated with current chemotherapeutic agents. In contrast, CPI-613[®] (devimistat) was either minimally taken up into or produced little effect in a variety of healthy cells. In pre-clinical combination therapy studies, CPI-613[®] (devimistat) exhibited no additive toxicity. The drug also demonstrated significant synergy with other chemotherapeutic agents (Pardee et. al. Clin Cancer Res. 2018 May 1;24(9):2060-2073). 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 all animal models. Prolonged survival was observed when compared to untreated controls and more commonly used chemotherapeutic agents. GLP toxicology studies showed that any events related to CPI-613[®] (devimistat) were transient and mostly observed during dosing, and animals returned to normal post-dose (i.e. toxicities were reversible 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 very good safety margins to cover PK exposures of C_{max} and AUC of CPI-613[®] (devimistat) from AML and pancreatic cancer patients in clinical trials, i.e. safety margins of 2.5 – 11.6 folds based on the highest observed C_{max} and AUC at maximum tolerated dose (MTD) from 13-week rat and 13-week minipigs studies divided by the highest observed C_{max} and AUC at MTD of CPI-613[®] (devimistat) in combination with chemotherapies in AML and pancreatic cancer patients.

The manufacturing of CPI-613[®] (devimistat) is relatively low cost, efficient, and scalable. In addition to intravenous CPI-613[®] (devimistat), development of oral formulation of CPI-613[®] (devimistat) is currently underway.

Clinical:

More than 350 patients were dosed with CPI-613[®] (devimistat) to date in 16 ongoing or completed clinical trials.

Five new trials started enrolling participants (including 2 Phase III trials)

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

Twenty patients were enrolled in this 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 1000 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.). Given that in clinical trial evaluating the FOLFIRINOX regimen reported 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.) the further evaluation of CPI-613[®] (devimistat) in pancreatic cancer is believed to be warranted.

Based on the clinical experience of this trial in pancreatic cancer, Rafael has initiated a phase III 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 will compare the efficacy and safety of FOLFIRINOX (FFX, control arm) with CPI-613[®] (devimistat) in combination with mFFX. 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. The interim analysis of the study is estimated to be completed in the third quarter of the 2020 calendar year.

Acute Myeloid Leukemia: 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 I 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 I and phase II trials in elderly patients (≥ 60 years) with relapsed or refractory AML demonstrated 52% CR + CRi and median OS of 12.4 months. Given that in 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.), further evaluation of CPI-613[®] (devimistat) in AML is believed to be warranted.

Based on the clinical experience in these trials in AML, Rafael Pharmaceuticals has initiated a phase III pivotal trial (ARMADA 2000) of CPI-613[®] (devimistat) in patients with relapsed or refractory AML in November 2018. This study will compare the efficacy and safety of high dose cytarabine and mitoxantrone (HAM, control arm) with CPI-613[®] (devimistat) in combination with high dose cytarabine and mitoxantrone (CHAM). Patients ≥ 60 years with relapsed or refractory AML and an ECOG performance status of 0 to 2 are eligible for this study. The interim analysis of the study is expected to be completed in the fourth quarter of 2020.

Peripheral T-cell Lymphoma: Phase I Dose-Escalation Study of CPI-613[®] (devimistat), in Combination with Bendamustine, in Patients with Relapsed or Refractory T-cell Lymphoma

To date, 10 patients have received at least one dose of CPI-613[®] (devimistat) in combination with bendamustine. 8 patients are evaluable for safety and efficacy. Overall, the patients exhibited a good safety profile. The most common grade 3 or higher toxicities were lymphopenia and neutropenia. CPI-613[®] (devimistat) in combination with bendamustine exhibited very good signal of efficacy with 75% ORR, 9.2 months median OS and 6.4 months median PFS. All 3 patients with CR were diagnosed with peripheral T cell lymphoma, not otherwise specified (PTCL-NOS). Although the numbers are small, continued investigation is warranted as these response rates in a poor risk population of patients with relapsed or refractory T-Cell Lymphoma are very exciting.

Based on the clinical experience of this trial in T-cell lymphoma, Rafael Pharmaceuticals is planning to initiate a phase II study of CPI-613[®] (devimistat), in combination with bendamustine in the fourth quarter of 2019.

Other Ongoing Clinical Trials:

- *A phase I study of CPI-613[®] (devimistat) in combination with gemcitabine and nab-paclitaxel for patients with locally advanced or metastatic pancreatic cancer*
- *A phase II study of CPI-613[®] (devimistat) in combination with modified FOLFIRINOX in patients with locally advanced pancreatic cancer*
- *A Phase II 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*

LipoMedix

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.

Rafael Holding holds 50.6% of the issued and outstanding ordinary shares of LipoMedix.

In Fiscal 2019 and 2018, we provided debt and equity financing of \$250,000 and \$875,000, respectively, to LipoMedix.

Science and Preclinical:

LipoMedix was established in order 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. LipoMedix believes that this formulation, known as Promitil® — Pegylated Liposomal Mitomycin-C Lipidic Prodrug (PL-MLP) — overcomes the problems associated with the mitomycin-C toxicity of certain current treatments and turns it into passively targeted, anti-cancer drug 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 who is also the co-inventor and co-developer of Doxil® (doxorubicin hydrochloride liposome injection), 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 over conventional anticancer agents that have serious adverse side effects, and limited efficacy with resistance to treatment. Promitil® is based on an innovative and breakthrough technology that could potentially help cancer patients receive safer therapy with a more potent anti-tumor effect.

In preclinical trials, Promitil® inhibited a range of cancer types in animal models (pancreatic, colorectal, stomach, breast, ovarian, melanoma) and potentiated the activity of 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. In preclinical trials, Promitil® significantly reduced mitomycin-C's systemic toxicity and mitigated its side-effects. Promitil® is a highly stable formulation with prolonged storage shelf life of over 4 – 5 years.

Clinical:

A total of 88 patients have been treated with Promitil® as a single agent or in combination with other anticancer drugs under the framework of a phase 1A/1B clinical study. Promitil® was well tolerated and safe for use at a broad dose range. The majority of the adverse events reported were mild to moderate and unrelated to the study drug.

A Phase 1A dose escalation open trial (Golan et al., “Pegylated liposomal mitomycin C prodrug enhances tolerance of mitomycin C: a phase I study in advanced solid tumor patients.” *Cancer Medicine*, 4:1472–1483, 2015) has demonstrated that Promitil® has successfully and substantially modified the pharmacokinetic characteristics of mitomycin C delivery, resulting in the ability to clinically administer much larger amounts of active drug (approximately 3 times greater mitomycin C-equivalent dose than the maximal tolerated dose of mitomycin C), with an acceptable toxicity profile, and with long circulation time to ensure adequate tumor drug delivery.

A Phase 1B continuation trial in advanced colon cancer patients receiving Promitil® as 3rd line therapy has confirmed the safety and pharmacokinetic features of Promitil® in this patient population, as well as the feasibility of combining Promitil® with Bevacizumab and/or Capecitabine. This stage of colon cancer has an ominous patient prognosis with median survival of approximately 5 months for untreated patients, and 6 – 7 months using any of the two approved therapies (Regorafenib, TAS-102), and a rate of objective partial responses (tumor shrinkage) nearly zero.

In this phase 1B study, 40% (21/52) of patients that underwent disease evaluation on week 9-12 of study showed Stable Disease with a 1-year survival rate of 52% and median survival of 13.9 months (Phase 1 Clinical Study Report, data on file at LipoMedix), suggesting that Promitil® activity in colon cancer is substantial, but requires confirmation in phase 2 studies. LipoMedix believes that the next development step should be to conduct a Phase 2B trial of Promitil® against an active comparator (e.g. Regorafenib) using as endpoints PFS and OS, which will provide information on the added value of Promitil® in colorectal cancer. LipoMedix believes that an approximately 100-patient strong study should determine the relative value of Promitil® in advanced colorectal carcinoma. Given the large number of patients

with this condition, LipoMedix anticipates this study can be completed relatively quickly (approximate enrollment time 18 months) with centers in 4 countries only. An IND application for this study has been approved by the FDA in November 2018. An effective treatment for this patient population represents an important unmet clinical need that Promitil® will attempt to fill, and for which LipoMedix intends to pursue a 505b2 NDA regulatory strategy with a 5-year exclusivity period entitled to new chemical entities.

Additional trials with LipoMedix flagship product, Promitil®, undergoing or in planning include:

- Phase 1B open study of Promitil® in combination with radiotherapy in patients with inoperable or metastatic cancers and oligometastases (Liporad Study). This is a separate avenue of clinical development sprouting from preclinical observations (Tian X. et al., *Int J Radiat Oncol Biol Phys.* 2016 Nov 1;96(3):547-55), and from several positive responses to the combination of Promitil® and radiotherapy in compassionately treated patients (Tahover et al., *Front Oncol.* 2018 Nov 26;8:544.): mechanistic basis and preliminary clinical experience”). This phase 1B study of Promitil®, approved by the Israel MOH, has been initiated in January 2019 in 3 clinical sites in Israel.
- Promitil® with concurrent chemoradiation therapy for locally advanced pancreatic cancer (Phase 2A study) will be initiated in United States.

Promitil®-based products:

In addition to Promitil®, LipoMedix has developed a pipeline of 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. LipoMedix has completed a GLP animal study demonstrating the safety of Promi-Fol administered by the intravesical route and is seeking a partner for sublicense of this technology and testing in clinical studies. A patent application to cover PromiFol has been submitted.
- Promi-Dox, a highly potent dual drug liposome with MLP and doxorubicin (the “SuperDoxil”) for a basket of tumors. If a strong clinical signal can be detected there are several possible cancer settings with substantial patient numbers and significant unmet need where PromiDox could be utilized. This formulation requires further product development. A patent application to cover PromiDox has been submitted.

Intellectual Property:

Two new patent applications covering the use of Promitil®, in combination with other chemotherapies and with radiotherapy have been approved by the USPTO in 2018.

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 implementing 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' and LipoMedix's (collectively, referred to as "the Pharmaceutical Investment 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, to 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, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. 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.

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 Investment 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.

OUR STRATEGY

Real Estate

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;
- selectively seeking to acquire properties to create incremental cash flow and capital appreciation; and
- executing timely monetization through sales or joint ventures of current real estate holdings.

Pharmaceutical Investments

We plan to continue to invest in Rafael Pharmaceuticals and LipoMedix, as approved by our Board and deemed strategic, in order for those companies to execute on their plans and continue clinical trials as warranted by results and developments while continuing to seek other opportunities to invest in additional pharmaceutical or biotechnology companies. In addition, we have established a wholly-owned venture to develop a pipeline of therapeutic compounds, including compounds to regulate cancer metabolism. The venture is pursuing collaborative research agreements with scientists from top academic institutions.

Rafael Pharmaceuticals

The mission of Rafael Pharmaceuticals is to develop innovative, highly selective, well tolerated and highly effective anti-cancer agents by selectively targeting altered metabolism in cancer cells.

Rafael Pharmaceutical's immediate goal is extending and enhancing the lives of patients with gastrointestinal (GI) cancers (along with selected hematological malignancies) with immediate objective to improve the quality of life of patients with pancreatic cancer, which is believed to be the deadliest cancer worldwide with very limited treatment options.

As per Rahib et al, 2014; Pancreatic Cancer will surpass breast, prostate, and colorectal cancers by 2030 and will become the second leading causes of cancer-related death. Since 1997, the median overall survival following standard frontline therapies in metastatic pancreatic cancer has increased from 6.8 months (gemcitabine) to 11.1 months (FOLFIRINOX) (Conroy et al., N Engl J Med 2011;364:1817-25. Von Hoff et al., N Engl J Med 2013;369:1691-703). Pancreatic ductal adenocarcinoma (PDAC) is an immune-privileged cancer and appears to escape from the antitumor immune response unlike other neoplastic entities. In PDAC, response rate with immune checkpoint inhibitors anti-programmed cell death protein 1 (PD-1) or anti-cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) alone or in combination is not satisfactory to date (Kabacaoglu et al., Front Immunol. 2018 Aug 15;9:1878).

In an early stage trial, CPI-613[®] (devimistat) in combination with modified FOLFIRINOX exhibited a promising signal of efficacy with 61% objective response rate (ORR), 19.9 months overall survival (OS) and 9.9 months progression-free survival (PFS). The combination was also well tolerated. This is in comparison to the earlier clinical trial evaluating the FOLFIRINOX regimen for approval wherein they reported an 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.) the further evaluation of CPI-613[®] (devimistat) in pancreatic cancer is warranted.

As a part of the immediate goal of the Company to improve the quality of life of patients with pancreatic cancer, Rafael Pharmaceutical has initiated following trials:

1. A phase III pivotal trial (AVENGER 500[®]) of CPI-613[®] (devimistat) in combination with modified FOLFIRINOX as first-line treatment for patients with metastatic pancreatic cancer. The interim analysis of the study is expected to be completed as early as the third quarter of the 2020 calendar year. The goal of this trial is to provide compelling evidence of the safety and efficacy and leading to a regulatory approval for CPI-613[®] (devimistat) for use in patients with metastatic adenocarcinoma of pancreas.
2. A phase I study of CPI-613[®] (devimistat) in combination with gemcitabine and nab-paclitaxel for patients with locally advanced or metastatic pancreatic cancer. The phase II/III trial in this setting is estimated to start in 2019.
3. A phase II study of CPI-613[®] (devimistat) in combination with modified FOLFIRINOX in patients with locally advanced pancreatic cancer

FOLFIRINOX / FOLFOX / FOLFIRI are standard of care for several gastrointestinal (GI) cancers (e.g. colorectal, esophagus, anal canal). With a broadly applicable mechanism of action, Rafael Pharmaceutical expects that CPI-613[®] (devimistat) will also exhibit promising safety and efficacy profiles in GI cancers where FOLFIRINOX is used as standard of care. With this expectation, Rafael Pharmaceutical is planning to initiate a phase I/II trial of devimistat in combination with FOLFOX and bevacizumab.

LipoMedix Strategy

The strategy for LipoMedix is as follows:

1. Continue phase 1B trial (LIPORAD) of Promitil[®] in combination with radiotherapy in Israel and extend it to Europe and/or United States, after consultation with the FDA/EMA on the best regulatory path for approval.
2. Initiate the study of Promitil[®] with concurrent chemoradiation therapy for locally advanced pancreatic cancer in United States.
3. Continue clinical development of Promitil[®] for advanced colon cancer within a phase 2B trial.
4. Continue research and development, toxicity, and product development of LipoMedix's pipeline aiming at out-licensing for Folate-targeted Promitil[®] (PromiFol) and PromiDox.
5. Strengthening the intellectual property to cover the product manufacturing process and securing the robustness of the manufacturing process.

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.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While Rafael Pharmaceuticals believes that Rafael Pharmaceuticals' technology, development experience and scientific knowledge provide us 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 including, but not limited to, Celgene, Inc., Pfizer, Inc., Agios Pharmaceuticals, 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, and Selvita S.A., Inc. Some of the key companies developing drugs for pancreatic cancer including, but not limited to, AB Science, Inc. and Halozyme, Inc. and some of the key companies developing drugs for AML including, but not limited to, GlycoMimetics, Inc., Bellicum Pharmaceuticals, Inc., Helsinn Healthcare SA, Roche Holdings, Inc. Daiichi Sankyo Company Ltd., AROG Pharmaceuticals, Inc. and Actinium Pharmaceuticals Inc.

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 (mostly 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) large companies such as Roche.

INTELLECTUAL PROPERTY

Licenses

Rafael Pharmaceuticals maintain 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 RF patents 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 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 Pharmaceutical 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.

LipoMedix maintains an exclusive license agreement with Yissum Research and Development Company or Yissum, 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 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 22, 2019, Rafael Pharmaceuticals owns or in-licenses over ten U.S. patents, over forty 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 for its platform technologies are scheduled to expire in years 2028 through 2040. These dates do not include patent term extensions. Rafael Pharmaceuticals has worldwide rights, and has obtained U.S. orphan drug designation for CPI-613[®] (devimistat) in the treatment of MDS, AML, pancreatic carcinoma, Burkitt's lymphoma, and peripheral T-cell lymphoma.

LipoMedix has four USPTO granted patents. Two of them are licensed from Yissum: 1. Patent WO2000/064484 (filed April 2000: expected 20-year expiry term April 2020) "Conjugate having Cleavable Linkage for use in a Liposome" This patent relates to conjugates of a hydrophobic moiety (such as a lipid) linked through a cleavable dithiobenzyl linkage to a therapeutic agent (such as MMC). 2. Patent WO2004/110497 (filed April 2004: expected 20-year expiry term 2024) "Mitomycin Conjugates Cleavable by Thiols" or "Method for Treating Multi-Drug Resistant Tumors". This patent relates to a method for administering Mitomycin-C to a multi-drug resistant cell by using a liposome, and a method for reducing the in vivo cytotoxicity of Mitomycin-C using a liposome composition. Two additional patents, covering the combination of Promitil with other chemotherapies and with radiotherapy, have been recently granted and have 20-year expiry term in 2036. In addition, LipoMedix has two published international patent applications covering the application of Promitil to the local treatment of bladder tumors (Folate-targeted Promitil or PromiFol), and its co-encapsulation with doxorubicin (PromiDox, the "SuperDoxil").

Manufacturing

The Pharmaceutical Investment Companies do not own or operate, and currently have no plans to establish, any manufacturing facilities or fill-and-finish facilities. The Pharmaceutical Investment 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 Investment Companies obtain our supplies from these established contract manufacturers on a purchase order basis and do not have a long-term supply arrangement in place. The Pharmaceutical Investment Companies do not currently

have arrangements in place for redundant supply for bulk drug substance or drug product. For all of the product candidates, the Pharmaceutical Investment Companies intend to identify and qualify additional manufacturers to provide the active pharmaceutical ingredient and the formulation and fill-and-finish services prior to submission of a new drug application to the FDA or along the first steps of marketing.

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 Prometil 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. MLP is currently synthesized by a third party using a proprietary, reliable and reproducible synthetic process from readily available raw materials. The MLP API is then shipped to another third-party facility specialized in liposome manufacture for clinical use. In principle, a single batch of API can serve for manufacture of several batches of Prometil liposomes.

The Pharmaceutical Investment Companies generally expect to rely on third parties for the manufacture of any companion diagnostics they develop.

EMPLOYEES

As of October 2, 2019, we had 17 full and no part-time employees primarily dedicated to the real estate group and corporate entity. We have begun to expand our team in the pharmaceutical sector. Rafael Pharmaceuticals employs 26 full-time and 4 part-time employees, who are involved in operations, research and development and LipoMedix employs 2 full-time and 2 part-time employees involved in operations, research and development, in addition to Prof. Gabizon.

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, particularly the discussions about competition. 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 Business

Risk Related to our Real Estate Assets

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;
- 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 and other natural disasters, civil unrest, terrorist acts or acts of war, which may result in uninsured or underinsured losses;
- 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.

Our real estate is all commercial property and may leave our profitability vulnerable to a downturn in that sector.

All of our properties are commercial real estate. As a result, we are subject to risks inherent in operating a single type of property. The impact of the downturn in demand for office properties has been more pronounced than if we owned a more fully diversified portfolio of real estate properties.

An increase in real estate taxes may decrease our net operating income from properties.

From time to time our property taxes may increase as property values or assessment rates change or for other reasons deemed relevant by the assessors. An increase in the assessed valuation of a property for real estate tax purposes results in an increase in the related real estate taxes on that property. Although some tenant leases may permit us to pass through the tax increases to the tenants for payment, there is no assurance that renewal leases or future leases will be negotiated on the same basis and we may be responsible for these increases as well as unleased portions of the properties. Increases not passed through to tenants will adversely affect our net operating income and our cash available to pay distributions, if any.

We may suffer uninsured losses relating to real property or pay excessively expensive premiums for insurance coverage.

Although we attempt to ensure that all of our properties are adequately insured to cover casualty losses, there are certain types of losses, generally catastrophic in nature, such as losses due to wars, acts of terrorism, earthquakes, floods, hurricanes, pollution or environmental matters, which are uninsurable or not economically insurable, or may be insured subject to limitations, such as large deductibles or co-payments. Insurance risks associated with potential terrorist acts could sharply increase the premiums we pay for coverage against property and casualty claims. Mortgage lenders generally insist that specific coverage against terrorism be purchased by commercial property owners as a

condition for providing mortgage, bridge or mezzanine loans. We cannot be certain that this coverage will continue to be available, or available at reasonable cost, if at all, which could inhibit our ability to finance or refinance our properties. We may be required to provide other financial support, either through financial assurances or self-insurance, to cover potential losses. We cannot assure you that we will have adequate coverage for any losses we may suffer. In addition, other than any capital reserve we may establish, we will have limited sources of funding to repair or reconstruct any uninsured damaged property, and we cannot assure you that those reserves will be sufficient.

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 majority of our revenue from IDT and Genie. In the fiscal year ended July 31, 2019, IDT and Genie accounted for approximately 43% of our revenue. This decrease in concentration was primarily the result of a decrease in revenues from IDT and Genie due to modification of the terms of the leases. The loss of, or a significant reduction in, revenue from IDT and Genie would materially and adversely affect our revenue and results of operations.

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.

We face risks associated with property acquisitions.

We may acquire interests in properties, individual properties and portfolios of properties, including large portfolios that could significantly increase our size and alter our capital structure. Our acquisition activities may be exposed to, and their success may be adversely affected by, the following risks:

- we may be unable to meet required closing conditions;
- we may be unable to finance acquisitions and developments of properties on favorable terms or at all;
- we may be unable to lease our acquired properties on the same terms or to the same level of occupancy as our existing properties;
- acquired properties may fail to perform as we expected;
- we may expend funds on, and devote management time to, acquisition opportunities which we do not complete, which may include non-refundable deposits;
- our estimates of the costs we incur in renovating, improving, developing or redeveloping acquired properties may be inaccurate;
- we may not be able to obtain adequate insurance coverage for acquired properties; and
- we may be unable to quickly and efficiently integrate new acquisitions and developments, particularly acquisitions of portfolios of properties, into our existing operations, and therefore our results of operations and financial condition could be adversely affected.

We may acquire properties subject to both known and unknown liabilities and without any recourse, or with only limited recourse to the seller. As a result, if a liability were asserted against us arising from our ownership of those properties, we might have to pay substantial sums to settle it, which could adversely affect our cash flow. Unknown liabilities with respect to properties acquired might include:

- claims by tenants, vendors or other persons arising from dealing with the former owners of the properties;
- liabilities incurred in the ordinary course of business;
- claims for indemnification by general partners, directors, officers and others indemnified by the former owners of the properties; and
- liabilities for clean-up of undisclosed environmental contamination.

Competition for acquisitions may reduce the number of acquisition opportunities available to us and increase the costs of those acquisitions.

We may face competition for acquisition opportunities from other investors, particularly those investors who are willing to incur more leverage, and this competition may adversely affect us by subjecting us to the following risks:

- an inability to acquire a desired property because of competition from other well-capitalized real estate investors, including publicly traded and privately held REITs, private real estate funds, domestic and foreign financial institutions, life insurance companies, sovereign wealth funds, pension trusts, partnerships and individual investors; and
- an increase in the purchase price for such acquisition property.

If we are unable to successfully acquire additional properties, our ability to grow our business could be adversely affected. In addition, increases in the cost of acquisition opportunities could adversely affect our results of operations.

Risks Related to our Pharmaceutical Industry Investments

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

We have invested a significant amount of capital into Rafael Pharmaceuticals. Their ability to generate product revenue will depend heavily on the successful development and eventual commercialization of their product candidates.

The success of devimistat (CPI-613[®] (devimistat)) will depend on many factors, including the following:

- successful enrollment in, and completion of, clinical trials;
- safety, tolerability and efficacy profiles that are satisfactory to the FDA, the EMA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals from applicable regulatory authorities;
- establishing both clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- the performance of any collaborators;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for their medicines;
- launching commercial sales of the medicines, if and when approved, whether alone or in collaboration with others;
- acceptance of the medicines, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- continuing acceptable safety profile for the medicines following approval;
- enforcing and defending intellectual property rights and claims; and
- achieving desirable medicinal properties for the intended indications.

Many of these factors are beyond our or their control, including clinical development, the regulatory submission process, potential threats to their intellectual property rights and the manufacturing, marketing and sales efforts of any collaborator. If they or any collaborators do not achieve one or more of these factors in a timely manner or at all, they or such collaborators could experience significant delays or an inability to successfully commercialize devimistat (CPI-613[®] (devimistat)) as the most advanced product candidate, which would materially harm our business.

Our pharmaceutical investments may not be able to develop any medicines of commercial value.

Any drug that companies develop in preclinical and clinical studies, may not be able to succeed in demonstrating safety and efficacy of the product candidate in human clinical trials. Screening for and identifying product candidates may not result in the discovery and development of commercially viable medicines to treat cancer and other illnesses the failure of which would harm to our pharmaceutical investments.

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

The key elements of Rafael Pharmaceuticals' and LipoMedix's (collectively, referred to as "the Pharmaceutical Investment Companies") strategy are for Rafael Pharmaceuticals to identify and test compounds that target alterations found in the enzymes of cancer cells related to its production of energy widely known as cancer metabolism, 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 Investment Companies are conducting involves new compounds and drug discovery methods and suitable drug delivery systems, including the Pharmaceutical Investment Companies' proprietary technology. The drug discovery that the Pharmaceutical Investment Companies are conducting using the Pharmaceutical Investment Companies' proprietary technology may not be successful in identifying compounds that are useful in treating cancer. The Pharmaceutical Investment 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 Investment Companies may choose to focus the Pharmaceutical Investment Companies' efforts and resources on a potential product candidate that ultimately proves to be unsuccessful.

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

If clinical trials of the Pharmaceutical Investment Companies' product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, the Pharmaceutical Investment Companies may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of the Pharmaceutical Investment Companies' product candidates.

The Pharmaceutical Investment Companies, and any collaborators, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the United States Food and Drug Administration (FDA). Foreign regulatory authorities, such as the European Medicines Agency, or the EMA, impose similar requirements. The Pharmaceutical Investment Companies have not previously submitted a new drug application, or NDA, to the FDA or similar drug approval filings to comparable foreign regulatory authorities for any of the Pharmaceutical Investment Companies' product candidates. Before obtaining marketing approval from regulatory authorities for the sale of the Pharmaceutical Investment Companies' product candidates, the Pharmaceutical Investment Companies must conduct extensive clinical trials to demonstrate the safety and efficacy of the Pharmaceutical Investment Companies' lead product candidates in humans as well as extensive preclinical development followed by extensive human clinical trials for any future candidates.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. The Pharmaceutical Investment Companies cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of the Pharmaceutical Investment Companies' product candidates is susceptible to the risk of failure inherent at any stage of product development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events

that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if one or more of the Pharmaceutical Investment Companies' product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of the Pharmaceutical Investment Companies' clinical trials. Conversely, as a result of the same factors, the Pharmaceutical Investment Companies' clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in the Pharmaceutical Investment Companies' clinical trials the Pharmaceutical Investment Companies may fail to detect toxicity of or intolerability caused by the Pharmaceutical Investment Companies' product candidates, or mistakenly believe that the Pharmaceutical Investment Companies' product candidates are toxic or not well tolerated when that is not in fact the case.

Any inability to successfully complete preclinical and clinical development could result in additional costs to the Pharmaceutical Investment Companies, or any future collaborators, and impair the Pharmaceutical Investment Companies' ability to generate revenue from product sales, regulatory and commercialization milestones and royalties. Moreover, if the Pharmaceutical Investment Companies or the Pharmaceutical Investment Companies' collaborators are required to conduct additional clinical trials or other testing of the Pharmaceutical Investment Companies' product candidates beyond those that the Pharmaceutical Investment Companies currently contemplate, if the Pharmaceutical Investment Companies or the Pharmaceutical Investment Companies' collaborators are unable to successfully complete clinical trials of the Pharmaceutical Investment Companies' product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, the Pharmaceutical Investment Companies or the Pharmaceutical Investment Companies' collaborators may:

- be delayed in obtaining marketing approval for the Pharmaceutical Investment Companies' product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the medicine removed from the market after obtaining marketing approval.

The Pharmaceutical Investment Companies' failure to successfully complete clinical trials of the Pharmaceutical Investment Companies' product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of the Pharmaceutical Investment Companies' product candidates would significantly harm our investment.

If the Pharmaceutical Investment Companies, or any collaborators, experience any of a number of possible unforeseen events in connection with clinical trials of the Pharmaceutical Investment Companies' product candidates, potential clinical development, marketing approval or commercialization of the Pharmaceutical Investment Companies' product candidates could be delayed or prevented.

The Pharmaceutical Investment Companies or their collaborators may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent the Pharmaceutical Investment Companies' ability to receive marketing approval or commercialize the Pharmaceutical Investment Companies' product candidates, including:

- regulators or institutional review boards may not authorize the Pharmaceutical Investment Companies or their collaborators or investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the Pharmaceutical Investment Companies or their collaborators may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of the Pharmaceutical Investment Companies' product candidates may produce negative or inconclusive results, and the Pharmaceutical Investment Companies or their collaborators may decide, or regulators may require them, to conduct additional clinical trials or abandon product development programs;

- the number of patients required for clinical trials of the Pharmaceutical Investment Companies' product candidates may be larger than they anticipate; enrollment in these clinical trials, which may be particularly challenging for some of the orphan diseases the Pharmaceutical Investment Companies target in their programs, may be slower than the Pharmaceutical Investment Companies anticipate; or participants may drop out of these clinical trials at a higher rate than they anticipate;
- third-party contractors used by the Pharmaceutical Investment Companies' or their collaborators may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all;
- the Pharmaceutical Investment Companies or their collaborators might have to suspend or terminate clinical trials of the Pharmaceutical Investment Companies' product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators, institutional review boards, or the data safety monitoring board for such trials may require that the Pharmaceutical Investment Companies, their collaborators or their investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of the Pharmaceutical Investment Companies' product candidates may be greater than anticipated;
- the supply or quality of the Pharmaceutical Investment Companies' product candidates or other materials necessary to conduct clinical trials of the Pharmaceutical Investment Companies' product candidates may be insufficient or inadequate;
- the Pharmaceutical Investment Companies' product candidates may have undesirable side effects or other unexpected characteristics, causing the Pharmaceutical Investment Companies, their collaborators or their investigators, regulators or institutional review boards to suspend or terminate the trials; and
- the Pharmaceutical Investment Companies' may be unable to meet the endpoints established by the FDA for approval.

Product development costs for the Pharmaceutical Investment Companies, or any collaborators, will increase if the Pharmaceutical Investment Companies, or they, experience delays in testing or pursuing marketing approvals and the Pharmaceutical Investment Companies may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of the Pharmaceutical Investment Companies' product candidates. The Pharmaceutical Investment Companies do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured or will be completed on schedule or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which the Pharmaceutical Investment Companies, or any future collaborators, may have the exclusive right to commercialize the Pharmaceutical Investment Companies' product candidates or allow the Pharmaceutical Investment Companies' competitors, or the competitors of any collaborators, to bring products to market before the Pharmaceutical Investment Companies, or any collaborators do and impair the Pharmaceutical Investment Companies' ability, or the ability of any collaborators, to successfully commercialize the Pharmaceutical Investment Companies' product candidates and may harm the Pharmaceutical Investment Companies' business and results of operations. In addition, many of the factors that lead to clinical trial delays may ultimately lead to the denial of marketing approval of any of the Pharmaceutical Investment Companies' product candidates. The occurrence of any of these events would negatively impact the value of our investments.

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

The Pharmaceutical Investment Companies or their collaborators may not be able to initiate or continue clinical trials for the Pharmaceutical Investment Companies' product candidates if the Pharmaceutical Investment Companies or they 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 Investment Companies target in the Pharmaceutical Investment

Companies' programs. In addition, some of the Pharmaceutical Investment Companies' competitors may have ongoing clinical trials for product candidates that would treat the same indications as the Pharmaceutical Investment Companies' product candidates, and patients who would otherwise be eligible for the Pharmaceutical Investment Companies' clinical trials may instead enroll in clinical trials of the Pharmaceutical Investment Companies' competitors' product candidates.

Patient enrollment is also affected by other factors including:

- severity of the disease under investigation;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria for the study in question;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Rafael Pharmaceuticals focuses its development activities on patients with rarer or more difficult to treat forms of cancer. As a result, the potential patient populations for Rafael Pharmaceuticals' clinical trials are narrowed, and Rafael Pharmaceuticals may experience difficulties in identifying and enrolling a sufficient number of patients in Rafael Pharmaceuticals' clinical trials.

In addition, other companies are conducting clinical trials, or may in the future conduct clinical trials, which may have similar eligibility criteria as the Pharmaceutical Investment Companies' current or future clinical trials and which could implicate enrollment of patients and selection of clinical trial sites.

Furthermore, the Pharmaceutical Investment Companies rely on contract research organizations, or CROs, and clinical trial sites to ensure the proper and timely conduct of the Pharmaceutical Investment Companies' clinical trials and while the Pharmaceutical Investment Companies have agreements governing their committed activities, the Pharmaceutical Investment Companies have limited influence over their actual performance. The Pharmaceutical Investment Companies' or their collaborators' inability to enroll a sufficient number of patients for the Pharmaceutical Investment Companies' clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in the Pharmaceutical Investment Companies' clinical trials may result in increased development costs for the Pharmaceutical Investment Companies' product candidates, which would cause the value of the Pharmaceutical Investment Companies' to decline and limit the Pharmaceutical Investment Companies' ability to obtain additional financing. The occurrence of any of these events would negatively impact the value of our investments.

If serious adverse side effects or unexpected characteristics are identified during the development of the Pharmaceutical Investment Companies' product candidates, the Pharmaceutical Investment Companies may need to abandon or limit the Pharmaceutical Investment Companies' development of some of the Pharmaceutical Investment Companies' product candidates.

All of the Pharmaceutical Investment Companies' lead product candidates are still in clinical stage development and their risk of failure is high. It is impossible to predict when or if any of the Pharmaceutical Investment Companies' product candidates will prove effective or safe in humans or will receive marketing approval. Adverse events or undesirable side effects caused by, or other unexpected properties of, the Pharmaceutical Investment Companies' product candidates could cause us, any future collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of one or more of the Pharmaceutical Investment Companies' product candidates and could result in a more restrictive label, or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If adverse effects were to arise in patients being treated with any of the Pharmaceutical Investment Companies' product candidates, it could require them to halt, delay or interrupt clinical trials of such product candidate or adversely affect the Pharmaceutical Investment Companies' ability to obtain requisite approvals to advance the development and commercialization of such product candidate. If any of the Pharmaceutical Investment Companies' product candidates is associated with adverse events or undesirable side effects or has properties that are

unexpected, the Pharmaceutical Investment Companies, or any future collaborators, may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially show promise in earlier stage testing for treating cancer, or other diseases have later been found to cause side effects that prevented further development of the compound. If the Pharmaceutical Investment Companies are unable to develop any of their product candidates, it would negatively impact the value of our investments.

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 Investment 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 Investment 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 Investment Companies, or future collaborators, believe that the results of clinical trials for the Pharmaceutical Investment Companies' product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of the Pharmaceutical Investment 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 Investment Companies fail to receive positive results in clinical trials of the Pharmaceutical Investment Companies' product candidates, the development timeline and regulatory approval and commercialization prospects for the Pharmaceutical Investment Companies' most advanced product candidates, and, correspondingly, the Pharmaceutical Investment Companies' business and financial prospects would be negatively impacted.

The Pharmaceutical Investment 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 Investment Companies have limited financial and managerial resources, their focus on research programs and product candidates that they may or will identify for specific indications. As a result, the Pharmaceutical Investment 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 Investment Companies' resource allocation decisions may cause them to fail to capitalize on viable commercial medicines or profitable market opportunities. The Pharmaceutical Investment 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 Investment 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.

The Pharmaceutical Investment Companies have never obtained marketing approval for a product candidate and may be unable to obtain, or may be delayed in obtaining, marketing approval for any of their product candidates.

The Pharmaceutical Investment Companies have never obtained marketing approval for a product candidate. It is possible that the FDA or foreign regulatory authorities may refuse to accept for substantive review, any NDAs that the Pharmaceutical Investment Companies submit or may conclude after review of the Pharmaceutical Investment Companies' data that the relevant application is insufficient to obtain marketing approval of the relevant product candidates. If the FDA, or foreign regulatory authorities, does not accept or approve the Pharmaceutical Investment

Companies' NDAs for any of their product candidates, those authorities may require that the Pharmaceutical Investment Companies conduct additional clinical trials, preclinical studies or manufacturing validation studies and submit that data before they will reconsider the applications. Depending on the extent of these or any other FDA-required trials or studies, approval of any NDA or application that the Pharmaceutical Investment Companies submit may be delayed by several years or may require them to expend more resources than they have available. It is also possible that additional trials or studies, if performed and completed, may not be considered sufficient by the FDA to approve the Pharmaceutical Investment Companies' NDAs. Any delay in obtaining, or an inability to obtain, marketing approvals would prevent commercialization of the Pharmaceutical Investment Companies' product candidates, generating revenue and achieving and sustaining profitability. If any of these outcomes occur, the Pharmaceutical Investment Companies may be forced to abandon their development efforts, which could significantly harm the Pharmaceutical Investment Companies' business and the value of our investments.

Even if any of the Pharmaceutical Investment Companies' product candidates receives marketing approval, the Pharmaceutical Investment Companies or others may later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, which could compromise the Pharmaceutical Investment Companies' ability, or that of any future collaborators, to market the product.

Clinical trials of the Pharmaceutical Investment Companies' product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that the Pharmaceutical Investment Companies' clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, the Pharmaceutical Investment Companies, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- the Pharmaceutical Investment Companies, or any future collaborators, may be required to recall the product, change the way the product is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- the Pharmaceutical Investment Companies may be subject to government fines, seizures, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- the Pharmaceutical Investment Companies, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- the Pharmaceutical Investment Companies, or any future collaborators, could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- the Pharmaceutical Investment Companies' reputation may suffer.

Should any of these events occur, the value of our pharmaceutical investments may be negatively impacted.

Even if any of the Pharmaceutical Investment 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 Investment 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

Investment Companies' product candidates do not achieve an adequate level of acceptance, the Pharmaceutical Investment Companies may not generate significant product revenue and may not become profitable. The degree of market acceptance of the Pharmaceutical Investment Companies' product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the approval, availability, market acceptance and reimbursement for the companion diagnostic;
- the ability to offer the Pharmaceutical Investment 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.

The failure to achieve market acceptance could significantly harm the Pharmaceutical Investment Companies' business and the value of our investments.

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

The Pharmaceutical Investment 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 Investment 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 Investment 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 Investment 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 Investment 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 Investment Companies cannot retain or reposition their sales and marketing personnel.

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

- the Pharmaceutical Investment 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; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If the Pharmaceutical Investment Companies enter into arrangements with third parties to perform sales, marketing and distribution services, their product revenue or the profitability of product revenue to them are likely to be lower than if the Pharmaceutical Investment Companies were to market and sell any medicines that they develop themselves. In addition, the Pharmaceutical Investment 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 Investment 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 Investment Companies' medicines effectively. If the Pharmaceutical Investment Companies do not establish sales and marketing capabilities successfully, either on their own or in collaboration with third parties, the Pharmaceutical Investment Companies will not be successful in commercializing their product candidates.

The Pharmaceutical Investment Companies face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than they do.

The development and commercialization of new drug products is highly competitive. The Pharmaceutical Investment Companies face competition with respect to their current product candidates, and the Pharmaceutical Investment 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 Investment 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 Investment 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 Investment 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 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 Investment Companies expect that if their product candidates are approved, they will be priced at a significant premium over competitive generic 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.

Rafael Pharmaceutical is 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)); and (iv) immunotherapy approaches in gastrointestinal malignancies (for example Merck USA), antibodies and/or vaccinations; and (v) other large companies such as Roche.

The Pharmaceutical Investment 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 Investment Companies' competitors may discover biomarkers that

more efficiently measure metabolic pathways than the Pharmaceutical Investment Companies' methods, which may give them a competitive advantage in developing potential products. The Pharmaceutical Investment Companies' competitors may also obtain marketing approval from the FDA or other regulatory authorities for their products more rapidly than the Pharmaceutical Investment Companies may obtain approval, which could result in the Pharmaceutical Investment Companies' competitors establishing a strong market position before they are able to enter the market.

Many of the Pharmaceutical Investment 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 Investment 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 Investment 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 Investment 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 Investment Companies' programs.

Even if the Pharmaceutical Investment 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 Investment Companies' business.

The commercial success of the Pharmaceutical Investment Companies' product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of the Pharmaceutical Investment 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 Investment Companies, or any future collaborators, may not be able to successfully commercialize the Pharmaceutical Investment 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 Investment 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 Investment 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 Investment 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 Investment Companies are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder the Pharmaceutical Investment Companies' ability or the ability of any future collaborators to recoup the Pharmaceutical Investment Companies' or their investment in one or more product candidates, even if the Pharmaceutical Investment 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 Investment Companies' ability, and the ability of any future collaborators, to commercialize any of the Pharmaceutical Investment 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 Investment Companies' ability or that of any future collaborators to sell the Pharmaceutical Investment Companies'

product candidates profitably. These payors may not view the Pharmaceutical Investment Companies' products, if any, as cost-effective, and coverage and reimbursement may not be available to the Pharmaceutical Investment Companies' customers, or those of any future collaborators, or may not be sufficient to allow the Pharmaceutical Investment 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 Investment Companies, or they, might establish for products, which could result in lower than anticipated product revenue. If the prices for the Pharmaceutical Investment Companies' products, if any, decrease or if governmental and other third-party payors do not provide coverage or adequate reimbursement, the Pharmaceutical Investment 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 Investment 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 Investment 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 Investment Companies' product candidates for which they, or any future collaborator, obtain marketing approval could significantly harm the Pharmaceutical Investment Companies' operating results, the Pharmaceutical Investment Companies' ability to raise capital needed to commercialize products and the Pharmaceutical Investment Companies' overall financial condition.

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

The Pharmaceutical Investment Companies and their collaborators face an inherent risk of product liability exposure related to the testing of the Pharmaceutical Investment Companies' product candidates in human clinical trials and will face an even greater risk if the Pharmaceutical Investment Companies or they commercially sell any medicines that the Pharmaceutical Investment Companies or they may develop. If the Pharmaceutical Investment Companies or their collaborators cannot successfully defend themselves against claims that the Pharmaceutical Investment Companies' product candidates or medicines caused injuries, the Pharmaceutical Investment 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 Investment Companies may develop;
- injury to the Pharmaceutical Investment 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 Investment Companies' management to pursue the Pharmaceutical Investment Companies' business strategy; and
- the inability to commercialize any medicines that the Pharmaceutical Investment Companies may develop.

Although the Pharmaceutical Investment Companies maintain product liability insurance coverage, it may not be adequate to cover all liabilities that the Pharmaceutical Investment Companies may incur. The Pharmaceutical Investment Companies anticipate that they will need to increase their insurance coverage when the Pharmaceutical Investment Companies continues clinical trials and if the Pharmaceutical Investment Companies successfully commercializes any medicine. Insurance coverage is increasingly expensive. The Pharmaceutical Investment 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 Investment Companies' products.

If the Pharmaceutical Investment 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 Investment 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 Investment Companies' operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. The Pharmaceutical Investment Companies' operations also produce hazardous waste products. The Pharmaceutical Investment Companies generally contract with third parties for the disposal of these materials and wastes. The Pharmaceutical Investment 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 Investment Companies could be held liable for any resulting damages, and any liability could exceed their resources. The Pharmaceutical Investment Companies also could incur significant costs associated with civil or criminal fines and penalties.

Although the Pharmaceutical Investment 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 Investment Companies do not maintain 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 Investment 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 Investment Companies' research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

Despite the implementation of security measures, the Pharmaceutical Investment Companies' internal computer systems and those of third parties with which the Pharmaceutical Investment 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 the Pharmaceutical Investment 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 the Pharmaceutical Investment 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, the Pharmaceutical Investment Companies' data or applications, or inappropriate disclosure of confidential or proprietary information, the Pharmaceutical Investment Companies could incur liability and their product research, development and commercialization efforts could be delayed.

Even if the Pharmaceutical Investment Companies complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent them from obtaining approvals for the commercialization of some or all of their product candidates. If the Pharmaceutical Investment Companies or their collaborators are not able to obtain, or if there are delays in obtaining, required regulatory approvals, they will not be able to commercialize, or will be delayed in commercializing, their product candidates, and their ability to generate revenue will be materially impaired.

The Pharmaceutical Investment Companies' product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, export and import, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and comparable regulatory authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. The Pharmaceutical Investment Companies and their collaborators have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. The Pharmaceutical Investment Companies have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expects to rely on third-party contract research organizations to assist in this process.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. The Pharmaceutical Investment Companies' product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude the Pharmaceutical Investment Companies obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval the Pharmaceutical Investment Companies or their collaborators ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved medicine not commercially viable.

Accordingly, if the Pharmaceutical Investment Companies or their collaborators experience delays in obtaining approval or if the Pharmaceutical Investment Companies or they fail to obtain approval of their product candidates, the commercial prospects for their product candidates may be harmed and their ability to generate any revenue will be materially impaired.

Current and future legislation may increase the difficulty and cost for the Pharmaceutical Investment Companies and any future collaborators to obtain marketing approval of the Pharmaceutical Investment 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 Investment Companies' other product candidates, restrict or regulate post-approval activities and affect the Pharmaceutical Investment Companies' ability, or the ability of any future collaborators, to profitably sell any products for which the Pharmaceutical Investment Companies, or they, obtain marketing approval. The Pharmaceutical Investment Companies expects 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 Investment Companies, or any future collaborators, may receive for any approved products.

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA. Among the provisions of the PPACA of potential importance to the Pharmaceutical Investment Companies' business and the Pharmaceutical Investment 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;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program 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 offer 50% 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;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs; and
- a Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of any certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain mandated fees under the PPACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the PPACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". The Trump administration has also announced that it will discontinue the payment of cost-sharing reduction, or CSR, payments to insurance companies until Congress approves the appropriation of funds for the CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the PPACA. A bipartisan bill to appropriate funds for CSR payments has been introduced in the Senate, but the future of that bill is uncertain. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the PPACA. Although none of these measures has been enacted by Congress to date, Congress may

consider other legislation to repeal and replace elements of the PPACA. Any repeal and replace legislation may have the effect of limiting the amounts that government agencies will pay for healthcare products and services. Due to these efforts, there is significant uncertainty regarding the future of the PPACA.

Policy changes, including potential modification or repeal of all or parts of the PPACA or the implementation of new health care legislation could result in significant changes to the health care system, which may prevent The Pharmaceutical Investment Companies from being able to generate revenue, attain profitability or commercialize our drugs. 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 our product candidates, or additional pricing pressures.

Further, 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 programs, and reform government program reimbursement methodologies for drug products.

We expect that healthcare reform measures that may be adopted in the future, could have a material adverse effect on the Pharmaceutical Investment 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.

Risk Related to Business Generally

The reporting requirements associated with our being a public company subjects us to significant expenses.

We are a public reporting company and are required to file with the Securities and Exchange Commission reports required by the Exchange Act of 1934. Specifically, among other requirements, we need to file quarterly reports on Form 10-Q, annual reports on Form 10-K and under some circumstances, current reports on Form 8-K, in accordance with strict timelines. We are also required to file annual proxy materials. In addition, as part of those filings, we are required to provide annual audited financial statements. Compliance with such requirements significantly increased our legal and accounting costs and demand significant attention from management. The resources and time required to comply with rules applicable to public companies divert financial and human resources from focusing on our business, and we can provide no assurance that the benefits of our being public outweigh the disadvantages and costs associated with compliance. We currently approximate our total costs to be \$2,000,000 a year as a result of being a public reporting company.

We are controlled by our principal stockholder, which limits the ability of other stockholders to affect the management of the Company.

Howard S. Jonas our Chairman of our Board of Directors and our Chief Executive Officer controls a majority of the voting power of our capital stock. As of September 23, 2019, Mr. Jonas has voting power over 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 4,443,857 shares of our Class B common stock, representing approximately 72.7% of the combined voting power of our outstanding capital stock. Mr. Jonas will 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 is limited.

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.

Upon the completion of the Spin-Off, we became a public company in the United States subject to the Sarbanes-Oxley Act of 2002. Under Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, a newly public company is not required to comply with either the management or the auditor reporting requirements related to internal control over financial reporting until its second annual report, if applicable.

Further, we qualify as an “emerging growth company” as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- an extended transition period to comply with new or revised accounting standards applicable to public companies; and
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002.

We may take advantage of these provisions 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 \$1.0 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.

In addition, if we no longer qualify as an emerging growth company, as an accelerated filer, our independent registered public accounting firm must attest to and report on the effectiveness of our internal control over financial reporting. Our management may conclude that our internal control over financial reporting is not effective. Moreover, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm, after conducting its own independent testing, may issue a report that is qualified if it is not satisfied with our internal controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. In addition, after we become a public company, our reporting obligations may place a significant strain on our management, operational and financial resources and systems for the foreseeable future. We may be unable to timely complete our evaluation testing and any required remediation.

During the course of documenting and testing our internal control procedures, in order to satisfy the requirements of Section 404, we may identify other weaknesses and deficiencies in our internal control over financial reporting. In addition, if we fail to maintain the adequacy of our internal control over financial reporting, as these standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. If we fail to achieve and maintain an effective internal control environment, we could suffer material misstatements in our financial statements and fail to meet our reporting obligations, which would likely cause investors to lose confidence in our reported financial information. This could in turn limit our access to capital markets, harm our results of operations, and lead to a decline in the trading price of our stock.

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. We may also be required to restate our financial statements from prior periods.

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.

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

Howard S. Jonas, our controlling stockholder, Chairman of our Board of Directors and our Chief Executive Officer is also the chairman and controlling stockholder of IDT Corporation, chairman of the board and controlling stockholder of Genie and is chairman of the board of Rafael Pharmaceuticals 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.

Furthermore, one additional member of our executive management team serves as an officer of IDT.

We exercised our option for the “controlled company” exemption under NYSE American rules with respect to our Nominating Committee.

We are a “controlled company” as defined in section 801(a) of the NYSE American Company Guide because more than 50% of the combined voting power of all of our outstanding common stock is beneficially owned by a single stockholder. As a “controlled company,” we are exempt from certain NYSE American rules requiring a board of directors with a majority of independent members, a compensation committee composed entirely of independent directors and a nominating committee composed entirely of independent directors. These independence standards are intended to ensure that directors who meet those standards are free of any conflicting interest that could influence their actions as directors. We applied this “controlled company” exemption for our corporate governance practices only with respect to the independence requirements of our Nominating Committee. Accordingly, with respect to our Nominating Committee you will not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of the NYSE American, and if we were to apply the controlled company exemption to other independence requirements, you would not have the protection afforded by those requirements either.

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.

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

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 16% of the issued and outstanding equity is owned by our subsidiary CS Pharma and the remaining 35% is held by our subsidiary IDT Rafael Holdings. Our subsidiary IDT Rafael 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 October 2, 2019, we, and our affiliates, would need to pay approximately \$15 million to exercise the Warrant in full. On an as-converted fully diluted basis (for all convertible securities of Rafael Pharmaceuticals currently outstanding), we, and our affiliates would need to pay approximately \$45 million to exercise the Warrant to keep our ownership at 51%. On an as-converted fully diluted basis (for all convertible securities of Rafael Pharmaceuticals outstanding), we, and our affiliates would need to pay approximately \$70 million to exercise the Warrant in full. Howard Jonas holds 10% of the interest in IDT Rafael 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 IDT-Rafael Holdings and CS Pharma. 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.

Our historical financial information may not be indicative of our future results as an independent company.

Our historical financial information may not reflect what our results of operations, financial position and cash flows would have been had we been an independent company during the prior periods presented or be indicative of what our results of operations, financial position and cash flows may be in the future now that we are an independent company.

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 real estate/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 new product or service offerings, significant acquisitions, strategic partnerships 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.

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 publish about us and our business. We do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock after the completion of the Spin-Off, 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 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.

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 you can evaluate our business and prospects. We expect to encounter risks and difficulties frequently encountered by early-stage companies in the industries in which we operate.

All of the Pharmaceutical Investment Companies product candidates are still in preclinical development. We have not yet demonstrated our ability to initiate or 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 you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business in general, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors.

If we do not successfully address these risks, our revenue could decline and our ability to pursue our growth strategy and attain profitability could be compromised.

Comprehensive tax reform bills could adversely affect our business and financial condition.

The U.S. government recently enacted comprehensive tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, (i) a permanent reduction to the corporate income tax rate, (ii) a partial limitation on the deductibility of business interest expense, (iii) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) and (iv) a one-time tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate. Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected.

Risks Related to Our Financial Condition

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

As of July 31, 2019, we held approximately \$12 million in cash and cash equivalents, approximately \$730,000 in third-party and related party receivables, approximately \$5.1 million in interests in hedge funds and approximately \$2.0 million in securities in another entity that are not liquid. 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 they 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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

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

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 Oncology department 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.

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 August 21, 2018, the Company entered into a settlement agreement with a building service provider in order to avoid the risks, delays and expenses inherent in and resulting from litigation. The Company was fully indemnified by IDT for the entire \$100,000 settlement.

On September 17, 2018, LipoMedix was notified of a claim initiated by one of its founders seeking payment of consulting fees in the amount of approximately \$377,000 and seeking to place restrictions on LipoMedix' bank accounts and other assets to protect his claim. LipoMedix did not believe that the individual had the right to receive any payment at the current time. LipoMedix responded to the demand for the placement of restrictions on its assets. In May 2019, LipoMedix received a letter from the other founder requesting payment of his consulting fees. On July 15, 2019, the parties settled the matters and the two founders will be paid a percentage of future investments and certain other proceeds.

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, NJ. 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.

For the matters disclosed above a general legal accrual for approximately \$250,000 has been made for legal fees and losses believed to be both probable and reasonably estimable, but an exposure to loss may exist in excess of the amount accrued.

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 NYSE American under the symbol “RFL.” Trading commenced on the NYSE American on March 27, 2018.

On October 2, 2019, there were 299 holders of record of our Class B common stock and one holder 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 2, 2019, the last sales price reported on the NYSE American for the Class B common stock was \$20.49 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, 2019, 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. Selected Financial Data.

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.

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 and Combined Financial Statements and Notes thereto included in Item 8 of this Annual Report.

Overview

Rafael Holdings, Inc., (“Rafael Holdings” or the “Company”), a Delaware corporation, owns interests in commercial real estate assets and clinical stage pharmaceutical companies. The assets are operated as two separate lines of business. 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, and an associated 800-car public garage, an office/data center building in Piscataway, New Jersey and a portion of a building in Israel. The pharmaceutical holdings include preferred equity interests and a warrant to purchase additional equity interests in Rafael Pharmaceuticals, Inc., or Rafael Pharmaceuticals, which 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, and a majority equity interest in LipoMedix Pharmaceuticals Ltd., or LipoMedix, a clinical stage oncological pharmaceutical company based in Israel.

Results of Operations

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

Real Estate Segment

Revenues. Rental and Parking revenues increased by approximately \$80,000 in the year ended July 31, 2019, compared to the prior fiscal year, primarily due to additional third-party tenants in 520 Broad Street having started rental payments after the start of fiscal 2019.

Selling, general and administrative expenses. Selling, general and administrative expenses consists mainly of payroll, benefits, facilities, consulting and professional fees. The increase in selling, general and administrative expenses in the year ended July 31, 2019 compared to the year ended July 31, 2018 is primarily due to increased costs related to complying with public company requirements and costs of building maintenance and repairs.

Depreciation and amortization expenses. Depreciation and amortization expenses in the year ended July 31, 2019 were consistent with the expenses in the year ended July 31, 2018.

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

	Year Ended July 31,		Change	
	2019	2018	\$	%
Rental – Third Party	\$ 1,452	\$ 1,275	\$ 177	13.9%
Rental – Related Party	2,125	2,223	(98)	(4.4)
Parking	874	873	1	0.1
Other – Related Party	480	—	480	100
Selling, general and administrative	8,236	5,455	2,781	51
Depreciation and amortization	1,778	1,694	84	5
Loss from operations.	<u>\$ 5,083</u>	<u>\$ 2,778</u>	<u>\$ 2,305</u>	<u>83%</u>

Pharmaceuticals Segment

To date, the Pharmaceuticals segment has not generated any revenues. The entirety of the expenses in the Pharmaceuticals segment relate to the activities of LipoMedix. For the year ended July 31, 2019, we held a 50.6% interest in LipoMedix and consolidated our majority interest in LipoMedix for the year. For the year ended July 31, 2018, expenses are our proportionate share of LipoMedix, in which we held a 38.9% interest before increasing to a majority stake during November 2017.

Our consolidated and combined income and expense for our Pharmaceuticals segment were as follows:

	Year Ended July 31,		Change	
	2019	2018	\$	%
Selling, general and administrative	\$ 585	\$ 64	\$ 521	814.1%
Research and development	1,027	995	32	3.2
Depreciation and amortization	1	2	(1)	(50)
Loss from operations	<u>\$ 1,613</u>	<u>\$ 1,061</u>	<u>\$ 552</u>	<u>(52)%</u>

Consolidated and combined operations

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

	Year Ended July 31,		Diff \$	Diff %
	2019	2018		
Loss from operations	\$ (6,696)	\$ (3,841)	\$ (2,855)	74%
Interest income, net	469	16	453	2832%
Net gains resulting from foreign exchange transactions	47	32	15	46%
Net loss on equity investments	—	(104)	104	(100)%
Gain on sales of marketable securities	330	12	318	2654%
Unrealized gain on Investments – Hedge Funds	907	—	907	100%
Gain on disposal of bonus shares	—	246	(246)	(100)%
Loss before income taxes	<u>(4,943)</u>	<u>(3,639)</u>	<u>(1,304)</u>	<u>36%</u>
Benefit from (provision for) income taxes	19	(8,437)	8,456	(100)%
Net loss	<u>(4,924)</u>	<u>(12,076)</u>	<u>7,152</u>	<u>(59)%</u>
Net loss attributable to noncontrolling interests	(231)	(427)	196	(46)%
Net loss attributable to Rafael Holdings, Inc.	<u>\$ (4,693)</u>	<u>\$ (11,649)</u>	<u>\$ 6,956</u>	<u>(60)%</u>

Interest income, net. Interest income, net, increased in the year ended July 31, 2019 due to interest on the approximately \$50.0 million of cash and marketable securities contributed by IDT as of the Spin-Off on March 26, 2018 and interest on the Rafael Pharmaceuticals Series D Convertible Note, which were offset by interest expense on the related party convertible debt.

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

Net loss on equity investment. Net loss on equity investment for the year ended July 31, 2018 relates entirely to our proportionate share of the net loss recorded by LipoMedix, in which we held a 38.9% interest before increasing to a majority stake during November 2017. For the year ended July 31, 2019, we held a 50.6% interest in LipoMedix and consolidated our majority interest in LipoMedix.

Gain on sale of marketable securities and unrealized gain on investments. The Company implemented ASU 2016-01 effective August 1, 2018 and no longer recognizes unrealized gains and losses in other comprehensive income. Realized and unrealized gains and losses are now included in net loss. For the year ended July 31, 2019, the Company recorded a gain of approximately \$330,000 on the sale of marketable securities net of unrealized losses recorded in the first quarter of fiscal 2019. The Company also recorded an unrealized gain of approximately \$907,000 for the year ended July 31, 2019. ASU 2016-01 was not implemented for the comparable quarter in fiscal 2018.

Provision for income taxes. During the year ended July 31, 2019, we recorded a valuation allowance of \$8.1 million for the entirety of the Company's domestic deferred tax asset during the first quarter of fiscal 2018. We reserved for the entirety of the Company's domestic deferred tax asset.

Net Loss Attributable to Noncontrolling Interests. The change in the net loss attributable to noncontrolling interests in the year ended July 31, 2019 compared to fiscal 2018 was due to the net loss attributable to the noncontrolling interests in LipoMedix in the year ended July 31, 2019, offset by the interest on the Rafael Pharmaceuticals Series D Convertible Note attributable to the noncontrolling interests in CS Pharma and IDT-Rafael Holdings.

Liquidity and Capital Resources

General

In connection with the Spin-Off, IDT transferred assets to Rafael Pharmaceuticals such that, at the time of the Spin-Off, we had approximately \$42.7 million in cash and cash equivalents and liquid marketable securities and approximately \$3.9 million in interests in hedge funds.

As of July 31, 2019, we had cash and cash equivalents of \$12.0 million. We expect our cash from operations in the next 12 months and the balance of cash and cash equivalents and liquid marketable securities that we held as of July 31, 2019 to be 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 and combined financial statements.

	July 31,	
	2019	2018
Cash flows (used in) provided by		
Operating activities	\$ (3,132)	\$ (1,815)
Investing activities	(31,238)	4,109
Financing activities	30,889	1,750
Effect of exchange rates on cash and cash equivalents	(298)	3
(Decrease) increase in cash and cash equivalents	\$ (3,779)	\$ 4,047

Operating Activities

Our cash flows from operations varies from year to year, depending on our operating results and the timing of operating cash receipts and payments, specifically payments of trade accounts payable. The increase in cash flows used in operating activities in the year ended July 31, 2019 as compared to the year ended July 31, 2018, related to increased accounts receivable related to tenants in 520 Broad Street, an increase in prepaid expenses due to timing of real estate taxes and insurance payments and payoff of charges due to related parties.

Investing Activities

Cash used in investing activities for the year ended July 31, 2019 related to the exercise of a portion of the Warrant to purchase a 51% equity interest in Rafael Pharmaceuticals for approximately \$55.9 million offset, by the net proceeds from the sale of marketable securities of approximately \$25.0 million.

Financing Activities

Cash provided by financing activities for the year ended July 31, 2019 related to approximately \$4.6 million received from the minority holder of interests in a consolidated entity, \$15.0 million convertible note received from Howard Jonas, \$7.8 million received from the sale of Class B common shares to Howard Jonas, and repayment of the \$3.3 million loan to Rafael Pharmaceuticals.

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.

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 and Combined Financial Statements in this Annual Report for a complete discussion of our significant accounting policies.

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.

In connection with the Spin-Off, we and IDT entered into a tax separation agreement, which sets forth the responsibilities of IDT and us with respect to, among other things, liabilities for federal, state, local and foreign taxes for periods before and including the Spin-Off, the preparation and filing of tax returns for such periods and disputes with taxing authorities regarding taxes for such periods. IDT is generally responsible for our federal, state, local and foreign income taxes for periods before and including the Spin-Off. We are generally responsible for all other taxes relating to our business. We and IDT will each generally be responsible for managing those disputes that relate to the taxes for which each of us is responsible and, under certain circumstances, may jointly control any dispute relating to taxes for which both of us are responsible.

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

FOREIGN CURRENCY RISK

Revenue from tenants located in Israel represented 3% and 6% of our consolidated and combined revenues in the fiscal year ended July 31, 2019 and 2018, 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 they 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 and Combined Financial Statements of the Company and the reports of the independent registered public accounting firms thereon starting on page F-2 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, 2019. 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 accounting principles generally accepted in the United States of America.

Management conducted an assessment of the effectiveness of the Company's internal control over financial reporting as of July 31, 2019 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, 2019 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 accounting principles generally accepted in the United States; (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, 2019 that has materially affected, or is 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.

Part III

Item 10. Directors, Executive Officers and Corporate Governance.

The following is a list of our directors and executive officers 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 and Chief Executive Officer
David Polinsky — Chief Financial Officer
Menachem Ash — President and General Counsel

Directors

Howard S. Jonas — Chairman of the Board

Stephen Greenberg
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, 2019, 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, 2019, 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, 2019, 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, 2019, 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, 2019, 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. Reports of Independent Registered Public Accounting Firms on Consolidated and Combined Financial Statements.

Consolidated and Combined Financial Statements covered by Reports of Independent Registered Public Accounting Firms.

2. Financial Statement Schedule.

All schedules have been omitted since they are either included in the Notes to Consolidated and Combined 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
3.1 ⁽¹⁾	Amended and Restated Certificate of Incorporation of Rafael Holdings, Inc.
3.2 ⁽²⁾	Amended and Restated By-Laws of Rafael Holdings, Inc.
10.1 ⁽¹⁾	2018 Equity Incentive Plan
21.01*	Subsidiaries of the Registrant
23.01*	Consent of CohnReznick LLP, Independent Registered Public Accounting Firm
23.02*	Consent of Zwick & Banyai, PLLC, 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*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* filed herewith.

(1) Incorporated by reference to Form 10-12G/A, filed March 26, 2018.

(2) Incorporated by reference to Form 8-K, filed September 26, 2019.

Item 16. Form 10-K Summary

None.

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Rafael Holdings, Inc.

Index to Consolidated and Combined Financial Statements

Reports of Independent Registered Public Accounting Firms	F-2
Consolidated Balance Sheets as of July 31, 2019 and 2018.	F-4
Consolidated and Combined Statements of Operations and Comprehensive Loss for the years ended July 31, 2019 and 2018.	F-5
Consolidated and Combined Statements of Equity for the years ended July 31, 2019 and 2018.	F-6
Consolidated and Combined Statements of Cash Flows for the years ended July 31, 2019 and 2018.	F-8
Notes to Consolidated and Combined Financial Statements	F-10

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Rafael Holdings, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Rafael Holdings, Inc. (the “Company”) as of July 31, 2019, and the related consolidated statements of operations and comprehensive loss, equity and cash flows for the year 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, 2019, and the results of its operations and its cash flows for the year 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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, 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 audit 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 audit 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 audit provide a reasonable basis for our opinion.

/s/ CohnReznick LLP

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

Roseland, New Jersey

October 3, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Rafael Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Rafael Holdings, Inc. (“Rafael Holdings” or the “Company”) as of July 31, 2018, and the related consolidated and combined statement of operations, comprehensive loss, stockholders’ and members’ equity, and cash flows for the year ended July 31, 2018, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of July 31, 2018, and the results of its operations and its cash flows for year ended July 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

ZWICK & BANYAI, PLLC

We have served as the Company’s auditor since 2017.

Southfield, MI
October 15, 2018

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

	July 31,	
	2019	2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 12,024	\$ 15,803
Trade accounts receivable, net of allowance for doubtful accounts of \$122 and \$82 at July 31, 2019 and 2018, respectively	450	287
Marketable securities	—	24,701
Due from Rafael Pharmaceuticals	280	3,300
Prepaid expenses and other current assets	507	421
Total current assets	13,261	44,512
Property and equipment, net	48,733	50,113
Investments – Rafael Pharmaceuticals	70,018	13,300
Investments – Other Pharmaceuticals	2,000	2,000
Investments – Hedge Funds	5,125	4,218
Deferred income tax assets, net	19	—
In-process research and development and patents	1,575	1,651
Other assets	1,412	1,126
TOTAL ASSETS	\$ 142,143	\$ 116,920
LIABILITIES AND EQUITY		
CURRENT LIABILITIES		
Trade accounts payable	\$ 795	\$ 367
Accrued expenses	605	500
Other current liabilities	27	24
Total current liabilities	1,427	891
Due to Related Parties	65	276
Convertible debt, net of discount of \$54 – Related Party	14,946	—
Other liabilities	292	188
Accrued interest on convertible note – Related Party	649	—
TOTAL LIABILITIES	17,379	1,355
COMMITMENTS AND CONTINGENCIES		
EQUITY		
Class A common stock, \$0.01 par value; 50,000,000 shares authorized, 787,163 shares issued and outstanding as of July 31, 2019 and 2018, respectively	8	8
Class B common stock, \$0.01 par value; 200,000,000 shares authorized, 13,142,502 and 11,762,346 shares issued and outstanding as of July 31, 2019 and 2018, respectively	131	118
Additional paid-in capital	112,898	103,636
Accumulated deficit	(5,840)	(1,108)
Accumulated other comprehensive income	3,784	4,043
Total equity attributable to Rafael Holdings, Inc.	110,981	106,697
Noncontrolling interests	13,783	8,868
TOTAL EQUITY	124,764	115,565
TOTAL LIABILITIES AND EQUITY	\$ 142,143	\$ 116,920

See accompanying notes to consolidated and combined financial statements.

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

	Year Ended July 31,	
	2019	2018
REVENUES:		
Rental – Third Party	\$ 1,452	\$ 1,275
Rental – Related Party	2,125	2,223
Parking	874	873
Other – Related Party	480	—
Total Revenue	4,931	4,371
COSTS AND EXPENSES:		
Selling, general and administrative	8,821	5,519
Research and development	1,027	995
Depreciation and amortization	1,779	1,698
Loss from operations	(6,696)	(3,841)
Interest income, net	469	16
Net gains resulting from foreign exchange transactions	47	32
Net loss on equity investments	—	(104)
Gain on sales of marketable securities	330	12
Unrealized gain on Investments – Hedge Funds	907	—
Gain on disposal of bonus shares	—	246
Loss before income taxes	(4,943)	(3,639)
Benefit from (provision for) income taxes	19	(8,437)
Net Loss	(4,924)	(12,076)
Net loss attributable to noncontrolling interests	(231)	(427)
Net loss attributable to Rafael Holdings, Inc.	\$ (4,693)	\$ (11,649)
OTHER COMPREHENSIVE LOSS		
Net Loss	\$ (4,924)	\$ (12,076)
Unrealized loss on marketable securities	—	(308)
Unrealized gain on available-for-sale securities	—	1,869
Foreign currency translation adjustments	298	166
Total Comprehensive Loss	(4,626)	(10,349)
Comprehensive income (loss) attributable to noncontrolling interests	173	(107)
Total Comprehensive Loss attributable to Rafael Holdings, Inc.	\$ (4,453)	\$ (10,456)
Loss per share attributable to Rafael Holdings, Inc. common stockholders:		
Basic and diluted	\$ (0.35)	\$ (0.93)
Weighted average number of shares used in calculation of loss per share:		
Basic and diluted	13,275,239	12,485,000

See accompanying notes to consolidated and combined financial statements.

RAFAEL HOLDINGS, INC.
CONSOLIDATED AND COMBINED STATEMENTS OF EQUITY
FOR THE YEARS ENDED JULY 31, 2019 AND 2018
(in thousands, except share data)

	Year Ended July 31, 2019									
	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, 2018	787,163	\$ 8	11,762,346	\$ 118	\$ 103,636	\$ (1,108)	\$ 4,043	\$ 9,427	\$ 116,124	
Net loss for the year ended July 31, 2019 . .	—	—	—	—	—	(4,693)	—	(231)	(4,924)	
Adoption effect of ASU 2016-01 . .	—	—	—	—	—	(39)	39	—	—	
Stock-based compensation . .	—	—	74,637	1	264	—	—	—	265	
Stock options exercised.	—	—	38,710	—	190	—	—	—	190	
Sale of Class B Common Shares	—	—	1,254,200	12	8,630	—	—	—	8,642	
Stock-based compensation to Board of Directors.	—	—	12,609	—	107	—	—	—	107	
Debt discount on convertible debt.	—	—	—	—	71	—	—	—	71	
Capital contribution for noncontrolling interest	—	—	—	—	—	—	—	4,587	4,587	
Foreign currency translation adjustment	—	—	—	—	—	—	(298)	—	(298)	
BALANCE AT JULY 31, 2019 . . .	<u>787,163</u>	<u>\$ 8</u>	<u>13,142,502</u>	<u>\$ 131</u>	<u>\$ 112,898</u>	<u>\$ (5,840)</u>	<u>\$ 3,784</u>	<u>\$ 13,783</u>	<u>\$ 124,764</u>	

RAFAEL HOLDINGS, INC.
CONSOLIDATED AND COMBINED STATEMENTS OF EQUITY
FOR THE YEARS ENDED JULY 31, 2019 AND 2018 (Continued)
(in thousands, except share data)

Year Ended July 31, 2018

	Common Stock, Series A		Common Stock, Series B		Group Equity	Additional Paid-in Capital	Accumulated Deficit	Accumulated other comprehensive income	Noncontrolling interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount						
BALANCE AT										
JULY 31, 2017 . . .	—	\$ —	—	\$ —	\$50,427	\$ —	\$ —	\$ 2,316	\$ 9,335	\$ 62,078
Net loss for the year ended July 31, 2018 . .	—	—	—	—	(10,541)	—	(1,108)	—	(427)	(12,076)
Stock-based compensation . .	—	—	7,511	—	—	51	—	—	—	51
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	—	—	(40)	(40)
Non-cash compensation related to the distribution of bonus shares . . .	—	—	—	—	—	—	—	1,561	—	1,561
Incorporation of Company, capital contribution from IDT and share distribution on Spin-Off	787,163	8	11,754,835	118	(39,886)	103,485	—	—	—	63,725
Indemnification from IDT for settled lawsuit . .	—	—	—	—	—	100	—	—	—	100
Foreign currency translation adjustment	—	—	—	—	—	—	—	166	—	166
BALANCE AT										
JULY 31, 2018 . . .	<u>787,163</u>	<u>\$ 8</u>	<u>11,762,346</u>	<u>\$ 118</u>	<u>—</u>	<u>\$ 103,636</u>	<u>\$ (1,108)</u>	<u>\$ 4,043</u>	<u>\$ 8,868</u>	<u>\$ 115,565</u>

See accompanying notes to consolidated and combined financial statements.

RAFAEL HOLDINGS, INC.
CONSOLIDATED AND COMBINED STATEMENTS OF CASH FLOWS
(in thousands, except share data)

	Year Ended July 31,	
	2019	2018
Operating activities		
Net loss	\$ (4,924)	\$ (12,076)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,779	1,698
Deferred income taxes	(19)	8,859
Interest income on Rafael Pharmaceuticals Series D Convertible Note	(848)	—
Interest income	(37)	—
Net realized and unrealized gain on sale of marketable securities	(330)	—
Net realized and unrealized gain on Investments – Hedge Funds	(907)	—
Provision for doubtful accounts	122	—
Non-cash compensation	372	104
Amortization of debt discount	17	657
Realized gain on disposal of bonus shares	—	(246)
Loss on disposal of fixed assets	—	13
Net gain resulting from foreign exchange transactions	—	(32)
Change in assets and liabilities:		
Trade accounts receivable	(285)	(23)
Other current assets and prepaid expenses	(86)	(258)
Write off of patents	76	—
Other assets	275	(586)
Accounts payable and accrued expenses	533	(35)
Other current liabilities	3	(10)
Due to Related Party	654	2
Due from Related Party	(280)	—
Accrued Interest – Related Party	649	—
Other liabilities	104	118
Net cash used in operating activities	(3,132)	(1,815)
Investing activities		
Purchases of property and equipment	(399)	(710)
Proceeds from sale and maturity of marketable securities	25,031	6,670
Purchase of investments	—	(151)
Cash advances to IDT Corporation, net of repayments	—	(1,700)
Investment in Rafael Pharmaceuticals	(55,870)	—
Net cash (used in) provided by investing activities	(31,238)	4,109
Financing activities		
Contribution from noncontrolling interest of consolidated entity	4,587	—
Repayment of loan by Rafael Pharmaceuticals, including interest	3,335	—
Proceeds from sale of shares	7,777	—
Proceeds from exercise of options	190	864
Cash advances from IDT Corporation, net of repayments	—	886
Proceeds from issuance of convertible note	15,000	—
Net cash provided by financing activities	30,889	1,750
Effect of exchange rate changes on cash and cash equivalents	(298)	3
Net (decrease) increase in cash and cash equivalents	(3,779)	4,047
Cash and cash equivalents at beginning of year	15,803	11,756
Cash and cash equivalents at end of year	\$ 12,024	\$ 15,803

RAFAEL HOLDINGS, INC.
CONSOLIDATED AND COMBINED STATEMENTS OF CASH FLOWS (Continued)
(in thousands, except share data)

	Year Ended July 31,	
	2019	2018
Supplemental Schedule of Non-Cash Investing and Financing Activities		
Adoption effect of ASU 2016-01	\$ 39	\$ —
Beneficial conversion feature of convertible debt – related party	\$ 71	\$ —
Series D Convertible Note and accrued interest converted to Series D Preferred Stock	\$ 10,848	\$ —
Related Party deposit utilized to purchase Class B Common Stock.	\$ 864	\$ —
Cash payments made for taxes	\$ —	\$ —
Cash payments made for interest	\$ —	\$ —

See accompanying notes to consolidated and combined financial statements.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

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

Description of Business

Rafael Holdings, Inc. (“Rafael Holdings” or the “Company”), a Delaware corporation, owns interests in commercial real estate assets and clinical-stage pharmaceutical companies. The assets are operated as two separate lines of business. The commercial real estate holdings consist of the building at 520 Broad Street in Newark, New Jersey that houses headquarters for the Company and certain affiliated entities, and an associated 800-car public garage, an office/data center building in Piscataway, New Jersey and a portion of a building in Israel. The pharmaceutical holdings include preferred equity interests and a warrant to purchase additional equity interests in Rafael Pharmaceuticals, Inc., or Rafael Pharmaceuticals, which 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, and a majority equity interest in LipoMedix Pharmaceuticals Ltd., or LipoMedix, a clinical-stage oncological pharmaceutical company based in Israel.

On March 26, 2018, IDT Corporation, or IDT, the former parent corporation of the Company, completed a tax-free spinoff (the “Spin-Off”) of the Company’s capital stock, through a pro rata distribution of common stock to its stockholders of record as of the close of business on March 13, 2018.

Basis of Presentation

The “Company” in these financial statements refers to Rafael Holdings on a consolidated basis from the date of the Spin-Off and on a combined basis from the date prior to the Spin-Off as if Rafael Holdings existed and owned the above interests in all periods presented.

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 2019 refers to the fiscal year ended July 31, 2019).

The preparation of our consolidated and combined financial statements and accompanying notes have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”).

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

Company	Country of Incorporation	Percentage Owned
Rafael Holdings, Inc.	Unites States – Delaware	100%
Broad Atlantic Associates, LLC	Unites States – Delaware	100%
IDT 225 Old NB Road, LLC	Unites States – Delaware	100%
IDT R.E. Holdings Ltd.	Israel	100%
IDT Capital, Inc.	Unites States – Delaware	100%
IDT-Rafael Holdings, LLC	Unites States – Delaware	90%
CS Pharma Holdings, LLC	Unites States – Delaware	45%*
LipoMedix Pharmaceuticals Ltd.	Israel	50.6%

* 50% of CS Pharma Holdings, LLC is owned by IDT-Rafael Holdings, LLC. We have a 90% ownership in IDT-Rafael 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 the amounts reported in the financial statements and accompanying notes. Actual results may differ from those estimates.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

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

Reclassifications

Certain line items in prior period financial statements have been reclassified to conform to currently reported presentations.

The Company's Spin-Off

The Company was formerly a subsidiary of IDT. On March 26, 2018, IDT spun-off the Company to IDT's stockholders and the Company became an independent public company through a pro rata distribution of the Company's common stock held by IDT to IDT's stockholders. As a result of the Spin-Off, each of IDT's stockholders received: (i) one share of the Company's Class A common stock for every two shares of IDT's Class A common stock held of record on March 13, 2018 (the "Record Date"), and (ii) one share of the Company's Class B common stock for every two shares of IDT's Class B common stock held of record on the Record Date. On March 26, 2018, 787,163 shares of the Company's Class A common stock and 11,754,835 shares of the Company's Class B common stock were issued and outstanding, which includes 114,945 restricted stock units issued to employees and consultants in connection with the Spin-Off.

The Company entered into various agreements with IDT prior to the Spin-Off including a Separation and Distribution Agreement to effect the separation and provide a framework for the Company's relationship with IDT after the Spin-Off, and a Transition Services Agreement, which provides for certain services to be performed by IDT to facilitate the Company's transition into a separate publicly-traded company. These agreements provide for, among other things, (1) the allocation between the Company and IDT of employee benefits, taxes and other liabilities and obligations attributable to periods prior to the Spin-Off, (2) transitional services to be provided by IDT relating to human resources and employee benefits administration, and (3) finance, accounting, tax, investor relations and legal services to be provided by IDT to the Company following the Spin-Off. In addition, the Company entered into a Tax Separation Agreement with IDT, which sets forth the responsibilities of the Company and IDT with respect to, among other things, liabilities for federal, state, local and foreign taxes for periods before and including the Spin-Off, the preparation and filing of tax returns for such periods and disputes with taxing authorities regarding taxes for such periods.

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.

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, 2019, related parties and one other customer represented 53%, and 10% of the Company's revenue, respectively, and as of July 31, 2019, five customers represented 38%, 17%, 16%, 12%, and 7% of the Company's accounts receivable balance, respectively. For the year ended July 31, 2018, related parties and one other customer represented 51%, and 10% of the Company's revenue, respectively, and as of July 31, 2018, five customers represented 28%, 16%, 12%, 12%, and 12% of the Company's accounts receivable balance, respectively.

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 and current credit statuses, 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

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

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

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 53% and 51% of the Company’s total revenue for the years ended July 31, 2019 and 2018, respectively. The Company recorded bad debt expense of approximately \$40,000 and \$0 for the years ended July 31, 2019 and 2018, 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 and combined financial statements include the Company’s controlled affiliates. In addition, Rafael Pharmaceuticals (see Note 2) is a variable interest entity; 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. All significant intercompany accounts and transactions between the consolidated and combined 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. Cost method investments are presented as “Investments — Rafael Pharmaceuticals” and “Investments — Other Pharmaceuticals” in the accompanying consolidated balance sheets. The Company no longer has investments accounted for under the equity method since the consolidation of LipoMedix in November 2017. 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 “Other Expenses, net” in the accompanying consolidated and combined statements of operations, and a new basis in the investment is established.

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

The Company tests the recoverability of its long-lived assets with finite useful lives whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. The Company tests for recoverability based on the projected undiscounted cash flows to be derived from such asset. If the projected undiscounted future cash flows are less than the carrying value of the asset, the Company will record an impairment loss, if any, based on the difference between the estimated fair value and the carrying value of the asset. The Company generally measures fair value by considering sale prices for similar assets or by discounting estimated future cash flows from such asset using an appropriate discount rate. Cash flow projections and fair value estimates require significant estimates and assumptions by management. Should the estimates and assumptions prove to be incorrect, the Company may be required to record impairments in future periods and such impairments could be material.

Properties

The Company owns commercial real estate located at 520 Broad Street, Newark, New Jersey, and a related 800-car public parking garage across the street, as well as a building located at 225 Old New Brunswick Road in Piscataway, New Jersey. Additionally, the Company owns a portion of the 6th floor of a building located at 5 Shlomo Halevi Street, Har Hotzvim, in Jerusalem, Israel.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

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

Revenue Recognition

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, *Revenue from Contracts with Customers (Topic 606)* or ASU 2014-09. The objective of the ASU is to establish a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers, which supersedes most of the existing revenue recognition guidance, including industry-specific guidance. The core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In applying the ASU, companies will perform a five-step analysis of transactions to determine when and how revenue is recognized. The five-step analysis 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. ASU 2014-09 applies to all contracts with customers except those that are within the scope of other topics in the FASB’s ASC. The Company adopted ASU 2014-09 effective August 1, 2018 using the modified retrospective approach. The Company reviewed all contracts that were not completed as of August 1, 2018 and the adoption did not have a material impact on the Company’s consolidated and combined financial statements.

The Company disaggregates its revenue by source within its consolidated and combined statements of operations. As an owner and operator of real estate, the Company derives the majority of its revenue from leasing space to tenants at its properties. As a result, the majority of the Company’s revenue is accounted for pursuant to ASC 840 *Leases* or ASC 840 and is reflected within Rental Revenue in the consolidated and combined statements of operations. In addition, the Company earns revenue from recoveries from tenants, consisting of amounts due from tenants for common area maintenance, real estate taxes, utilities, and other recoverable costs. Revenue from recoveries from tenants is recognized under the guidance ASC 840 until the adoption of ASC 842 *Leases* at which time it may fall within the guidance under ASC 606.

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 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.

The Company also earns revenue from parking which is derived primarily from monthly and transient daily parking. In addition, the Company has certain lease arrangements for parking accounted for under the guidance in ASC 840. 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.

Income Taxes

The accompanying consolidated and combined financial statements include provisions for federal, state and foreign income taxes. Prior to the Spin-Off, the Company joined with its Parent and other affiliates in filing a federal income tax return on a combined basis. Income taxes for the Company for periods prior to the Spin-Off are calculated on a separate tax return basis. Our income taxes for the period subsequent to the Spin-Off will be filed on our initial consolidated standalone return with the IRS.

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

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

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

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.

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 subsidiary operating outside of the United States is the New Israeli Shekel, the currency of the primary economic environment in which the subsidiary primarily expends cash. The Company translates that subsidiary's financial

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

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

statements into U.S. Dollars. The Company translates assets and liabilities at the exchange rate in effect as of the financial statement date, and translate accounts from the statements of 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.

Research and Development Costs

Costs for research and development are charged to expense as incurred. Research and development costs in the relevant periods were incurred solely by LipoMedix.

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.

Earnings (Loss) Per Share

Basic earnings (loss) per share is computed by dividing net income (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 earnings (loss) per share is determined in the same manner as basic earnings (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.

Stock-Based Compensation

The Company accounts for stock-based compensation using the provisions of ASC 718, *Accounting for Stock Compensation*, which requires the recognition of the fair value of stock-based compensation. Furthermore, the Company adopted ASU 2016-09 which simplified several aspects of the accounting for stock-based compensation, including income tax effects, forfeitures, statutory withholding requirements and cash flow statement classifications. Stock-based compensation is estimated at the grant date based on the fair value of the awards. Since this compensation cost is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. ASU 2016-09 allows companies to elect an accounting policy either to continue to estimate the total number of awards for which the requisite service period will not be rendered or to account for forfeitures when they occur. The Company has elected to account for the forfeitures when 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.

Recently Issued Accounting Standards Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use (“ROU”) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is in the process of reviewing all contracts with suppliers, vendors, customers and other outside parties to identify whether such contracts contain an embedded lease as defined under the new guidance and whether there will be any impact of the pending adoption of the new standard on its financial statements. The Company intends to adopt the standard on August 1, 2019.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

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

In June 2016, the FASB issued 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, 2019, 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 and combined financial statements and intends to adopt the standard on August 1, 2020.

Recently Adopted Accounting Pronouncements

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* or ASU 2016-18. The new guidance is intended to reduce diversity in practice by adding or clarifying guidance on classification and presentation of changes in restricted cash on the statement of cash flows. ASU 2016-18 is effective for annual and interim periods beginning after December 15, 2017. The amendments in this ASU are required to be applied retrospectively to all periods presented. The Company adopted this guidance retrospectively on August 1, 2018 with no material impact on the Company’s financial position, results of operations or cash flows. On a prospective basis, ASU 2016-18 will only impact the Company’s financial position and cash flows to the extent it has restricted cash.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, which required us to prospectively record changes in the fair value of our equity investments, except for those accounted for under the equity method, in net income instead of in accumulated other comprehensive income. The Company implemented ASU 2016-01 in the first quarter of fiscal 2019 effective August 1, 2018. A cumulative-effect adjustment was recorded as of August 1, 2018 to reclassify approximately \$39,000 of unrealized loss on equity securities from accumulated other comprehensive loss to retained earnings resulting in prior-periods no longer being comparable.

	Accumulated Other Comprehensive Income	Accumulated Deficit
	<i>(in thousands)</i>	
Balances as of July 31, 2018	\$ 4,043	\$ (1,108)
Impact from adoption of ASU 2016-01	39	(39)
Balances as of August 1, 2018	\$ 4,082	\$ (1,147)

SEC Disclosure Update and Simplification

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, *Disclosure Update and Simplification*, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders’ equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders’ equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule was effective on November 5, 2018. The Company included a reconciliation of the changes in equity in its Form 10-Q for the quarter ended April 30, 2019.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

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 interests/rights in Rafael Pharmaceutical through a 90%-owned non-operating subsidiary, IDT-Rafael Holdings, LLC, or IDT-Rafael Holdings.

IDT-Rafael Holdings also owns 50% of CS Pharma Holdings, LLC (“CS Pharma”), a non-operating entity. Accordingly, the Company holds an effective 45% indirect interest in the assets held by CS Pharma.

Howard Jonas, Chairman of the Board and Chief Executive Officer of the Company, and Chairman of the Board of Rafael Pharmaceuticals owns 10% of IDT-Rafael Holdings.

IDT-Rafael Holdings holds 36.7 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, and will expire upon the earlier of December 31, 2020, a qualified initial public offering, or liquidation event of Rafael Pharmaceuticals.

IDT-Rafael Holdings also holds certain governance rights in Rafael Pharmaceuticals including appointment of directors.

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 in January 2019.

The Company and its subsidiaries collectively own securities representing 51% of the outstanding capital stock of Rafael Pharmaceuticals and 38% 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, winding up shall be distribute 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 IDT-Rafael Holdings, and IDT-Rafael 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 IDT-Rafael Holdings to 50% (based on current ownership) of such distributions. Similarly, if IDT-Rafael 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.

Rafael Pharmaceuticals is a variable interest entity; 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.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

NOTE 2 — INVESTMENT IN RAFAEL PHARMACEUTICALS (cont.)

Separately, Howard Jonas and Deborah Jonas jointly own \$525,000 of Series C Convertible Notes of Rafael Pharmaceuticals, and The Howard S. and Deborah Jonas Foundation owns \$525,000 of Series C Notes of Rafael Pharmaceuticals.

On September 19, 2017, IDT approved a compensatory arrangement with Howard Jonas related to the right held by IDT-Rafael Holdings to receive additional Rafael Pharmaceutical shares (“Bonus Shares”) upon the achievement of certain milestones. Under that arrangement, IDT and the Company transferred to Howard Jonas 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 that was previously held by IDT-Rafael Holdings, which is contingent upon achieving certain milestones. This right was previously held by IDT-Rafael Holdings, subject to its right to transfer to recipients that IDT-Rafael Holdings, in its sole discretion, felt merit because of special efforts by such persons in assisting Rafael Pharmaceuticals and its products. IDT-Rafael Holdings distributed the rights to its members and the Company transferred the portion it received to Howard Jonas. If any of the milestones are met, the Bonus Shares are to be issued without any additional payment. Howard Jonas has the right to transfer the Bonus Shares, in his discretion, to others, including those who are instrumental to the future success of Rafael Pharmaceuticals.

Based on the current shares issued and outstanding of Rafael Pharmaceuticals as of October 2, 2019, we and our affiliates would need to pay approximately \$15 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 \$45 million to exercise the Warrant to keep our ownership at 51%. On an as-converted fully diluted basis (for all convertible securities of Rafael Pharmaceuticals outstanding), we and our affiliates would need to pay approximately \$70 million to exercise the Warrant in full. Howard Jonas holds 10% of the interest in IDT Rafael Holdings and would need to contribute 10% of any cash needed 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 IDT-Rafael Holdings and CS Pharma. If the Bonus Shares are issued to Howard Jonas or Rafael Pharmaceuticals issues any additional equity instruments, we will need additional cash to maintain our ownership percentage or exercise the Warrant in full.

NOTE 3 — MARKETABLE SECURITIES

During fiscal 2019, all marketable securities held by the Company were liquidated in connection with the partial exercise of the Rafael Pharmaceuticals Warrant. There were no marketable securities held by the Company as of July 31, 2019.

The following is a summary of marketable securities as of July 31, 2018:

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
	<i>(in thousands)</i>			
Available-for-sale securities:				
July 31, 2018:				
Certificates of deposit*	\$ 7,757	\$ —	\$ (23)	\$ 7,734
Federal Government Sponsored Enterprise notes	2,837	—	(23)	2,814
International agency notes	522	—	(17)	505
Mutual funds	5,469	—	(98)	5,371
Corporate bonds	2,948	1	(56)	2,893
U.S. Treasury notes	5,476	—	(92)	5,384
Municipal bonds	—	—	—	—
Total	<u>\$ 25,009</u>	<u>\$ 1</u>	<u>\$ (309)</u>	<u>\$ 24,701</u>

* Each of the Company’s certificates of deposit has a CUSIP, was purchased in the secondary market through a broker, and may be sold in the secondary market.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

NOTE 3 — MARKETABLE SECURITIES (cont.)

Proceeds from maturities and sales of available-for-sale securities were \$25.0 million and \$6.7 million in fiscal years 2019 and 2018, respectively. The gross realized gains that were included in earnings as a result of sales were \$330,000 and \$12,000 in fiscal years 2019 and 2018, respectively. There were no gross realized losses that were included in earnings as a result of sales in fiscal year 2019 or fiscal year 2018. The Company uses the specific identification method in computing the gross realized gains and gross realized losses on the sales of marketable securities.

NOTE 4 — FAIR VALUE MEASUREMENTS

The Fair Value Measurements and Disclosures topic of the FASB ASC requires disclosures about how fair value is determined for assets and liabilities and a hierarchy for which these assets and liabilities must be grouped is established, based on significant levels of inputs 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.

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, 2019 and July 31, 2018:

	At July 31, 2019			
	Level 1	Level 2	Level 3	Total
	<i>(in thousands)</i>			
Available-for-sale securities:				
Hedge Funds	\$ —	\$ —	\$ 5,125	\$ 5,125
Total	\$ —	\$ —	\$ 5,125	\$ 5,125
	At July 31, 2018			
	Level 1	Level 2	Level 3	Total
	<i>(in thousands)</i>			
Available-for-sale securities:				
Marketable Securities	\$ 10,755	\$ 13,946	\$ —	\$ 24,701
Hedge Funds	—	—	4,218	4,218
Rafael Pharmaceuticals convertible promissory notes	—	—	7,900	7,900
Total	\$ 10,755	\$ 13,946	\$ 12,118	\$ 36,819

At July 31, 2019 and July 31, 2018, the Company did not have any liabilities measured at fair value on a recurring basis.

At July 31, 2018, the fair value of the Rafael Pharmaceuticals Series D Convertible Note (the "Series D Note") was classified as Level 3, was estimated based on a valuation of Rafael Pharmaceuticals by reference to recent transactions in its securities, the Series D Note investment, as well as utilizing a discounted cash flow technique under the Income Approach and other factors that could not be corroborated by the market. The Series D Note was converted into shares of Series D Convertible Preferred Stock of Rafael Pharmaceuticals in January 2019.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

NOTE 4 — 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):

	At July 31,	
	2019	2018
	<i>(in thousands)</i>	
Balance, beginning of year	\$ 12,118	\$ 6,300
Contributions by former Parent at Spin-Off	—	3,949
Conversion of Rafael Pharmaceuticals Series D Convertible Note	(7,900)	—
Total gains included in earnings	907	1,869
Balance, end of year	\$ 5,125	\$ 12,118

Prior to the Spin-Off, IDT contributed \$2.0 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 Company’s related investment is accounted for using the cost method and, therefore, this investment is not measured at fair value.

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 other current liabilities. At July 31, 2019 and July 31, 2018, 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, 2019 and July 31, 2018, 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 amount 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, 2019 or July 31, 2018.

NOTE 5 — TRADE ACCOUNTS RECEIVABLE

Trade Accounts Receivable consisted of the following:

	July 31,	
	2019	2018
	<i>(in thousands)</i>	
Trade Accounts Receivable – Third Party	\$ 561	\$ 358
Trade Accounts Receivable – Related Party	11	11
Less Allowance for Doubtful Accounts	(122)	(82)
Trade Accounts Receivable, net	\$ 450	\$ 287

The current portion of deferred rental income included in Prepaid Expenses and Other Current Assets was approximately \$34,000 and \$88,000 as of July 31, 2019 and July 31, 2018, respectively.

The noncurrent portion of deferred rental income included in Other Assets was approximately \$1.4 million and \$1.0 million as of July 31, 2019 and July 31, 2018, respectively.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

NOTE 6 — PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	At July 31,	
	2019	2018
	<i>(in thousands)</i>	
Building and Improvements	\$ 54,241	\$ 52,818
Land	10,412	10,412
Furniture and Fixtures	1,145	1,145
Other	255	255
Construction in Progress	—	1,024
	66,053	65,654
Less Accumulated Depreciation	(17,320)	(15,541)
Total	\$ 48,733	\$ 50,113

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

Depreciation and amortization expense pertaining to property and equipment was approximately \$1.8 million and \$1.7 million for fiscal years 2019 and 2018, respectively.

NOTE 7 — 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 a result of its initial \$100,000 investment, the Company received approximately 3.2% of the common shares outstanding. During the second quarter of fiscal year 2017, the Company made an additional \$300,000 investment in LipoMedix, increasing its ownership to 13.95% of the issued and outstanding ordinary shares, and provided LipoMedix with an additional advance of \$200,000 against anticipated future equity investments. During the fourth quarter of fiscal year 2017, the Company made an additional \$1.1 million investment, inclusive of the \$200,000 advance, in LipoMedix, increasing its ownership to 38.86% of the issued and outstanding ordinary shares. As such, the Company began accounting for this investment under the equity method as of and for the fourth quarter of fiscal year 2017.

On November 16, 2017, the Company exercised its option to purchase additional shares in LipoMedix for \$900,000, which increased its ownership to 50.6% of the issued and outstanding ordinary shares. As such, the Company began consolidating this investment as of and for the second quarter of fiscal year 2018.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

NOTE 7 — INVESTMENT IN LIPOMEDIX PHARMACEUTICALS LTD. (cont.)

The impact of the acquisition's purchase price allocations on the Company's consolidated balance sheet and the acquisition date fair value of the total consideration transferred were as follows:

<i>(in thousands)</i>	At November 16, 2017
Other current assets	\$ 16
Property and equipment, net	8
In Process Research and Development	1,575
Patents	155
Accounts payable	(85)
Accrued expenses	(22)
Net assets, excluding cash acquired and noncontrolling interest	\$ 1,647
Supplemental information:	
Cash paid	\$ 2,400
Cash acquired	1,060
Cash paid, net of cash acquired	1,340
Historical loss on investment	(252)
Noncontrolling interest	559
Total consideration, net of cash acquired and noncontrolling interest	\$ 1,647

The noncontrolling interest balance of LipoMedix of approximately \$559,000 was not included in the balance of noncontrolling interest as of July 31, 2018. An opening balance adjustment was booked as of August 1, 2018 to correct this amount.

In 2019, the Company changed its accounting for recording patent fees. All fees associated with the legal costs incurred in connection with a patent application are being expensed as incurred including all prior legal costs for the patent costs previously capitalized. These expenses, totaling approximately \$440,000 are included in selling, general, and administrative expense in the accompanying consolidated and combined financial statements.

In April 2019, the Company provided no-interest bridge financing of \$250,000 to LipoMedix (the "2019 Bridge Note"). The 2019 Bridge Note is automatically convertible into shares of LipoMedix as follows: (i) upon an issuance of an aggregate \$2.0 million of additional equity securities (excluding the conversion of the Bridge Notes); or (ii) upon a liquidation or dissolution of LipoMedix or a sale of LipoMedix or its assets. If converted, the 2019 Bridge Note will be converted into shares of the most senior class of equity of LipoMedix then issued. If converted upon an equity financing, the 2019 Bridge Note will be converted at a conversion price per share that is equal to 75% of the price paid in the equity offering. If converted upon a liquidation or sale event, the 2019 Bridge Note will be converted at a conversion price per share that is equal to 75% of the per share distribution received by LipoMedix equity holders in connection with the event or if greater the Company will receive a payment equal to the 2019 Bridge Note (\$250,000). If none of such events occurs prior to September 28, 2019, the 2019 Bridge Note will be converted into the most senior class of shares LipoMedix has then issued at a conversion price per share equal to \$0.53 (calculated on the basis of LipoMedix's pre-money valuation of \$5.0 million).

In July 2018, the Company provided no-interest bridge financing of \$875,000 to LipoMedix (the "2018 Bridge Note"). The 2018 Bridge Note is convertible into shares of LipoMedix as follows: (i) upon an issuance of an aggregate \$2.0 million of additional equity securities (excluding the conversion of the 2018 Bridge Note) (the "Financing"), the 2018 Bridge Note amount shall be converted into shares of LipoMedix of the same class and series with the same rights, preferences and privileges as shall be issued in the Financing at a conversion price per share equal to 75% or the lowest price per share paid by the investor(s) in the Financing; (ii) upon a Distribution Event (as defined in the Founder's Agreement among LipoMedix and certain of its founders), the 2018 Bridge Note shall be converted into shares of the most senior class of shares of LipoMedix then issued, at a conversion price per share that is equal to 75% of the per share distribution received by LipoMedix equity holders in connection with the Distribution Event, or

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

NOTE 7 — INVESTMENT IN LIPOMEDIX PHARMACEUTICALS LTD. (cont.)

the Company shall be entitled to receive a redemption payment equal to the 2018 Bridge Note (\$875,000); and (iii) if neither a Financing nor Distribution Event occurs prior to January 6, 2020 (18 months following the effective date of the 2018 Bridge Note), the 2018 Bridge Note will be converted into the most senior class of shares LipoMedix has then issued at a conversion price per share equal to \$0.53 (calculated on the basis of LipoMedix’s pre-money valuation of \$5.0 million, divided by its fully diluted share capital as of July 6, 2018).

NOTE 8 — INCOME TAXES

On December 22, 2017, the U.S. government enacted “An Act to Provide for Reconciliation Pursuant to Titles II and V of the Concurrent Resolution on the Budget for fiscal Year 2018”, which is commonly referred to as “The Tax Cuts and Jobs Act” (the “Tax Act”). The Tax Act provides for comprehensive tax legislation that, among other things, reduces the U.S. federal statutory corporate tax rate from 35.0% to 21.0% effective January 1, 2018, broadens the U.S. federal income tax base, requires companies to pay a one-time repatriation tax on earnings of certain foreign subsidiaries that were previously tax deferred (“transition tax”), and creates new taxes on certain foreign sourced earnings.

The Company has completed its accounting for the income tax effects of the enactment of the Tax Act. At July 31, 2019, the Company did not have any undistributed earnings of its foreign subsidiaries. As a result, no additional income or withholding taxes were provided for, for the undistributed earnings or any additional outside basis differences inherent in the foreign entities. The Company reviewed the global intangible low taxed income (“GILTI”) and base erosion anti-abuse tax (“BEAT”) that became effective August 1, 2018 and has not recorded any impact associated with either.

At July 31, 2019, the Company has federal net operating loss (“NOL”) carryforwards from domestic operations of approximately \$22.3 million, to offset future taxable income. The Company has state NOLs of \$3.2 million. The Company has NOLs from foreign operations of \$1.2 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.

The Company anticipates that its assumptions and estimates may change as a result of future guidance and interpretation from the Internal Revenue Service, the SEC, the FASB, and various other taxing jurisdictions. In particular, the Company anticipates that the U.S. state jurisdictions will continue to determine and announce their conformity with or decoupling from the Tax Act, either in its entirety or with respect to specific provisions. Legislative and interpretive actions could result in adjustments to the Company’s provisional estimates when the accounting for the income tax effects of the Tax Act is completed.

The components of loss before income taxes are as follows:

	For the Year Ended	
	July 31,	
	2019	2018
	<i>(in thousands)</i>	
Domestic	\$ (3,410)	\$ (2,581)
Foreign	(1,533)	(1,058)
Loss before Income Taxes	<u>\$ (4,943)</u>	<u>\$ (3,639)</u>

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

NOTE 8 — INCOME TAXES (cont.)

Benefits from (provision for) income taxes as presented in the consolidated and combined statement of operations consisted of the following:

	For the Year Ended July 31,	
	2019	2018
	<i>(in thousands)</i>	
Current:		
Foreign	\$ —	\$ 11
Federal	—	—
State	—	—
Total current expense	—	11
Deferred:		
Foreign	(19)	—
Federal	—	8,219
State	—	207
Total deferred expense	(19)	8,426
Income tax (benefit) expense	\$ (19)	\$ 8,437

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,	
	2019	2018
	<i>(in thousands)</i>	
U.S. federal income tax at statutory rate	\$ (908)	\$ (886)
State income tax	(172)	(141)
Valuation allowance	(30)	7,105
Foreign tax rate differential	(24)	(290)
Tax law change	—	2,499
Permanent differences	102	144
Rate Change	1,030	—
Other	(17)	6
Income tax expense	\$ (19)	\$ 8,437

The Company has not recorded U.S. income tax expense for foreign earnings because it has not recorded any post spin off from IDT.

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

	At July 31,	
	2019	2018
	<i>(in thousands)</i>	
Deferred tax assets:		
Net operating loss carryforwards	\$ 5,316	\$ 5,753
AMT carryforwards	2,692	—
Reserves and accruals	34	2,344
Stock-based compensation	119	14
Gross deferred tax assets	8,161	8,111
Less valuation allowance	(8,142)	(8,111)
Total deferred tax assets	19	—
Total deferred tax liabilities	—	—
Deferred tax assets, net	\$ 19	\$ —

Net deferred tax assets are included in "Deferred Taxes" in the consolidated balance sheets.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

NOTE 9 — COMMITMENTS AND CONTINGENCIES

Legal Proceedings

On August 21, 2018, the Company entered into a settlement agreement with a building service provider in order to avoid the risks, delays and expenses inherent in and resulting from litigation. The \$100,000 settlement was included in “Selling, general and administrative” expenses in the 2018 consolidated and combined statements of operations and in “Accrued Expenses” in the accompanying consolidated balance sheets. As the Company is fully indemnified by IDT for the settlement amount, a corresponding receivable was included in “Due to Related Parties” in the accompanying consolidated balance sheets. This amount has since been repaid in the first quarter of fiscal 2019.

Under a Founders Agreement among LipoMedix and other parties, two of LipoMedix’ founders would become entitled to consulting payments in the approximate amounts of \$385,000 and \$358,000, respectively, upon the satisfaction of certain conditions thereto. LipoMedix believes that those conditions have not been satisfied and does not believe that they are likely to be satisfied until LipoMedix is successful in raising significant capital in the future.

On September 17, 2018, LipoMedix was notified of a claim initiated by one of its founders seeking payment of consulting fees in the amount of approximately \$377,000 and seeking to place restrictions on LipoMedix’ bank accounts and other assets to protect his claim. LipoMedix did not believe that the individual had the right to receive any payment at the current time. LipoMedix responded to the demand for the placement of restrictions on its assets. And on November 26, 2018, the court denied the request by the founder to place restrictions on the assets. In May 2019, LipoMedix received a letter from the other founder requesting payment of his consulting fees. On July 15, 2019, the parties settled the matters and the two founders will be paid a percentage of future investments and certain other proceeds.

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, NJ. 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.

For the matters disclosed above a general legal accrual for approximately \$250,000 has been made for legal fees and losses believed to be both probable and reasonably estimable, but an exposure to loss may exist in excess of the amount accrued.

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, 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 10 — CONVERTIBLE NOTE

On November 15, 2018, Howard Jonas, the Company’s Chairman, CEO, and controlling stockholder entered into an agreement to purchase a convertible note from the Company for \$15.0 million. The term of the note was three years with interest accruing on the principal amount at a rate of 6% per annum, compounded quarterly. The note was subsequently assigned by Mr. Jonas to the Howard S. Jonas 2017 Annuity Trust. At the option of the Company, interest on the note can be capitalized and added to principal or payable in cash. The note was convertible at the option of the holder into shares of Class B common stock at a conversion price of \$8.47 per share, the closing price of the Company’s Class B common stock on the trading day before the date of the investment agreement. The initial principal amount of the note was convertible into 1,770,956 shares of Class B common stock, and if all interest for the three-year term of the note is capitalized, the note would have been convertible into 2,117,388 shares of Class B common stock. If the closing price of the Company’s Class B common stock on the NYSE American is 200% of the conversion price for at least thirty (30) consecutive days, the Company had the right to cause conversion of the note.

At issuance, the Company recorded a debt discount of approximately \$70,000 related to the beneficial conversion feature of the note and amortized approximately \$16,000 of the discount in fiscal 2019 which was included in interest expense. In addition, the Company recorded approximately \$650,000 and \$418,000 of interest expense for the year ended July 31, 2019 and 2018, respectively, that is included in accrued expenses in the accompanying consolidated balance sheets.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

NOTE 10 — CONVERTIBLE NOTE (cont.)

	At July 31, 2019 <i>(in thousands)</i>
Convertible Note:	
Principal value of 6% convertible note at July 31, 2019, due November 15, 2021	\$ 15,000
Debt discount	(54)
Total long-term carrying value of convertible note	<u>\$ 14,946</u>

In August 2019, the note including interest of approximately \$667,000 was converted into 1,849,749 shares of common stock.

NOTE 11 — RELATED PARTY TRANSACTIONS

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 and payroll costs for the Company’s personnel that were paid by IDT. This is partially offset by rental income paid to the Company by various companies under common control to IDT. The Company also maintains a due from related parties account which includes the balance due for charges and for services provided by the Company to Rafael Pharmaceuticals for rent, accounting and other administrative expenses.

On March 26, 2018, IDT spun off the Company. In connection with the spin-off, IDT and the Company entered into a Transition Services Agreement, dated March 26, 2018 (the “TSA”), pursuant to which IDT, which is controlled by Howard S. Jonas and for which Howard S. Jonas serves as the Chairman of the Board, provides certain services to the Company. The services include, but are not limited to: administrative, tax and legal. IDT billed the Company approximately \$390,000 under the TSA during fiscal 2019 and approximately \$60,000 for invoices paid by IDT on the Company’s behalf. In addition, during fiscal 2019, the Company billed IDT approximately \$64,000 for real estate advisory services provided to IDT, and approximately \$25,000 for invoices paid by the Company on IDT’s behalf. IDT collected cash of approximately \$174,000 on behalf of the Company, primarily from third parties who use the Company’s parking garage while the Company was in the process of changing its billing and collection systems. As of July 31, 2019, the Company owed IDT approximately \$60,000 included in due to related parties.

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 fiscal 2019. As of July 31, 2019, IDT owed the Company approximately \$9,000 for office rent and parking.

Genie Energy, Ltd. (“Genie”), a company controlled by Howard Jonas, the Company’s Chairman of the Board and controlling stockholder, leases office space from the Company at 520 Broad Street. Billings for such services totaled approximately \$218,000 in fiscal 2019. The Company charges Genie \$23.46 per square foot annually for approximately 8,631 square feet of space. As of July 31, 2019, Genie had no amounts due to the Company.

The Company provides Rafael Pharmaceuticals with administrative, finance, accounting, tax and legal services. Howard S. Jonas serves as a Chairman of the Board of Rafael Pharmaceuticals and owns an equity interest in Rafael Pharmaceuticals. The Company billed Rafael Pharmaceuticals \$480,000 during fiscal 2019. As of July 31, 2019, Rafael Pharmaceuticals owed the Company \$280,000 included in due from related parties.

On April 26, 2018, the Corporate Governance Committee authorized, approved and confirmed an underlying Related Person Transaction involving Howard Jonas with respect to the Company’s proposed sale to Mr. Jonas of 1,254,200 shares of the Company’s Class B common stock at a price per share of \$6.89, which was the closing price for the Class B common stock on the NYSE American on April 26, 2018 (the last closing price before approval of the arrangement) for an aggregate purchase price of approximately \$8,641,000, the purchase price of which would be reduced by the amount of any dividends whose record date is between the date hereof and the issuance of the shares (the “Sale”). The Sale took place on January 18, 2019, following stockholder approval on January 10, 2019. The

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

NOTE 11 — RELATED PARTY TRANSACTIONS (cont.)

Company’s liability at July 31, 2018 was comprised of a deposit of \$864,000 from Howard Jonas, Chairman of the Board, Chief Executive Officer and controlling stockholder of the Company partially offset by amounts due from IDT and Rafael Pharmaceuticals.

IDT-Rafael Holdings, LLC, the Company’s 90%-owned subsidiary and the remaining 10% of which is held by Howard Jonas, currently holds 36.7 million shares of Rafael Pharmaceutical’s Series D Convertible Preferred Stock and a warrant to increase ownership to up to 56% of the fully diluted equity interests in Rafael Pharmaceuticals. IDT-Rafael Holdings, LLC also owns 50% of CS Pharma Holdings, LLC (“CS Pharma”), a non-operating entity that holds 16.7 million shares of Rafael Pharmaceutical’s Series D Convertible Preferred Stock. The Company and its subsidiaries collectively own securities representing 51% of the outstanding capital stock of Rafael Pharmaceuticals and 38% of the capital stock on a fully diluted basis (excluding the remainder of the Warrant).

In September 2018, CS Pharma, in which the Company owns an effective 45% interest, exercised a warrant to purchase 8 million shares of Rafael Pharmaceutical’s Series D Convertible Preferred Stock for \$10 million representing approximately 8% of the equity on a fully-diluted basis (excluding the remainder of the Warrant) of Rafael Pharmaceuticals. The Warrant in full is exercisable for up to 56% of the fully diluted equity of Rafael Pharmaceuticals. The right to exercise the first \$10 million of the Warrant was held by CS Pharma. CS Pharma is owned by 0.25% by Michael Weiss, a non-employee director of the Company. The remainder of the Warrant is held by IDT-Rafael Holdings, LLC.

On November 5, 2018, IDT-Rafael Holdings, LLC partially exercised a warrant to purchase 4 million shares of Rafael Pharmaceutical’s Series D Convertible Preferred Stock for \$5 million, of which \$500,000 was contributed by Howard Jonas.

On January 10, 2019, IDT-Rafael Holdings, LLC partially exercised a warrant to purchase 5.1 million shares of Series D Convertible Preferred Stock of Rafael Pharmaceuticals for \$6.4 million, of which \$640,000 was contributed by Howard Jonas.

On January 23, 2019, IDT-Rafael Holdings, LLC partially exercised a warrant to purchase 36.3 million shares of Series D Convertible Preferred Stock of Rafael Pharmaceuticals for \$34.4 million, of which \$3.4 million was contributed by Howard Jonas.

On November 15, 2018, Howard Jonas entered into an agreement to purchase a convertible note from the Company for \$15 million that has since been converted to shares of common stock. See Note 10.

NOTE 12 — FUTURE MINIMUM RENTS

Certain of the Company’s properties are leased to tenants under net operating leases with initial term expiration dates ranging from 2021 to 2030. The future contractual minimum lease payments to be received (excluding operating expense reimbursements) by the Company as of July 31, 2019, under non-cancelable operating leases which expire on various dates through 2028, are as follows:

Year ending July 31,	Related Parties	Other	Total
		<i>(in thousands)</i>	
2020.....	\$ 1,992	\$ 1,054	\$ 3,046
2021.....	2,041	1,136	3,177
2022.....	2,078	993	3,071
2023.....	2,117	630	2,747
2024.....	2,155	1,185	3,340
Thereafter	1,659	3,468	5,127
Total Minimum Future Rental Income	<u>\$ 12,042</u>	<u>\$ 8,466</u>	<u>\$ 20,508</u>

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

NOTE 12 — FUTURE MINIMUM RENTS (cont.)

Related parties represented approximately 53% and 51% of the Company's total revenue for the years ended July 31, 2019 and 2018, respectively. The Company amended all of its related party leases as of August 1, 2017. 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, 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 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. Upon expiration of the lease, related parties have the right to renew the leases for another five years.

NOTE 13 — BUSINESS SEGMENT INFORMATION

The Company conducts business as two operating segments, Real Estate and Pharmaceuticals. 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 chief operating decision makers.

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

Beginning in the second quarter of fiscal 2018, the Pharmaceuticals segment is comprised of debt interests and a warrant to purchase equity interests in Rafael Pharmaceuticals and a majority equity interest in LipoMedix. Comparative results have been reclassified and restated as if the Pharmaceuticals segment existed for all periods presented. To date, the Pharmaceuticals segment has not generated any revenues.

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 loss from operations. All investments in Rafael Pharmaceuticals and assets and expenses associated with LipoMedix are tracked separately in the Pharmaceuticals segment. All corporate costs are allocated to the Real Estate segment.

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

<i>(in thousands)</i>	Real Estate	Pharmaceuticals	Total
At Year Ended July 31, 2019			
Revenues	\$ 4,931	\$ —	\$ 4,931
Loss from operations	(5,083)	(1,613)	(6,696)
At Year Ended July 31, 2018			
Revenues	\$ 4,371	\$ —	\$ 4,371
Loss from operations	(2,780)	(1,061)	(3,841)

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,	2019	2018
Revenue from tenants located in Israel	3%	6%

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

NOTE 13 — BUSINESS SEGMENT INFORMATION (cont.)

Net long-lived assets and total assets held outside of the United States, which are located in Israel, were as follows:

<i>(in thousands)</i>	United States	Israel	Total
July 31, 2019			
Long-lived assets, net	\$ 47,096	\$ 1,637	\$ 48,733
Total assets	138,535	3,608	142,143
July 31, 2018			
Long-lived assets, net	\$ 48,415	\$ 1,698	\$ 50,113
Total assets	113,279	3,641	116,920

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.

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 1,064,048 shares which may be awarded in the form of incentive stock options or restricted shares.

In connection with the Spin-Off, options to purchase 626,662 shares of Class B common stock options were issued to IDT employees and service providers related to options to purchase IDT stock held by those individuals. The options have an exercise price of \$4.90 per share, which was equal to the closing price of the Company’s Class B common stock on the first trading day following the consummation of the Spin-Off. The expiration date of the options is equal to the later of (i) the expiration of the IDT option held by such option holder and (ii) a date on or about the first anniversary of the Spin-Off when the Company’s insiders will be free to trade in shares of the Company under the Company’s insider trading policy. The options to purchase shares of the Company were issued under the Plan.

Option awards to Company employees under the Plan are generally granted with an exercise price equal to the market price of the Company’s stock on the date of grant. Option awards generally vest on a graded basis over five years of service and have ten-year contractual terms. No options were granted in fiscal 2019.

In fiscal 2019, options to purchase 38,710 shares of Class B common stock were exercised and 819 options were cancelled. No options were exercised or cancelled during fiscal 2018. At July 31, 2019, there was no unrecognized compensation cost related to non-vested stock options.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

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, 2018.	626,662	\$ 4.90		
Granted	—	—		
Exercised	(38,710)	4.90		
Cancelled/Forfeited.	(819)	4.90		
OUTSTANDING AT JULY 31, 2019	587,133	\$ 4.90	3.66	\$ 2,877
EXERCISABLE AT JULY 31, 2019	572,934	\$ 4.90	3.66	\$ 2,807

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.

As part of the Spin-Off, holders of restricted Class B common stock of IDT received, in respect of those restricted shares, one restricted share of the Company's Class B common stock for every two restricted shares of IDT that they held as of the record date for the Spin-Off. The Company issued an aggregate of 92,690 restricted shares of its Class B common stock to the holders of restricted Class B common stock of IDT. Such shares of the Company's Class B common stock are restricted under the same terms as the IDT restricted stock in respect of which they were issued. The restricted shares of the Company's Class B common stock received in the Spin-Off are subject to forfeiture on the same terms, and their restrictions will lapse at the same time, as the corresponding IDT shares.

On March 28, 2018, the Company granted employees and consultants 76,445 restricted shares of Class B Common Stock, which vested or will vest as to one-third of the granted shares on each of March 28, 2019, 2020 and 2021, unless otherwise determined by the Compensation Committee of the Company's Board of Directors. The aggregate fair value of the grant was approximately \$375,000, which is being charged to expense on a straight-line basis as the shares vest.

During fiscal 2019, the Company granted employees and consultants 74,637 restricted shares of Class B Common Stock, which will vest over 2 to 5 years. The aggregate fair value of the grants was approximately \$1.3 million, which is being charged to expense on a straight-line basis as the shares vest. One grant of 70,718 restricted shares with a fair value of \$1.2 million was granted to an officer of the Company.

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, 2018.	141,799	\$ 4.90
Granted	74,637	16.49
Vested	(60,010)	4.96
Cancelled/Forfeited.	—	—
NON-VESTED SHARES AT JULY 31, 2019	156,426	\$ 10.41

At July 31, 2019, there was \$1.2 million of total unrecognized compensation cost related to non-vested stock-based compensation arrangements, which is expected to be recognized over a weighted-average period of three years. The total grant date fair value of shares vested in fiscal 2019 and fiscal 2018 was approximately \$298,000 and \$344,000, respectively.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

NOTE 14 — EQUITY (cont.)

Approval of Sale of Shares of Class B Common Stock to Howard S. Jonas

On April 26, 2018, the Corporate Governance Committee authorized, approved and confirmed an underlying Related Person Transaction involving Howard Jonas with respect to the Company’s proposed sale to Mr. Jonas of 1,254,200 shares of the Company’s Class B common stock at a price per share of \$6.89, which was the closing price for the Class B common stock on the NYSE American on April 26, 2018 (the last closing price before approval of the arrangement) for an aggregate purchase price of \$8,641,438, the purchase price of which would be reduced by the amount of any dividends whose record date is between the date hereof and the issuance of the shares (the “Sale”). The Sale took place on January 18, 2019, following stockholder approval on January 10, 2019.

Grant to Board of Directors

Pursuant to the Company’s 2018 Equity Incentive Plan, each of our three non-employee directors of the Company was granted 4,203 restricted shares of our Class B common stock in January 2019 which fully vested on the date of the grant. The fair value of the awards on the date of the grant was approximately \$107,000, which was included in selling, general and administrative expense.

NOTE 15 — 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, 2019 and 2018, 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 securities, in common share equivalents, which have been excluded from the calculation of dilutive loss per share as their effect would be anti-dilutive:

	At July 31,	
	2019	2018
Stock Options	587,133	626,662
Convertible Note – Related Party	1,847,594	—
Total	2,434,727	626,662

In the years ended July 31, 2019 and 2018, 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 conversion of the convertible note would have been anti-dilutive.

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