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DELTA REPORT

10-K

RFL - RAFAEL HOLDINGS, INC.

10-K - JULY 31, 2024 COMPARED TO 10-K - JULY 31, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	4452
CHANGES	180
DELETIONS	1816
ADDITIONS	2456

REFINITIV

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 year ended July 31, 2023 July 31, 2024.
or
☐ Transition report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934.
Commission File Number: 000-55863

RAFAEL HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

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

520 Broad Street, Newark, New Jersey 07102
(Address of principal executive offices, zip code)
(212) 658-1450
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	☐	Accelerated filer ☐	☐
Non-accelerated filer ☒	☒	Smaller reporting company ☒	☒
Emerging growth company ☐	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐
☐
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, 2023 January 31, 2024 (the last business day of the registrant's most recently completed second fiscal quarter) of the Class B common stock of $4.14 $1.81 per share, as reported on the New York Stock Exchange, was approximately $70.2 million $34.4 million.
The number of shares outstanding of the registrant's common stock as of October 27, 2023 November 5, 2024 was:

Class A common stock, par value $0.01 per share:	787,163 shares
Class B common stock, par value $0.01 per share:	23,719,472 23,886,987 shares (excluding 162,536 treasury shares)

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant's Annual Meeting of Stockholders, to be held January 10, 2024, is incorporated by reference into Part III of this Form 10-K to the extent described therein.

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RAFAEL HOLDINGS, INC.

Annual Report on Form 10-K

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

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

Our business is subject to numerous risks as described in this section. Item 1A. Risk Factors. Some of these risks include:

- *We have limited resources and could find it difficult to raise additional capital.*
- *Our future success may depend on the results of Cyclo Therapeutics' Phase III trial for Trappsol® Cyclo™. If Cyclo is unable to gain regulatory approval or commercialize its product candidates or experiences significant delays in doing so, our business will be materially harmed.*
- *Preclinical and clinical drug development is a lengthy and expensive process, with an uncertain outcome. Our and the Pharmaceutical Companies' preclinical and clinical programs may experience delays or may never advance, which would adversely affect the ability to obtain regulatory approvals or commercialize product candidates on a timely basis or at all, which could have an adverse effect on our business business.*
- *Our future success may depend on prospects for Cornerstone's lead product candidate devimistat (CPI-613®) and results of Cyclo Therapeutics' Phase III trial for Trappsol® Cyclo™. If either company is unable to gain regulatory approval or commercialize its product candidates or experiences significant delays in doing so, our business will be materially harmed.*
- *We and the companies in which we hold interests may expend our and their limited resources to pursue a particular product candidate or an indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.*
- *Results of preclinical studies and early clinical trials may not be predictive of results of future preclinical studies or clinical trials.*
- *The companies in which we hold interests face substantial competition, and if competitors develop and market technologies or products more rapidly than those companies do or that are more effective, safer or less expensive than the product candidates that those companies develop, our commercial opportunities will be negatively impacted.*
- *Rafael Medical Devices' device candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved or cleared devices or investigational or approved drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential, result in significant negative consequences, or trigger potential product liability claims.*
- *We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business and that of the companies in which we hold interests effectively.*
- *We may not be able to consummate any investment, business combination or other transaction.*
- *We are controlled by our principal stockholder, which limits the ability of other stockholders to affect the management of the Company.*
- *If we or the companies in which we hold interests are unable to adequately maintain or protect their our proprietary technology and product candidates and device candidates and services, if the scope of the patent protection obtained is not sufficiently broad, or if the terms of patents are insufficient to protect product candidates, device candidates, services or technologies for an adequate amount of time, competitors could develop and commercialize technology and products similar or identical to that technology or those product candidates, device candidates and the services, and our ability to successfully commercialize technology or product candidates, device candidates or services may be materially impaired impaired.*
- *Public health threats The Exchange Ratio used in the Merger with Cyclo will be determined in accordance with a formula and is not yet knowable. The actual Exchange Ratio could have an adverse effect on the Company's operations and financial results. be materially different than currently anticipated.*

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 2023 2024 refers to the fiscal year ended July 31, 2023 July 31, 2024).

Item 1. Business.

OVERVIEW

Rafael Holdings, Inc. (NYSE:RFL), ("Rafael Holdings", "Rafael", "we" or the "Company"), a Delaware corporation, is a holding company with interests in clinical and early-stage pharmaceutical companies (the "Pharmaceutical Companies"), including an investment in Cornerstone Pharmaceuticals, (and planned merger with) Cyclo Therapeutics Inc. (Nasdaq: CYTH), formerly known as Rafael Pharmaceuticals Inc. ("Cyclo Therapeutics" or "Cyclo"), a cancer metabolism-based therapeutics clinical stage biotechnology company dedicated to developing Trappsol® Cyclo™, which is being evaluated in clinical trials for the potential treatment of Niemann-Pick Disease Type C1 ("NPC1"), a rare, fatal and progressive genetic disorder, a majority equity interest in LipoMedix Pharmaceuticals Ltd. ("LipoMedix"), a clinical stage pharmaceutical company, the Barer Institute Inc. ("Barer"), a wholly-owned preclinical cancer metabolism research operation, an investment and a majority interest in Cyclo Therapeutics, Cornerstone Pharmaceuticals, Inc. (Nasdaq: CYTH) ("Cyclo Therapeutics" or "Cyclo") Cornerstone"), formerly known as Rafael Pharmaceuticals Inc., a clinical-stage biotechnology company dedicated to developing life-changing medicines for patients and families living with challenging diseases through its lead therapeutic asset, Trappsol® Cyclo™. cancer metabolism-based therapeutics company. We also hold a majority interest in Rafael Medical Devices, LLC. ("Rafael Medical Devices"), an investment orthopedic-focused medical device company developing instruments to advance minimally invasive surgeries, and a majority interest in Day Three Labs, Inc. ("Day Three"), a company which reimagines empowers third-party manufacturers to reimagine their existing cannabis offerings with pharmaceutical-grade technology and innovation like Unlokt™ enabling them to bring to market better, cleaner, more precise and predictable products in the cannabis industry, versions by utilizing Day Three's pharmaceutical-grade technology and a majority interest in innovation like Unlokt™. Day Three and Rafael Medical Devices, LLC, an orthopedic-focused medical device company developing instruments to advance minimally invasive surgeries ("Rafael Medical Devices" and Day Three Labs together with the Pharmaceutical Companies, represent our "Investment "Portfolio Companies"). In November 2022, the Company resolved to curtail its early-stage development efforts, including pre-clinical research at Barer. The decision was taken to reduce spending as the Company focuses on exploring strategic opportunities. Since then, the Company has sought partners for programs at Farber and has entered into a license agreement for one of its technologies. The Company's primary focus is to expand our investment portfolio through opportunistic and strategic investments including therapeutics, which address high unmet medical needs. Upon closing of the planned merger with Cyclo, the Company intends to focus its efforts on making Trappsol® Cyclo™ its lead clinical program.

Historically, the Company owned multiple real estate assets. In 2020, the Company sold an office building located in Piscataway, New Jersey and, on August 22, 2022, the Company sold the building at 520 Broad Street in Newark, New Jersey that serves as headquarters for the Company and several tenants and an associated public garage (the "520 Property"). See Note 3 for further details on the sale transaction. Currently, As of July 31, 2024, the Company holds a portion of a commercial building in Jerusalem, Israel as its sole remaining owned real estate asset.

The Company holds debt and equity investments in Cornerstone Pharmaceuticals that includes preferred and common equity interests and a warrant to purchase additional equity. On June 17, 2021, In May 2023, the Company entered into a merger agreement to acquire full ownership of Cornerstone Pharmaceuticals first invested in exchange for issuing Company Class B common stock to the other stockholders of Cornerstone Pharmaceuticals. On October 28, 2021, the Company announced that the AVENGER 500 Phase 3 clinical trial for CPI-613® (devimistat), Cornerstone Pharmaceuticals' lead product candidate, did not meet its primary endpoint of significant improvement in overall survival in patients with metastatic adenocarcinoma of the pancreas. In addition, following a pre-specified interim analysis, the independent data monitoring committee for the ARMADA 2000 Phase 3 study for devimistat recommended the trial to be stopped due to a determination that it was unlikely to achieve the primary endpoint (the "Data Events"). In connection with the preparation of the Company's financial statements for the first quarter ended October 31, 2021, accounting principles generally accepted in the United States of America ("U.S. GAAP") required that the Company assess the impact of the Data Events and determine whether the carrying values of the Company's assets were impaired based upon the Company's expectations to realize future value. In light of the Data Events, the Company concluded that the likelihood of further development of and prospects for CPI-613 is uncertain and fully impaired in the first quarter ended October 31, 2021 the value of its loans, receivables, and investment in Cornerstone Pharmaceuticals based upon its valuation of Cornerstone Pharmaceuticals. On February 2, 2022, the Company terminated the Merger Agreement with Cornerstone Pharmaceuticals, effective immediately, in accordance with its terms. Subsequently, on February 2, 2022, the Company withdrew its Registration Statement on Form S-4 related to the proposed Merger. Cornerstone is in the process of a comprehensive restructuring transaction as discussed more fully below and in Note 4 to the Consolidated Financial Statements.

Cyclo Therapeutics, Inc. Therapeutics. Cyclo is a clinical stage clinical-stage biotechnology company that develops cyclodextrin-based products for the potential treatment of neurodegenerative diseases. Cyclo's lead drug candidate is Trappsol® Trappsol® Cyclo™ (hydroxypropyl beta cyclodextrin), a treatment for Niemann-Pick Type C disease Disease, type C1 ("NPC" NPC1"). NPC NPC1 is a rare and fatal autosomal recessive genetic disease resulting in disrupted cholesterol metabolism that impacts the brain, lungs, liver, spleen, and other organs. In January 2017 the FDA granted Fast Track designation to Trappsol® Trappsol® Cyclo™ for the treatment of NPC. NPC1. Initial patient enrollment in the U.S. Phase I study commenced in September 2017, and in May 2020 Cyclo announced Top Line data showing a favorable safety and tolerability profile for Trappsol® demonstrating Trappsol® Cyclo™ was well tolerated in this study. Cyclo is currently conducting a Phase 3 III Clinical Trial Evaluating Trappsol® Cyclo™ in Pediatric and Adult Patients with Niemann-Pick Disease, Type C1. In May 2023, we purchased 2,514,970 shares of common stock See Notes 11 and warrants 12 to purchase an additional 2,514,970 shares of common stock of the Consolidated Financial Statements for more information on the Company's investments in Cyclo. The purchase price for one share of common stock and a warrant to purchase one share of common stock was $0.835. The warrants have an exercise price of $0.71 and have a term of seven years.

As discussed in more detail below, on August 21, 2024, the Company entered into a merger agreement with Cyclo. In the event the merger is consummated, the Company intends to fund the TransportNPC phase III clinical trial, evaluating Trappsol® Cyclo™ in Niemann Pick C, to its interim analysis in the middle of 2025 and focus its efforts on Trappsol® Cyclo™ as its lead clinical program. At that point, the Company will make a determination as to whether or not to file an NDA for Trappsol® Cyclo™.

LipoMedix is a clinical stage Israeli company focused on the development of a product candidate that holds the potential to be an innovative, safe, and effective cancer therapy based on liposome delivery. As of July 31, 2024, the Company's ownership interest in LipoMedix was approximately 95%. LipoMedix has completed various clinical stages of Promitil® including Phase 1A (solid tumors) and 1B (as single agent and in combination with capecitabine and/or bevacizumab in colorectal cancer). Another phase 1B testing Promitil® as radiosensitizer is ongoing and near completion. A total of 149 patients have been treated with Promitil® as a single agent, or in combination with other anticancer drugs or radiotherapy, under the framework of a phase 1A and two 1B clinical studies and under named patient approval for compassionate use.

In 2019, the Company established Barer, a wholly owned preclinical cancer metabolism research operation, to focus on developing a pipeline of novel therapeutic compounds, including compounds designed to regulate cancer metabolism with potentially broader application in other indications beyond cancer. Barer has been comprised of scientists and academic advisors that are experts in cancer metabolism, chemistry, and drug development. In addition to its own internal discovery efforts, Barer pursued collaborative research agreements and in-licensing opportunities with leading scientists from top academic institutions. Barer's majority owned subsidiary, Farber Partners, LLC ("Farber"), was formed around one such agreement with Princeton University's Office of Technology Licensing ("Princeton") for technology from the laboratory of Professor Joshua Rabinowitz, in the Department of Chemistry, Princeton University, for an exclusive worldwide license to its SHMT (serine hydroxymethyltransferase) inhibitor program. In November 2022, the Company resolved to curtail its early-stage development efforts, including pre-clinical research at the Barer Institute. Since then, the Company has sought partners for Farber programs and has entered into a license agreement for one of its technologies.

In 2016, the

The Company first invested owns a 37.5% equity interest in LipoMedix Pharmaceuticals Ltd. RP Finance LLC ("LipoMedix" RP Finance"), a clinical stage pharmaceutical company and holds a majority which was, until March 13, 2024 (the date of the common stock. RP Finance Consolidation, as described below), accounted for under the equity method. RP Finance is an entity associated with members of the family of Howard Jonas (Executive Chairman, Chairman of the Board, and controlling stockholder of the Company) which holds 37.5% equity interest of RP Finance. RP Finance holds debt and equity investments in Cornerstone. Cornerstone received negative results of its Avenger 500 Phase 3 study for Devimistat in pancreatic cancer as well as a recommendation to stop its ARMADA 2000 Phase 3 study due to a determination that the trial would unlikely achieve its primary endpoint (the "Data Events"). Due to the Data Events, RP Finance fully impaired its then debt and equity investments in Cornerstone.

On March 13, 2024, Cornerstone consummated a restructuring of its outstanding debt and equity interests (the "Cornerstone Restructuring"). As a result of the Cornerstone Restructuring, Rafael became a 67% owner of the issued and outstanding common stock of Cornerstone (the "Cornerstone Acquisition"), and Cornerstone became a consolidated subsidiary of Rafael. The Cornerstone Acquisition is accounted for as an acquisition of a variable interest entity that is not a business in accordance with U.S. GAAP. The Company was determined to be the accounting acquirer for financial reporting purposes. See Note 3 to the Consolidated Financial Statements for additional information regarding the transaction. In April 2023, conjunction with the Cornerstone Restructuring and Cornerstone Acquisition, the Company invested in Day Three Labs, reassessed its relationship with RP Finance, and as a result determined that RP Finance is still a variable interest entity and that the majority-owner Company became the primary beneficiary of Day three Labs Manufacturing, a company RP Finance as the Company now holds the ability to control repayment of the RP Finance Line of Credit which reimagines existing cannabis offerings with pharmaceutical-grade technology directly impacts RP Finance's economic performance. Therefore, following the Cornerstone Restructuring and innovation like Unlokt™ Cornerstone Acquisition, the Company consolidated RP Finance (the "RP Finance Consolidation"). See Note 3 to bring to market better, cleaner, more precise and predictable products in the cannabis industry. Consolidated Financial Statements for additional information on the Consolidation.

In May 2021, we the Company formed Rafael Medical Devices, an orthopedic-focused medical device company developing instruments to advance minimally invasive surgeries. In August 2023, the Company raised $925,000 from third parties in exchange for 31.6% ownership of Rafael Medical Devices.
In April 2023, the Company first invested in Day Three, a company which empowers third-party manufacturers to reimagine their existing cannabis offerings enabling them to bring to market better, cleaner, more precise and predictable versions by utilizing Day Three's pharmaceutical-grade technology and innovation like Unlokt™. In January 2024, the Company entered into a series of transactions with Day Three and certain shareholders, acquiring a controlling interest of Day Three, which is now a consolidated subsidiary of the Company (the "Day Three Acquisition").

Financial information by segment is presented in Note 15 23 in the Notes to our Consolidated Financial Statements in Item 8 of this Annual Report.

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

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

RECENT DEVELOPMENTS

On October 20, 2023 August 21, 2024, we exercised the Company entered into an Agreement and Plan of Merger (the "Merger Agreement"), by and among: Rafael; Tandem Therapeutics, Inc., a warrant Nevada corporation and a wholly-owned subsidiary of the Company ("First Merger Sub"); Tandem Therapeutics, LLC, a Nevada limited liability company and a wholly-owned subsidiary of Rafael ("Second Merger Sub" and together with First Merger Sub, the "Merger Subs"); and Cyclo Therapeutics, Inc., a Nevada corporation ("Cyclo"). The Merger Agreement requires approval of Cyclo's stockholders and the issuance of the Company's Class B Common Stock, $0.01 par value per share ("Rafael Class B Common Stock") in the merger requires approval by Rafael's stockholders. Upon such approvals and satisfaction or waiver of all other conditions set forth in the Merger Agreement and the effectiveness of a registration statement on Form S-4 to purchase 2,514,970 register the shares of common stock the Company's Class B Common Stock to be issued in the merger based on an exchange ratio (an illustration of which is set forth as Schedule 5 to the Merger Agreement) valuing Cyclo and received a new warrant to purchase an additional 2,766,467 shares of common stock for an aggregate purchase price of $1,785,629. The new warrants have an exercise price of $0.95 at $.95 per share and a term the Company at its cash value combined with the value of four years. its marketable securities and certain other investments less current liabilities (of the Company on an unconsolidated basis), the merger will be consummated.

On August 2, 2023, we increased our investment in Cyclo by purchasing 4,000,000 shares of common stock of Cyclo and warrants to purchase an additional 4,000,000 shares of common stock of Cyclo for an aggregate purchase price of $5,000,000. The warrants have an exercise price of $1.25 and a term of seven years.

In August 2023, Rafael Medical Devices raised $925,000 from third parties after which we maintain approximately 53% of Rafael Medical Devices on a fully diluted basis

BUSINESS DESCRIPTION

We work to advance the pipeline development of our Investment Portfolio Companies, including Cornerstone Pharmaceuticals, Cyclo Therapeutics, LipoMedix, Cyclo Therapeutics, Barer, Rafael Medical Devices, Cornerstone and Day Three Labs. We also further seek to expand our investment portfolio through opportunistic and strategic investments including therapeutics which address high unmet medical needs. Historically, the Company owned real estate assets. In 2020, the Company sold an office building located in Piscataway, New Jersey and following the end of Fiscal in August 2022, the Company sold the 520 Property. Currently, the Company holds a portion a commercial building in Jerusalem, Israel as its remaining real estate asset.

Investment Portfolio Companies

Overview

We are a company with interests in clinical and early-stage pharmaceutical companies through including an investment in Cornerstone Pharmaceuticals, Inc., Cyclo Therapeutics, a clinical stage cancer metabolism-based therapeutics biotechnology company dedicated to developing Trappsol® Cyclo™, which is being evaluated in clinical trials for the potential treatment of Niemann-Pick Disease Type C1 ("NPC1"), a rare, fatal and progressive genetic disorder, a majority equity interest in LipoMedix, Pharmaceuticals, a clinical stage pharmaceutical company. Our company, Barer, a wholly-owned Barer Institute, is a preclinical cancer metabolism research operation, formed and a majority interest in 2019 Cornerstone, a cancer metabolism-based therapeutics company. We also hold a majority interest in Rafael Medical Devices, an orthopedic-focused medical device company developing instruments to focus on developing advance minimally invasive surgeries, and a pipeline of novel therapeutic compounds, including compounds majority interest in Day Three, a company which empowers third-party manufacturers to regulate cancer metabolism with potentially broader application in other indications beyond cancer. In addition reimagine their existing cannabis offerings enabling them to its own internal discovery efforts, Barer pursued collaborative research agreements bring to market better, cleaner, more precise and in-licensing opportunities with leading scientists from top academic institutions. Barer's majority owned subsidiary, Farber Partners, LLC ("Farber"), was formed around one such agreement with Princeton University's Office of Technology Licensing for predictable versions by utilizing Day Three's pharmaceutical-grade technology from the laboratory of Professor Joshua Rabinowitz, in the Department of Chemistry, Princeton University, for an exclusive worldwide license to its SHMT (serine hydroxymethyltransferase) inhibitor program. and innovation like Unlokt™. In November 2022, the Company resolved to curtail its early-stage development efforts, including pre-clinical research at Barer. We are invested in Cyclo Therapeutics, Inc. (Nasdaq: CYTH) ("Cyclo Therapeutics" or The decision was taken to reduce spending as the "Cyclo), a clinical-stage biotechnology company dedicated to developing life-changing medicines for patients and families living with challenging diseases through its lead therapeutic asset, Trappsol® Cyclo™. Our Company focuses on exploring strategic opportunities. The Company's primary focus to date has been to invest in and fund, discover, and develop novel therapies, and we further seek is to expand our investment portfolio through opportunistic and strategic investments including therapeutics, which address high unmet medical needs.

Cornerstone Cyclo Therapeutics Inc.

We own our interest Cyclo is a clinical -stage biotechnology company that develops cyclodextrin-based products for the potential treatment of neurodegenerative diseases. Cyclo filed a Type II Drug Master File with the U.S. Food and Drug Administration ("FDA") in Cornerstone through 2014 for its lead drug candidate, Trappsol® Cyclo™ (hydroxypropyl beta cyclodextrin) as a 90%-owned non-operating subsidiary, Pharma Holdings, LLC treatment for Niemann-Pick Disease, Type C1 ("Pharma Holdings" NPC1"). Pharma Holdings owns 50% NPC1 is a rare and fatal autosomal recessive genetic disease resulting in disrupted cholesterol metabolism that impacts the brain, lungs, liver, spleen, and other organs. In 2015, Cyclo launched an International Clinical Program for Trappsol® Cyclo™ as a potential treatment for NPC1. In 2016, Cyclo filed an Investigational New Drug application ("IND") with the FDA, which described its Phase I clinical plans for a randomized, double blind, parallel group study at a single clinical site in the U.S. The Phase I study evaluated the safety and pharmacokinetics of CS Pharma Holdings, LLC ("CS Pharma"), Trappsol® Cyclo™ along with markers of cholesterol metabolism and markers of NPC1 during a non-operating entity that owns equity interests 12-week treatment period of intravenous administration of Trappsol® Cyclo™ every two weeks to participants 18 years of age and older. FDA authorized the IND to move forward in Cornerstone, including 44.0 million shares September 2016, and in January 2017 the FDA granted Fast Track designation to Trappsol® Cyclo™ for the potential treatment of Cornerstone Series D Convertible Preferred Stock NPC1. Initial patient enrollment in the U.S. Phase I study commenced in September 2017, and, 979,617 common shares. Accordingly, the Company holds an effective 90% interest in its Cornerstone interests held by Pharma Holdings directly and an effective 45% indirect interest May 2020, Cyclo announced Top Line data showing Trappsol® Cyclo™ was well tolerated in its interest held by CS Pharma. this study.

Cornerstone is Cyclo has also completed a Phase I/II clinical study authorized by European regulatory bodies with clinical trial centers in the process United Kingdom, Sweden, and in Israel. The Phase I/II study evaluated the safety, tolerability and efficacy of Trappsol® Cyclo™ through a comprehensive restructuring transaction range of clinical outcomes, including neurologic, respiratory, and measurements of cholesterol metabolism and markers of NPC1. Consistent with the conversion 12-week phase 1 study (single US site), the European/Israel study administered Trappsol® Cyclo™ intravenously to NPC1 patients every two weeks in a double-blind, randomized trial, but differs in that the study period was for 48 weeks (24 doses). In March of 2021, Cyclo announced that 100% of patients who completed the trial (9 out of 12) improved or remained stable, and 89% met the efficacy outcome measure of improvement in at least two domains of the debt under 17-domain NPC1 severity scale. Cyclo did not conduct a line Phase II trial in the U.S. they relied on the data obtained from our Phase I/II trial abroad to support the commencement of credit agreement and the promissory note held by the Company, the conversion and modification of other Cornerstone debt obligations, the extension of the Cornerstone debt held by RP Finance, a reverse stock split, the conversion of all outstanding preferred stock of Cornerstone into common stock and the adoption of certain governance measures. This transaction is subject to a number of conditions which are beyond the Company's control. our Phase III trial.

Science In February 2020, Cyclo had a face-to-face "Type C" meeting with the FDA with respect to the initiation of a pivotal Phase III clinical trial of Trappsol® Cyclo™ based on the clinical data obtained to date. At that meeting, Cyclo also discussed with the FDA submitting a New Drug Application ("NDA") under Section 505(b)(1) of the Federal Food, Drug, and Preclinical:

CPI-613® (devimistat) is Cosmetic Act for the treatment of NPC1 in pediatric and adult patients with Trappsol® Cyclo™. A similar request was submitted to the European Medicines Agency ("EMA") in February 2020, seeking scientific advice and protocol assistance from the EMA for proceeding with a stable analog Phase III clinical trial in Europe. In October 2020, Cyclo received a "Study May Proceed" notification from the FDA with respect to the proposed Phase III clinical trial, and in June of normally transient, acylated catalytic intermediates 2021, Cyclo commenced enrollment in TransportNPC, a pivotal Phase III study of lipoate. The CPI-613® intermediates are designed to disrupt mitochondrial function and thereby decrease Trappsol® Cyclo™ for the TCA cycle function; thus, CPI-613® (devimistat) misinforms these tumor systems, triggering mitochondrial stress and turning off treatment of NPC1. In May 2024, Cyclo enrolled the cancer cell TCA cycle. CPI-613® is designed to broadly affect tumor metabolism, including disrupting mitochondria and potentially intercalating in cancer cell membranes. The metabolic and mitochondrial stress have been found to trigger apoptotic and necrotic cell death pathways in tumor cells (Zachar et al., J Mol Med, 2011, 89:1137-48; Stuart et al., Cancer Metab. 2014, 2, 4: reviewed in Bingham et al., Expert Rev Clin Pharmacol. 2014, 7:837-46 and Hammoudi et al., Chin J Cancer. 2011, ;30:508-25). Therefore CPI-613® is believed to have anti-cancer activity. Combining CPI-613® with generalized metabolic stressors like chemotherapy holds last of the potential to result 104 patients in the effective killing of even the most intractable tumors like pancreatic cancer. These effects were observed in Cornerstone Pharmaceuticals' Phase 1/2 trials to date (Alistar, et al., 2017; Pardee et al., 2018). CPI-613® has been found to be selectively accumulated in tumors in animal studies. CPI-613 is a lipoic acid analog with a fatty acid tail that may be able to utilize fatty acid transporters. Cancer cells have been shown to up-regulate fatty acid metabolism to support tumorigenesis. Cornerstone continues to study devimistat and its potential mechanism of action.

There are potential advantages of CPI-613® (devimistat) over alternative anti-metabolism and anti-cancer drugs. It is believed to be selectively taken up by cancer cells. Therefore, CPI-613® (devimistat) is anticipated to be minimally toxic to healthy cells (i.e., safe, and well tolerated), potentially allowing extended treatment courses. Moreover, its toxicity profile may allow CPI-613® (devimistat) to be used in combination with other drugs and in older patients. These potential combination regimens include established standards of care for major malignancies, allowing potential treatment of surgically unresectable cancers. Additionally, this toxicity profile could support the administration of

cocktails of anti-cancer drugs that may work synergistically with CPI-613®. Thus, CPI-613® (devimistat) is being investigated for broad-spectrum activity, and the potential to treat diverse tumor types, including difficult-to-treat cancers, high-risk cancers, solid tumors as well as hematologic malignancies and advanced-stage cancers by targeting cancer metabolism.

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

Clinical Highlights:On May 17, 2010, the FDA designated Trappsol® Cyclo™ as an orphan drug for the treatment of NPC1, which, if Trappsol® Cyclo™ were to be approved for that orphan-designated indication, would provide Cyclo with the exclusive right to sell Trappsol® Cyclo™ for the treatment of NPC1 for seven years following FDA drug approval. In April 2015, Cyclo also obtained Orphan Drug Designation for Trappsol® Cyclo™ in Europe, which will provide Cyclo with 10 years of market exclusivity in Europe following regulatory approval, which period will be extended to 12 years upon acceptance by the EMA's Pediatric Committee of Cyclo's pediatric investigation plan (PIP) demonstrating that Trappsol® Cyclo™ addresses the pediatric population. On January 12, 2017, Cyclo received Fast Track Designation from the FDA, and on December 1, 2017, the FDA designated NPC1 a Rare Pediatric Disease.

More than 890 patients have been dosed with CPI-613® (devimistat) Cyclo also continues to date operate its legacy fine chemical business, consisting of the sale of cyclodextrins and related products to the pharmaceutical, nutritional, and other industries, primarily for use in 24 ongoing or completed clinical trials. diagnostics and specialty drugs.

In Cyclo's core business has transitioned to a phase IB/II study biotechnology company primarily focused on the development of gemcitabine and cisplatin with or without CPI-613® (devimistat) as first-line therapy cyclodextrin-based biopharmaceuticals for patients with advanced biliary tract cancer (BilT-04), in phase 1B portion, the objective response rate is 45% (1 complete response and 8 partial responses). Median progression-free survival is 10.0 months. potential treatment of disease.

Currently, 4***Global Phase III Clinical Study (TransportNPC)***

Cyclo's ongoing Phase III clinical trials trial (CTD-TCNPC-301), TransportNPC, is a prospective, randomized, double-blind, placebo controlled therapeutic study for up to 93 patients age three and older with confirmed diagnosis of NPC1. The objective of this study is to evaluate the safety, tolerability and efficacy of 2000 mg/kg doses of Trappsol® Cyclo™ (hydroxypropyl betacyclodextrin) administered intravenously by slow infusion every two weeks as compared to placebo. Patients will be randomized to receive Trappsol® Cyclo™ or placebo at a 2:1 ratio. The study duration is 96 weeks, with an unblinded interim analysis at 48 weeks. An open-label extension of up to 96 weeks follows the interventional study. Patients whose disease progression worsens by two levels in the Clinical Global Impression of Severity scale over 12 weeks, starting at week 36, may be moved to open label treatment. Efficacy will be measured at week 48 and week 96 by a composite score of major disease features. A sub-study is ongoing and being conducted outside of the U.S. for up to 12 patients age 0 - 3 years who may be asymptomatic. Outcomes for the sub-study are enrolling participants: safety, clinical and caregiver impression of disease. In May 2024, Cyclo enrolled the last of the 104 patients in the Phase III study. Interim results from the study are expected during the first half of 2025.

European and Israeli Phase I/II Clinical Study

Cyclo completed a Phase I/II clinical study in Europe, the United Kingdom and Sweden. This study evaluated the safety, tolerability and efficacy of Trappsol® Cyclo™ through a range of clinical outcomes, including neurologic, and respiratory, in addition to measurements of cholesterol metabolism and markers of NPC1, in three dose groups (1500 mg/kg, 2000 mg/kg and 2500 mg/kg). The first patient was dosed in this study in July 2017, and in February 2020, Cyclo announced completion of enrollment of 12 patients in this study. The efficacy outcome measures and results from this study are as follows:

Efficacy Outcome Measure 1: At least a one-point reduction (or improvement) in two or more of the 17 domains measured under the Niemann-Pick Disease Type C ("NPC") Clinical Severity Scale.

Results:

- Six of seven patients met this endpoint (86% of those who completed).
- Improvements seen in swallow, ambulation, ability to manage seizures, saccadic eye movements, fine motor skills, and cognition. (Individual patient profiles differed, i.e., patients improved differently.)
- Patients not receiving any intervention beyond standard of care would be expected to worsen in total score by 1.5 points over one year.

Efficacy Outcome Measure 2: Change from baseline in "Global Impression of Disease" at 48 weeks.

Results:

- Using the Clinician's Global Impression of Improvement scale, five of seven patients who completed the trial improved, and the other 2 patients stabilized**.**
- *Five of seven improved in at least one of these features: walking, speaking, swallowing, fine motor or cognition. These five features are determined by NPC1 patients and their caregivers to be the most important for quality of life. A Multi-Center Randomized composite in improvement in these five features will be the primary outcome measure for our pivotal Phase IB/II Study of Gemcitabine and Cisplatin With or Without CPI-613*III trial.

Additional Data:

- As a group, the first seven patients to complete the clinical trial meet the outcome measures for the study.
- Trappsol® Cyclo™ was well tolerated.
- Trappsol® *as First Line Therapy Cyclo™ was shown to cross the blood brain barrier.*
- Successive administration of Trappsol® Cyclo™ decreased tau levels.
- Trappsol® Cyclo™ was seen to suggest improvements in neurological features of NPC1, including ataxia, and quality of life for Patients With Advanced Unresectable Biliary Tract Cancer (BilT-04) patients.
- Based on data provided, Cyclo selected the 2000 mg/kg dose for its pivotal Phase III trial.

US Phase I Clinical Study

In September 2016, the FDA authorized Cyclo to proceed with Cyclo's Phase I clinical plans for a randomized, double blind, parallel group study in the U.S. The Phase I study evaluated the safety of Trappsol® Cyclo™ along with markers of cholesterol metabolism and markers of NPC1 during a 14-week treatment period of intravenous administration of Trappsol® Cyclo™ every two weeks to participants 18 years of age and older in two dose groups (1500 mg/kg and 2500 mg/kg). Enrollment in this study was completed in October 2019, and in May 2020 Cyclo announced Top Line data showing favorable tolerability profile for Trappsol® Cyclo™ in this study. Additional date from this study includes the following data:

- Liver biopsies and biochemical data on cholesterol homeostasis indicated that Trappsol® Cyclo™ removes trapped cholesterol from liver cells and impacts cholesterol homeostasis.
- *Pilot Study Tau decreased after seven doses in a majority of CPI-613®, in Combination With Bendamustine, in Patients With Relapsed or Refractory T-Cell Non-Hodgkin Lymphoma*patients.
- *A Phase I Dose-Escalation Study All eligible patients requested continuation of CPI-613*Trappsol® *Cyclo™ administration in Combination With Chemoradiation in Patients With Pancreatic Adenocarcinoma*the extension protocol via home infusion.
- *Phase II Open-Label Multi-Cohort Study Evaluating CPI-613® in Combination With Hydroxychloroquine and 5-fluorouracil or Gemcitabine in Patients With Advanced Chemorefractory Colorectal, Pancreatic, or Other Solid Cancers*

Cornerstone is also contemplating additional clinical trials for devimistat in combination with other compounds for different indications.

In March 2023, Cornerstone purchased all assets and rights of telaglenastat (CB-839), a glutaminase inhibitor, from Calithera Biosciences, Inc. Cornerstone is currently exploring the options to develop telaglenastat in different oncology indications.

Barer

In 2019, the Company established Barer, as an early-stage small molecule research operation focused on developing a pipeline of novel therapeutic targets. The Barer programs are largely focused on new approaches to treat oncology including the regulation of cancer metabolism, synthetic lethal pathways, T-cell nutrients, and autoimmunity. Barer pursued collaborative research agreements and in-licensing opportunities with leading scientists from top academic institutions. Farber, a majority owned subsidiary of Barer, was formed around one such agreement with Princeton University's Office of Technology Licensing for technology from the laboratory of Professor Joshua Rabinowitz, in the Department of Chemistry, Princeton University, for an exclusive worldwide license to its SHMT (serine hydroxymethyltransferase) inhibitor program. In November 2022, the Company resolved to curtail its early-stage development efforts, including pre-clinical research at Barer.

LipoMedix

LipoMedix is a clinical stage Israeli company focused on the development of a product candidate that holds the potential to be an innovative, safe, and effective cancer therapy based on liposome delivery. As of July 31, 2022 July 31, 2024, the Company's ownership interest in LipoMedix was approximately 95%. As needed, the Company provides funding to LipoMedix through intercompany promissory notes which are used to support research and development activities.

About Promitil® Promitil®:

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

Promitil® Promitil® is designed for the targeted delivery of MMC in a proprietary prodrug form. Promitil® Promitil® confers tumor targeting advantage due to the enhanced permeability and retention effect (EPR) of liposomes. Once in the tumor cells, the prodrug is converted to the active drug (MMC) by thiolytic agents abundantly present in tumor tissues, and MMC induces DNA cross-linking leading to tumor cell death. In preclinical studies, Promitil® Promitil® inhibited cancer cells growth in animal models (pancreatic, colorectal, stomach, breast, ovarian, melanoma, bladder), including multidrug resistant tumors, as monotherapy as well as in combination with radiotherapy and/or approved cancer drugs. In these studies, Promitil® Promitil® was found to be more efficacious and less toxic than MMC by a 3-fold factor.

LipoMedix has completed 3 clinical studies with Promitil® Promitil® including:

1. ● Phase 1A, a dose escalation study of Promitil in patients with advanced cancers. (Golan et al., "Pegylated T, Grenader T, Ohana P, Amitay Y, Shmeeda H, La-Beck NM, Tahover E, Berger R, Gabizon A. Pegylated liposomal mitomycin C prodrug enhances tolerance of mitomycin C: a Phase phase 1 study in advanced solid tumor patients." *Cancer Medicine*, 4:1472–1483, 2015). Medicine. 2015;4(10):1472-83.)

2. ● Phase IB in advanced colorectal cancer patients with Promitil as single agent and in combination with capecitabine and/or bevacizumab. (Gabizon et al, "Pharmacokinetics A, Tahover E, Golan T, Geva R, Perets R, Amitay Y, Shmeeda H, Ohana P. Pharmacokinetics of mitomycin-c lipidic prodrug entrapped in liposomes and clinical correlations in metastatic colorectal cancer patients" *Investigational patients. Invest New Drugs*, Drugs. 2020;38(5):1411-1420, 2020). 1411-1420.)

3. ● Phase 1B of Promitil-based chemo-radiotherapy in patients with advanced cancers. These study results have been presented at the ESTRO-2022 meeting (Sapir E, Pffefer R, Wygoda M, Purim O, Levy A, Corn B, Amitay Y, Ohana P, Gabizon A. Pegylated Liposomal Mitomycin C Lipidic Prodrug in poster form. Combination with External Beam Radiation Therapy in Patients with Advanced Cancer: A Phase 1 Study. Int J Radiat Oncol. 2023; Volume 2023.)

Over 100 120 patients were treated with Promitil® Promitil® as a single agent or in combination with other anticancer drugs or radiotherapy in three clinical studies under a United States IND to assess the safety, PK profile, and preliminary efficacy, as well as 40 patients treated as named-patient for compassionate use. Promitil® Promitil® was given by intravenous infusion once every 3 or 4 weeks and appears to be well-tolerated at a dose up to 2 mg/kg. Except for mild myelosuppression, no other toxicities such as skin irritation, mouth ulcers, neuropathic pain, diarrhea, or hair loss were reported. Promitil® Promitil® was stable in plasma with a half-life of approximately 20 hours (vs 40-50 minutes for naked MMC).

Next Steps for Clinical Development:

Homologous recombination (HR) is an evolutionarily conserved process for repairing DNA double-strand breaks with high fidelity, and the BRCA1 and BRCA2 proteins play essential roles in this process. Patients harboring germline mutations in the BRCA1 and/or BRCA2 genes have significantly increased life-time risk of developing breast, ovarian cancer, pancreatic, and prostate cancer. Tumors with BRCA mutations are susceptible to platinum-based chemotherapy and hypersensitive to agents that inhibit poly(ADP-ribose) polymerase (PARP). However, despite their initial anti-tumor activity, multiple resistance mechanisms have been described and the development of resistance limits the clinical utility of platinum based and PARP inhibitor (PARPi) therapies. Overall, it remains a challenge in treating cancers associated with deleterious germline mutation in HR, such as BRCA1, BRCA2, and PALB2 (Partner and Localizer of BRCA2).

Preclinical studies have shown that MMC was effective in killing of BRCA2 mutant tumors. Clinical efficacy of MMC has also been reported in heavily pretreated ovarian cancer patients with BRCA1 mutations and patient with advanced, gemcitabine-resistant, pancreatic cancer who had PALB2 gene mutation. Pancreatic ductal adenocarcinoma (PDAC) continues to be one of the most lethal malignant neoplasms, with a 5-year survival rate of only 5%. Surgery is considered the sole potentially curative treatment; however, only 20% of patients diagnosed with PDAC are candidates for surgery at the time of diagnosis and is frequently followed by recurrence and therapeutic resistance. Despite advances made in the development of systemic combination chemotherapies in the last two decades, progress in improving survival outcomes in patients with PDAC is stagnant.

Based on the reported preclinical and clinical efficacy of MMC in BRCA mutated tumors together with the demonstrated improved safety profile of Promitil Promitil® in humans, LipoMedix believes that Promitil Promitil® could offer an important therapeutic option for patients with pancreatic cancer. Thus, a clinical trial is planned ongoing to evaluate the safety, tolerability, and effects of Promitil Promitil® in cancer patients who have deleterious germline mutation in BRCA1, BRCA2, or PALB2. PALB2 across six hospitals in Israel.

Promitil® Promitil®-based pipeline products:

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

- Folate-targeted Promitil® Promitil® (Promi-Fol), aimed at local treatment (intravesical) of superficial bladder cancer. Decorating Promitil Promitil® with folate ligands is designed to exploit the frequent overexpression of folate receptors in urothelial cancers for selective and enhanced delivery of Promitil® Promitil® to cancer cells. Promi-Fol holds the potential to be a safe and effective therapeutic alternative to widely used instillation of mitomycin-c for local treatment of the growing elderly patient population with superficial bladder cancer (Patil Y, et al.: “Targeting of pegylated liposomal mitomycin-C prodrug to the folate receptor of cancer cells: Intracellular activation and enhanced cytotoxicity.” Journal of Controlled Release, 225:87-95, 2016). A patent application to cover the use of Promi-Fol was granted in May 2020 by the European Patent Office.

- Promi-Dox, a highly potent dual drug liposome with MLP and doxorubicin targeting a potential basket of tumors (Gabizon et al., “Liposome co-encapsulation of anti-cancer agents for pharmacological optimization of nanomedicine-based combination chemotherapy.” Cancer Drug Resistance, 4:463-484, 2021). There are several possible cancer settings with substantial patient numbers and significant unmet need where Promi-Dox potentially could be utilized. This formulation requires further product development. A patent application covering the formulation of Promi-Dox has been granted by the USPTO.

Cyclo Therapeutics Inc. ***Farber***

Cyclo is Farber, a clinical stage biotechnology company that develops cyclodextrin-based products majority owned subsidiary of Barer, was formed around an agreement with Princeton University's Office of Technology Licensing for technology from the treatment laboratory of neurodegenerative diseases. Cyclo filed a Type II Drug Master File with the U.S. Food and Drug Administration ("FDA") in 2014 for its lead drug candidate, Trappsol® Cyclo™ (hydroxypropyl beta cyclodextrin) as a treatment for Niemann-Pick Type C disease ("NPC"). NPC is a rare and fatal autosomal recessive genetic disease resulting in disrupted cholesterol metabolism that impacts the brain, lungs, liver, spleen, and other organs. In 2015, Cyclo launched an International Clinical Program for Trappsol® Cyclo™ as a treatment for NPC. In 2016, Cyclo filed an Investigational New Drug application ("IND") with the FDA, which described its Phase I clinical plans for a randomized, double blind, parallel group study at a single clinical site Professor Joshua Rabinowitz, in the U.S. The Phase I study evaluated Department of Chemistry, Princeton University, for an exclusive worldwide license to its SHMT (serine hydroxymethyltransferase) inhibitor program. In November 2022, the safety Company resolved to curtail its early-stage development efforts, including pre-clinical research at Barer and pharmacokinetics Farber. Since then, the Company has sought partners for Farber programs and has entered into a license agreement for one of Trappsol® Cyclo™ along with markers of cholesterol metabolism and markers of NPC during a 12-week treatment period of intravenous administration of Trappsol® Cyclo™ every two weeks to participants 18 years of age and older. The IND was approved by the FDA in September 2016, and in January 2017 the FDA granted Fast Track designation to Trappsol® Cyclo™ for the treatment of NPC. Initial patient enrollment in the U.S. Phase I study commenced in September 2017, and in May 2020, Cyclo announced Top Line data showing a favorable safety and tolerability profile for Trappsol® Cyclo™ in this study. its technologies.

Cyclo has also completed a Phase I/II clinical study approved by European regulatory bodies with clinical trial centers in the United Kingdom, Sweden, and in Israel. The Phase I/II study evaluated the safety, tolerability and efficacy of Trappsol® Cyclo™ through a range of clinical outcomes, including neurologic, respiratory, and measurements of cholesterol metabolism and markers of NPC. Consistent with the 12-week phase 1 study (single US site), the European/Israel study administered Trappsol® Cyclo™ intravenously to NPC patients every two weeks in a double-blind, randomized trial, but differs in that the study period was for 48 weeks (24 doses). In March of 2021, Cyclo announced that 100% of patients who completed the trial (9 out of 12) improved or remained stable, and 89% met the efficacy outcome measure of improvement in at least two domains of the 17-domain NPC severity scale.***Cornerstone***

Additionally, We own our interest in February 2020, Cyclo had Cornerstone through a face-to-face "Type C" meeting with 90%-owned non-operating subsidiary, Pharma Holdings, LLC ("Pharma Holdings"). Pharma Holdings owns 50% of CS Pharma, a non-operating entity that owns equity interests in Cornerstone, including 44.0 million shares of Cornerstone common stock. Accordingly, the FDA with respect to Company holds an effective 90% interest in the initiation of a pivotal Phase III clinical trial of Trappsol® Cyclo™ based on Cornerstone interests held by Pharma Holdings, and an effective 45% interest in the clinical data obtained to date. At that meeting, Cyclo also discussed with the FDA submitting a New Drug Application (NDA) under Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for the treatment of NPC in pediatric and adult patients with Trappsol® Cyclo™. A similar request was submitted to the European Medicines Agency ("EMA") in February 2020, seeking scientific advice and protocol assistance from the EMA for proceeding with a Phase III clinical trial in Europe. In October 2020, Cyclo received a "Study May Proceed" notification from the FDA with respect to the proposed Phase III clinical trial, and in June of 2021, Cyclo commenced enrollment in TransportNPC, a pivotal Phase III study of Trappsol® Cyclo™ for the treatment of NPC. Cornerstone interests held by CS Pharma.

Preliminary data from their In March of 2024, Cornerstone completed clinical studies suggest that Trappsol® Cyclo™ clears toxic deposits of cholesterol and other lipids from cells, has a consistent pharmacokinetic profile peripherally, and crosses comprehensive restructuring transaction including, the blood-brain-barrier in individuals suffering from NPC, and results in neurological and neurocognitive benefits and other clinical improvements in NPC patients. The full significance of these findings will be determined as part conversion of the final analysis debt under a line of data derived from our clinical trials (both completed credit agreement and ongoing). the promissory note held by the Company, the conversion and modification of other Cornerstone debt obligations, the extension of the Cornerstone debt held by RP Finance, a reverse stock split, the conversion of all outstanding preferred stock of Cornerstone into common stock and the adoption of certain governance measures. Subsequent to the restructuring the Company owns 67% of Cornerstone.

On May 17, 2010, the FDA designated Trappsol® Cyclo™ as an orphan drug for the treatment of NPC, which would provide Cyclo with the exclusive right to sell Trappsol® Cyclo™ for the treatment of NPC for seven years following FDA drug approval. In April 2015, Cyclo also obtained Orphan Drug Designation for Trappsol® Cyclo™ in Europe, which will provide Cyclo with 10 years of market exclusivity following regulatory approval, which period will be extended to 12 years upon acceptance by the EMA's Pediatric Committee of our pediatric investigation plan (PIP) demonstrating that Trappsol® Cyclo™ addresses the pediatric population. On January 12, 2017, Cyclo received Fast Track Designation from the FDA,Science and on December 1, 2017, the FDA designated NPC a Rare Pediatric Disease. Preclinical:

Cyclo also continues Cornerstone's lead development candidate is CPI-613® (devimistat), a stable analog of normally transient, acylated catalytic intermediates of lipoate. The CPI-613® intermediates are designed to operate its legacy fine chemical business, consisting disrupt mitochondrial function and thereby decrease the TCA cycle function; thus, CPI-613® (devimistat) misinforms these tumor systems, triggering mitochondrial stress and turning off the cancer cell TCA cycle. CPI-613® is designed to broadly affect tumor metabolism, including disrupting mitochondria and potentially intercalating in cancer cell membranes. The metabolic and mitochondrial stress have been found to trigger apoptotic and necrotic cell death pathways in tumor cells (Zachar et al., J Mol Med, 2011, 89:1137-48; Stuart et al., Cancer Metab. 2014, 2, 4: reviewed in Bingham et al., Expert Rev Clin Pharmacol. 2014, 7:837-46 and Hammoudi et al., Chin J Cancer. 2011, ;30:508-25). These suggest that CPI-613® holds the potential to have anti-cancer activity. Combining CPI-613® with generalized metabolic stressors like chemotherapy holds the potential to result in the effective killing of even the sale of cyclodextrins and related products most intractable tumors like pancreatic cancer. These effects were observed in Cornerstone's Phase 1/2 trials to the pharmaceutical, nutritional, and other industries, primarily for use date (Alistar, et al., 2017; Pardee et al., 2018). CPI-613® has been found to be selectively accumulated in diagnostics and specialty drugs. tumors in animal studies. CPI-613 is a lipoic acid analog with a fatty acid tail that may be able to utilize fatty acid transporters. Cancer cells have been shown to up-regulate fatty acid metabolism to support tumorigenesis.

Cyclo's core business has transitioned There may be potential advantages of CPI-613® (devimistat) over alternative anti-metabolism and anti-cancer drugs. It is believed to be selectively taken up by cancer cells. As a biotechnology company primarily focused on result, CPI-613® (devimistat) holds the development potential to be minimally toxic to healthy cells (i.e., safe, and well tolerated), potentially allowing extended treatment courses. Moreover, its toxicity profile may allow CPI-613® (devimistat) to be used in combination with other drugs and in older patients. These potential combination regimens include established standards of cyclodextrin-based biopharmaceuticals care for the major malignancies, allowing potential treatment of disease. surgically unresectable cancers. Additionally, this toxicity profile could support the administration of cocktails of anti-cancer drugs that may work synergistically with CPI-613®.

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

Clinical Highlights:

More than 1024 patients have been dosed with CPI-613® (devimistat) to date in 24 ongoing or completed clinical trials.
Currently, there are two clinical trials enrolling participants in the following programs:

- Phase II open-label multi-cohort study evaluating CPI-613® (devimistat) in combination with hydroxychloroquine and 5-fluorouracil or gemcitabine in patients with advanced chemorefractory colorectal, pancreatic, or other solid cancers.
- A Phase I dose-escalation study of CPI-613® (devimistat) in combination with chemoradiation in patients with pancreatic adenocarcinoma.

In March 2023, Cornerstone purchased all assets and rights of telaglenastat (CB-839), a glutaminase inhibitor, from Calithera Biosciences, Inc. Cornerstone is currently exploring the options to develop telaglenastat in different indications.

Global Phase III Clinical Study (TransportNPC) Rafael Medical Devices

Cyclo's ongoing Phase III clinical trial (CTD-TCNPC-301), TransportNPC, Rafael Medical Devices is a prospective, randomized, double-blind, placebo controlled therapeutic study for up medical device company currently concentrating on developing surgical and procedural devices designed to 93 provide meaningful advantages to patients age three and older with confirmed diagnosis of NPC1. The objective of this study is to evaluate the safety, tolerability and efficacy of 2000 mg/kg doses of Trappsol® Cyclo™ (hydroxypropyl betacyclodextrin) administered intravenously by slow infusion every two weeks as compared to placebo. Patients will be randomized to receive Trappsol® Cyclo™ or placebo at a 2:1 ratio. The study duration is 96 weeks, with an unblinded interim analysis at 48 weeks. An open-label extension of up to 96 weeks follows the interventional study. Patients whose disease progression worsens by two levels healthcare providers in the Clinical Global Impression orthopedic market. One of Severity scale over 12 weeks, starting at week 36, may be moved to open label treatment. Efficacy will be measured at week 48 and week 96 by a composite score of major disease features. A sub-study its current lead products is ongoing and being conducted outside of the U.S. an orthopedic arthroscopy instrument for up to 12 patients age 0 - 3 years who may be asymptomatic. Outcomes for the sub-study are safety, clinical and caregiver impression of disease. carpal tunnel syndrome.

European Rafael Medical Devices has assembled an in-house team with expertise in engineering, device development quality control, and Israeli Phase I/II Clinical Study

Cyclo completed design discovery who have been part of teams that have created successful commercial medical devices in the past. It has begun to expand its expert network of experienced device creators, key opinion leaders, and is working to begin generating a Phase I/II clinical study in Europe, the United Kingdom and Sweden. This study evaluated the safety, tolerability and efficacy of Trappsol® Cyclo™ through a range of clinical outcomes, including neurologic, and respiratory, in addition to measurements of cholesterol metabolism and markers of NPC, in three dose groups (1500 mg/kg, 2000 mg/kg and 2500 mg/kg). The first patient was dosed in this study in July 2017, and in February 2020, Cyclo announced completion of enrollment of 12 patients in this study. The efficacy outcome measures and results from this study are as follows: commercial presence.

Efficacy Outcome Measure 1: At least Orthopedics comprise a one-point reduction (or improvement) in two or more large addressable market. Rafael Medical Devices is seeking to assemble a portfolio of the 17 domains measured under the NPC Clinical Severity Scale.
Results:

- Six of seven patients met this endpoint (86% of those who completed).
- Improvements seen in swallow, ambulation, ability to manage seizures, saccadic eye movements, fine motor skills, and cognition. (Individual patient profiles differed, i.e. patients improved differently.)
- Patients not receiving any intervention beyond standard of care would be expected to worsen in total score by 1.5 points over one year.

Efficacy Outcome Measure 2: Change from baseline in "Global Impression Class I, II and III devices to mitigate risk across a portfolio of Disease" at 48 weeks.
Results:

- Using the Clinician's Global Impression of Improvement scale, five of seven patients who completed the trial improved, and the other 2 patients stabilized.
- five of seven improved in at least one of these features: walking, speaking, swallowing, fine motor and cognition. These five features are determined by NPC patients and their caregivers to be the most important for quality of life. A composite in improvement in these five features will be the primary outcome measure for our pivotal Phase III trial.

Additional Data:

- As a group, the first seven patients to complete the clinical trial meet both efficacy outcome measures for the study.
- Individual patients showed improvements in all dose groups.
- Trappsol® Cyclo™ demonstrated a highly favorable safety profile.
- Trappsol® Cyclo™ was shown to cross the blood brain barrier.
- Successive administration of Trappsol® Cyclo™ decreased tau levels, suggesting neuroprotective benefit.
- Trappsol® Cyclo™ improves neurological features of NPC, including ataxia, and quality of life for patients.
- Based on data provided, Cyclo selected the 2000 mg/kg dose for its pivotal Phase III trial.

US Phase I Clinical Study

In September 2016, the FDA approved Cyclo's Phase I clinical plans for a randomized, double blind, parallel group study in the U.S. The Phase I study evaluated the safety of Trappsol® Cyclo™ along devices with markers of cholesterol metabolism overlapping needs and markers of NPC during a 14-week treatment period of intravenous administration of Trappsol® Cyclo™ every two weeks markets. This strategy is designed to participants 18 years of age and older in two dose groups (1500 mg/kg and 2500 mg/kg). Enrollment in this study was completed in October 2019, and in May 2020 Cyclo announced Top Line data showing a favorable safety and tolerability profile for Trappsol® Cyclo™ in this study. Additional date from this study includes the following data: minimize supply chain requirements while maximizing market potential.

- Liver biopsies and biochemical data on cholesterol homeostasis demonstrated that Trappsol® Cyclo™ removes trapped cholesterol from liver cells and impacts cholesterol homeostasis.
- Tau decreased after seven doses in a majority of patients, suggesting that IV administration of Trappsol® Cyclo™ is preventing neurodegeneration in NPC patients.
- Efficacy signals from Trappsol® Cyclo™ include neurological improvements, higher energy, and greater focus exhibited by the patient.
- All eligible patients requested continuation of Trappsol® Cyclo™ administration in the extension protocol via home infusion.
- In January 2021, Cyclo reported positive efficacy data on all eight patients participating in the protocol.

Day Three Labs

Day Three Labs is a technology company focused on creating solutions for increased bioavailability of other third-party manufacturers' hydrophobic compounds, with a specific focus on compounds used as active ingredients in pharmaceutical and food supplement products. Day Three Labs maintains its manufacturing, sales and marketing activities in the United States, and research and development activities in Israel. Day Three Labs' majority-owned subsidiary, Day Three Labs Manufacturing, is dedicated to the commercialization of technology in for the cannabis and hemp industries and has developed technological solutions specifically engineered for increased bioavailability of cannabinoids. cannabinoids, and Day Three Labs delivers those technologies as a processing service to other third-party manufacturers.

The Day Three Labs team, as well as that of its subsidiary Day Three Labs Manufacturing, has expertise in drug development, consumer product manufacturing and distribution, and product engineering, including pharmaceutical and food technology development. Day Three Labs as a group is positioning itself to target large addressable markets in the food supplement and pharmaceutical spaces, focusing its research and development on active ingredients with maximum addressable scope.

Research and Development

Spade Therapeutics, a wholly owned subsidiary of Day Three Labs Manufacturing, is responsible for leading Research and Development of all Day Three Labs projects. Currently, Spade Therapeutics is investigating potential use of the technology to improve upon other third parties' FDA approved cannabinoid-based pharmaceuticals. Spade is also investigating potential uses of the technology for molecules of other, non-hydrophobic molecules.

Rafael Medical Devices

Rafael Medical Devices is an orthopedic-focused medical device company currently concentrating on developing surgical and procedural devices designed to provide meaningful advantages to patients and healthcare providers. One of its current lead products is an orthopedic arthroscopy instrumentation.

Rafael Medical Devices has assembled an in-house team with expertise in engineering, quality, design discovery, and device development who have created successful commercial medical devices in the past. It has begun to expand its expert network of experienced device creators, key opinion leaders, and hoped to begin generating a commercial presence.

Orthopedics comprise a large addressable market. Rafael Medical Devices is seeking to assemble a portfolio of Class I, II and III devices to mitigate risk across a portfolio of devices with overlapping needs and markets. This strategy is designed to minimize supply chain requirements while maximizing market potential.

OUR STRATEGY

We are a company with interests in clinical and early-stage Investment Portfolio Companies, through our investment interests in Cornerstone Pharmaceuticals, Cyclo Therapeutics, our majority equity interest in LipoMedix, wholly-owned Barer, Institute, majority interests in Cyclo Therapeutics Rafael Medical Devices and Day Three Labs, and a majority interest in Rafael Medical Devices. Cornerstone. Historically, our focus was on investing in and funding entities to discover and develop novel cancer therapies. More recently, we have expanded our focus to opportunities in the pharmaceutical industry not exclusively focused on cancer therapies, other healthcare-related investments and opportunities outside of biopharma.

The focus of our efforts is subject to change with market conditions, results of our internal development efforts, the availability of investment opportunities on acceptable terms, the investment and acquisition opportunities we may pursue, and developments at those targets. More recently, we have expanded our focus to opportunities in the pharmaceutical industry not exclusively focused on cancer therapies, other healthcare-related investments and opportunities outside of biopharma.

Our goal within biopharma is to expand our portfolio and develop and bring to market therapeutics which address high unmet medical needs, opportunistic investments, acquisitions and in-licensing of assets.

We plan to continue to selectively invest in pre-clinical and clinical stage healthcare opportunities, including those in which we already own interests, when determined to be consistent with our goals, and move toward clinical stage programs as research and development results warrant, while being ready to exploit other opportunities that may arise.

Our internal and external investment decisions will be based on the progress and results of our development and pre-clinical activities and other operational developments, and the availability of targets for investment, acquisition or licensing.

GOVERNMENT REGULATION AND COMPLIANCE

Our operations, products, services, and potential future customers and those of our Portfolio Companies are subject to extensive government regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. The global regulatory environment is increasingly stringent, unpredictable, and complex. There is a global trend toward increased regulatory and enforcement activity related to all medical products.

In the U.S., our product candidates and device candidates are regulated as either drugs or biological products under the Federal Food, Drug and Cosmetic Act, or FFDCA, and the Public Health Service Act, or PHSA, and their implementing regulations, or as medical devices under the FFDCA and its implementing regulations, each as amended and enforced by the FDA. These laws govern the processes by which our product candidates and device candidates would be brought to market. The FDA has enacted extensive regulations that control all aspects of the development, design, performance, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, postmarket surveillance, and import and export of drugs, biological products, and medical devices. In addition, the FDA controls the access of products to market through processes designed to ensure that only products that are safe and effective for their intended use(s) and otherwise meet the applicable requirements of the FFDCA and/or PHSA before they are made available to the public.

Review And Approval Of Drugs In The United States

In the United States, the FDA approves and regulates drugs under the FFDCA, and its implementing regulations. The failure to comply with requirements under the FFDCA 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 compliance 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 Cornerstone's, LipoMedix's, Cyclo Therapeutics', LipoMedix's, Barer's, and Barer's Cornerstone's (collectively referred to as the "Pharmaceutical Companies") current 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 at each site;
- 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;
- submission of pediatric study plans and generation of data, unless inapplicable or otherwise deferred or waived, that are adequate to assess the safety and effectiveness of the drug candidate for the proposed indication(s) in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is determined to be safe and effective;
- 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 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 and packaged 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 GCP 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, or GLP, requirements. 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 FFDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved NDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements to use the study as support for an IND or subsequent application for regulatory 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 study site participating in the clinical trial must review and approve the plan for any clinical trial before it commences at each institution, site, 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 under certain limited circumstances when authorized in advance by FDA:

Phase 1. 1. The drug candidate 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 candidate is administered to a limited number of patients in the target patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for a specific targeted disease, and to determine dosage tolerance and optimal dosage.

Phase 3. 3. These clinical trials are commonly referred to as “pivotal” studies, which denotes a study or studies that present the pivotal data (but not the only data) that the FDA or other relevant regulatory agency will use to determine whether or not to approve a drug. drug candidate. The investigational drug is administered to an expanded number of patients in the target 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 required to be conducted, or a sponsor may decide on its own to conduct them, in order to collect additional data after initial regulatory approval. These studies are used to gain additional experience and additional safety and/or efficacy data from the treatment of patients in the intended therapeutic indication. Following review by FDA, data from Phase 4 studies can result in the suspension of marketing and/or the withdrawal of approval of the drug for safety or effectiveness reasons.

Progress reports detailing the results of the all 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 and packaging 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, the sponsor 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 in that packaging 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. Application, following payment of applicable user fees, if any, under PDUFA, the Prescription Drug User Fee Act. 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 detailed 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 or BLA 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 initially reviews all NDAs and BLAs submitted to identify if there are any deficiencies before it can officially accept the applications for in-depth review, also known as "filing" of the NDA or BLA. The FDA may also request additional information before deciding whether to accept an NDA or BLA for filing. filing, and the applicant generally must submit the requested information before FDA proceeds. Subject to any additional information requests by FDA, this is generally a 60-day filing period. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA.

After the NDA or BLA submission is accepted for filing, the FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality, and purity, and whether the product has appropriate labeling for its proposed intended use. There generally is a two-tiered system of review times – standard review and priority review. review – under the FDA's regulations and PDUFA performance goals and procedures. A priority review designation means FDA's current PDUFA goal is to review and take action on an application 90% of such applications within six months (compared to 10 months under standard review) in addition to the 2-month 60-day filing period. During the approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the drug or biologic following its approval. 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 a REMS is deemed to be required.

Before approving an NDA or BLA, 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 or BLA submission, including drug component manufacturing (e.g., active pharmaceutical ingredients), finished drug product manufacturing, labeling and packaging operations, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and all facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical trial 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 or BLA and accompanying information, including the results of the inspection of the manufacturing facilities and clinical trial sites, 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 a specific indication or indications. indications in accordance with approved labeling. A complete response letter generally outlines the deficiencies in the application and may require the sponsor to undertake substantial additional testing or gather significant additional data and information in order for the FDA to reconsider the application. If a complete response letter is issued, the applicant may either resubmit the application, addressing all of the deficiencies identified in the complete response letter, or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The In its current PDUFA performance goals and procedures, the FDA has committed to reviewing and acting on 90% of such resubmissions in two or six months depending on the type of information included and the FDA's classification of the resubmission. 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 a specific disease(s) and dosage(s) or the indication(s) for use or other product labeling 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 post-approval clinical trials designed to further assess a product's safety and/or effectiveness, and also 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 product candidates 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. Receipt of such a designation does not necessarily mean that a product candidate will receive an expedited approval.

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 non-accelerated approval. If post-marketing clinical studies fail to verify the anticipated 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, continued adherence to cGMP, 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 containing 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 review and 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, packagers or distributors 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 manufacturing or distribution or other restrictions. Other potential consequences include, among other things:

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

The FDA strictly regulates the marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs may be promoted only for the approved indication(s) and in accordance with the provisions of the approved label. labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting false or misleading promotion and the promotion of off-label uses, which require that promotion is truthful, not misleading, fairly balanced and provides adequate directions for use, and that all claims are substantiated, and which also prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling, in accordance with FDA guidance on off-label dissemination of information and responding to unsolicited requests for information. A company that is found to have improperly promoted off-label uses or engaged in any other false or misleading promotion may be subject to significant liability and enforcement actions.

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, and its implementing regulations, which together regulate, among other things, the distribution and tracking 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 and its implementing regulations impose requirements to ensure accountability in distribution and to identify, trace and remove counterfeit and other illegitimate products or harmful drugs from the market.

Abbreviated new drug applications for generic drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FFDCA, 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 FDA’s prior determination of safety and effectiveness based upon 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 FFDCA. 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 finding of safety and effectiveness of the RLD 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 RLD. The FDA may then approve the new product candidate for all, or some, of the label indication(s) for which the RLD has been approved, as well as and/or for any new indication(s) for which approval is 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 candidate for the claimed proposed indication(s) in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is determined to be safe and effective. With enactment in 2012 of the Food and Drug Administration Safety and Innovation Act, or 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 generally do not apply to products with orphan designation. However, in accordance with the FDA Reauthorization Act of 2017, or FDARA, 2017, certain orphan designated cancer drugs are no longer exempt from having to conduct pediatric studies. FDARA requires that any original NDA or BLA submitted on or after August 18, 2020, for a new active ingredient, must contain studies of molecularly targeted pediatric cancers, unless a deferral or a waiver is granted, if the drug that is the subject of the application is intended for the treatment of an adult cancer and directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

Orphan drug designation and exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition, generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product. A company must request orphan drug designation before submitting an NDA or BLA for the drug for the rare disease or condition. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use(s). 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 for a drug, or twelve years of exclusivity for a biologic, during which FDA may not approve the same drug for the same approved orphan indication unless the subsequent product is shown to be clinically superior or if the FDA withdraws exclusive approval or revokes orphan drug designation, or if the marketing application (NDA or BLA) for the orphan drug is withdrawn for any reason, or if the holder of the orphan exclusive approval fails to assure a sufficient quantity of the orphan drug.

Patent term restoration and extension

A patent claiming a new drug product or its method of use or its method of manufacturing 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 process. 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 or BLA, plus the time between the submission date of an NDA or BLA and the ultimate approval date, up to a maximum of five years. 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, or PTO, reviews and approves the application for any patent term extension in consultation with the FDA upon PTO's determination that the requirements for an extension have been met.

FDA approval and regulation of companion diagnostics

If safe and effective use of a therapeutic depends on a diagnostic, a medical device that is often an *in vitro* diagnostic or IVD, 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 candidate IVD companion diagnostic and its corresponding therapeutic should be co-developed and approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product's labeling. In July 2016, the FDA issued a draft guidance detailing general principles to guide co-development of an in vitro companion diagnostic device with a therapeutic product. In April 2020, the FDA issued final guidance intended to facilitate class labeling on diagnostic tests for oncology therapeutic products, where scientifically appropriate.

Review And Approval Or Clearance Of Medical Devices In The United States

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a Premarket Notification, or 510(k), FDA approval of a Premarket Approval, or PMA, application, or FDA marketing authorization in response to a De Novo request. Under the FFDCA, medical devices are classified into one of three classes – Class I, Class II or Class III – depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure the device's safety and effectiveness. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or that use advanced technology which is not substantially equivalent to that of a legally marketed device, are generally placed into Class III.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FFDCA requesting permission to commercially distribute the proposed device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Class III devices require approval of a PMA evidencing safety and effectiveness of the device. Certain novel devices of low to moderate risk, for which the FDA can make a risk-based classification of the device into Class I or II, can receive marketing authorization in response to a De Novo request.

To obtain 510(k) clearance, a manufacturer must pay the appropriate device user fee, unless eligible for a waiver or exemption, and submit a 510(k) premarket notification demonstrating to the FDA's satisfaction that the proposed device is at least as safe and effective as, that is, "substantially equivalent" to, another legally marketed device that itself does not require PMA approval, or a predicate device. A predicate device is a legally marketed device that is not subject to premarket approval, *i.e.*, a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The sponsor must submit data and information that supports its substantial equivalency claims. The FDA's 510(k) clearance process usually takes from three to twelve months, but often takes longer. FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees for medical device establishments.

Before the sponsor can market a new proposed device that is the subject of a 510(k) premarket notification, the sponsor must receive an order from the FDA finding substantial equivalence and clearing the new device for commercial distribution in the US. If the FDA agrees that the device is substantially equivalent to a lawfully marketed predicate device, it will grant 510(k) clearance to authorize the device for commercialization. If the FDA determines that the device is "not substantially equivalent," the device is automatically designated as a Class III device. The device sponsor then must either fulfill the more rigorous PMA requirements, or the sponsor can submit a De Novo request seeking a risk-based classification determination for the device in accordance with the FDA's De Novo classification process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. A sponsor also can submit a De Novo classification request directly, without first submitting a 510(k), if the sponsor determines that there is no legally marketed predicate device upon which to base a determination of substantial equivalence.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or De Novo classification. The FDA requires each manufacturer to determine in the first instance whether the proposed change requires submission of a 510(k), a De Novo classification request or a PMA, but the FDA can review any such decision and disagree with a sponsor's determination. If the FDA disagrees with a manufacturer's determination not to seek a new 510(k) or other form of marketing authorization for a modification to a 510(k)-cleared product, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) clearance or PMA approval is obtained or a De Novo classification is granted.

The PMA process is more demanding than either the 510(k) premarket notification process or the De Novo classification process and includes stringent clinical investigation and other requirements. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations, which govern investigational device labeling, prohibit promotion of investigational devices, and specify an array of recordkeeping, reporting, and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. In addition, the study must be approved in advance by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and the IRB may impose additional requirements for the conduct of the clinical trial. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval authorization from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and adhering to labeling and recordkeeping requirements.

In addition to clinical and preclinical data, the PMA must contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If FDA accepts the PMA for review, FDA has 180 days under the FFDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA generally will conduct a pre-approval inspection of the applicant and/or its third-party manufacturers' or suppliers' facilities to ensure compliance with the FDA's Quality System Regulation codified in 21 CFR Part 820, or QSR.

The FDA will approve the new device for commercial distribution if the FDA determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval. Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement, or in some cases a new PMA.

Both before and after a medical device is commercially released, the sponsor has ongoing responsibilities under the FFDCA and FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, recordkeeping, and manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices. Sponsors are also subject to periodic inspection by the FDA for compliance with the FDA's QSR, among other FDA requirements, such as requirements for advertising and promotion of medical devices. The sponsor's manufacturing operations, and those of any third-party manufacturers, are required to comply with the QSR, which require manufacturers, including third-party manufacturers and suppliers, to follow stringent design, testing, control, maintenance of records and documentation, and other quality assurance procedures during all aspects of the design and manufacturing process both before and after receiving device clearance or approval. The QSR requires that each manufacturer establish a quality system by which the manufacturer monitors the manufacturing process and maintains records that show compliance with the FDA regulations and the manufacturer's written specifications and procedures relating to each device. QSR compliance is necessary to receive and maintain FDA clearance or approval to market new and existing medical devices, and it is also necessary for distributing in the United States certain devices exempt from FDA clearance and approval requirements. The FDA conducts announced and unannounced periodic and ongoing inspections of medical device manufacturers, including third-party manufacturers and suppliers, to determine compliance with the QSR. If in connection with these inspections the FDA believes the manufacturer has failed to comply with applicable regulations and/or procedures, the FDA may issue inspectional observations on Form FDA-483, or Form 483, that would necessitate prompt corrective action. If the FDA inspectional observations are not addressed and/or corrective action is not taken in a timely manner and to the FDA's satisfaction, the FDA may issue a warning letter (which would similarly necessitate prompt corrective action) and/or proceed directly to other forms of enforcement action, including the imposition of operating restrictions, including a ceasing of operations, on one or more facilities, enjoining and restraining certain violations of applicable law pertaining to products, mandating recall of products, seizure of products, and assessing civil or criminal penalties against the manufacturer and its officers and employees. The FDA could also issue a corporate warning letter or a recidivist warning letter or negotiate the entry of a consent decree of permanent injunction with the manufacturer. The FDA may also recommend prosecution to the U.S. Department of Justice, or DOJ. Any adverse regulatory action, depending on its magnitude, may restrict a manufacturer from effectively manufacturing, marketing, and selling any medical device(s) and could have a material adverse effect on the manufacturer's business, financial condition, and results of operations.

After a device is cleared, receives marketing authorization, or is approved for marketing, numerous pervasive regulatory requirements continue to apply unless a device is explicitly exempt from them. These include, among other things:

- establishment registration and device listing with the FDA;
- continued adherence to the QSR requirements;
- marketing, labeling, advertising, and promotion regulations, which require that promotion is truthful, not misleading, fairly balance balanced and provides adequate directions for use, and that all claims are substantiated and in accordance with the provisions of the approved label, and which also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling, in accordance with FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- clearance or approval of product modifications to 510(k)-cleared, De Novo classified or PMA-approved devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of a cleared device;

devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of a cleared device;

- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury if the malfunction were to occur;

- correction, removal, and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FFDCA that may present a risk to health;

- complying with requirements governing Unique Device Identifiers on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database;

- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and/or regulations; and

- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Review And Approval Of Drugs In Europe And Other Foreign Jurisdictions

In addition to regulations in the US, a manufacturer of drugs 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, or the EU, a manufacturer must submit a marketing authorization application, or MAA, to the European Medicines Agency or EMA. For other countries outside of the EU, 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. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ significantly.

Review And Approval Of Medical Devices In Europe And Other Foreign Jurisdictions

In addition to regulations in the US, a manufacturer of medical devices is subject to a variety of regulations in foreign jurisdictions, which vary substantially from country to country, to the extent a manufacturer chooses to sell any medical devices in those foreign countries. In those countries, a manufacturer can be subject to supranational, national, regional, and local regulations affecting, among other things, the development, design, manufacturing, product standards, packaging, advertising, promotion, labeling, marketing, and postmarket surveillance of medical devices. In order to market a medical device in other countries, the sponsor must obtain regulatory approvals or certifications and comply with extensive safety and quality regulations enforced in those countries. The time required to obtain approval or certification by a foreign country may be longer or shorter than that required for FDA approval or clearance, and the requirements may differ significantly.

The EU has adopted specific directives and regulations regulating the design, manufacture, clinical investigation, conformity assessment, labeling, and adverse event reporting for medical devices. Until May 25, 2021, medical devices were regulated by Council Directive 93/42/EEC, the EU Medical Devices Directive, or MDD, which had created a single set of medical device regulations for devices marketed in all EU member countries. Compliance with the MDD and certification to a quality system (e.g., ISO 13485 certification) enabled a manufacturer to place a CE mark on its products. To obtain authorization to affix the CE mark to a product, a recognized European Notified Body had to assess a manufacturer's quality system and the product's conformity to the requirements of the MDD.

The MDD has been repealed and replaced by Regulation (EU) No 2017/745, the EU Medical Devices Regulation, or MDR, which imposes significant additional premarket and postmarket requirements on medical devices. The MDR entered into application on May 26, 2021. Under a corrigendum to the MDR finalized in December 2019, some low-risk medical devices being up-classified as a result of the MDR, including low-risk instruments, may were potentially eligible to receive a transitional period to comply by May 2024. 2024 under certain conditions. The European Commission recently extended the implementation period to the end of 2027 for high-risk devices and to the end of 2028 for medium- and low-risk devices.

The MDR establishes a uniform, transparent, predictable, and sustainable regulatory framework across the EU for medical devices and ensures a high level of safety and health while supporting innovation. Unlike the MDD, the MDR is directly applicable in EU member states without the need for member states to implement the MDR into national law, with the aim of increasing harmonization across the EU. The MDR, among other things:

- strengthens the rules on placing devices on the market (e.g., reclassification of certain devices and wider scope than the MDD) and reinforces surveillance once the devices are commercially available;
- establishes explicit provisions on manufacturers' responsibilities for follow-up on the quality, performance, and safety of devices placed on the market;
- establishes explicit provisions on importers' and distributors' obligations and responsibilities;
- imposes an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation; MDR;
- improves the traceability of medical devices throughout the supply chain to the end-user or patient through the introduction of a unique identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk;
- sets up a central database (MDR EUDAMED or EUDAMED), which is collaborative and interoperable and functions as a registration system, and a collaborative and a dissemination system (partially open to the public) that can, among other things, provide patients, healthcare professionals, and the public with information on products medical devices available in the EU; and
- strengthens rules for the assessment of certain high-risk devices, such as implants, which may have to undergo a clinical evaluation consultation procedure by experts before they are placed on the market.

Devices lawfully placed on the market pursuant to the MDD prior to May 26, 2021, or thereafter if eligible under the MDR transition provisions, may generally continue to be made available on the market or put into service until May 26, 2025, through the applicable extended transition period, provided that the requirements of the MDR's transitional provisions are fulfilled. In particular, Among other requirements, depending on the class of device, the certificate in question must still be valid. valid and not withdrawn, an MDR-compliant quality management system must be implemented and an application for a conformity assessment must be submitted by May 26, 2024, and an agreement for a conformity assessment must be executed with a Notified Body by September 26, 2024. However, even in this case, these cases, manufacturers must comply with a number of new or reinforced requirements set forth in the MDR, in particular the obligations described below.

The MDR requires that before placing a device, other than a custom-made device, on the market, manufacturers (as well as other economic operators such as authorized representatives and importers) must register by submitting identification information to the electronic system (EUDAMED), unless they have already registered. The information to be submitted by manufacturers (and authorized representatives) also includes the name, address, and contact details of the person or persons responsible for regulatory compliance. The MDR also requires that, before placing a device, other than a custom-made device, on the market, manufacturers must assign a unique identifier to the device and provide it along with other core data to the unique device identifier, or UDI, database. These new requirements aim at ensuring better identification and traceability of medical devices. Each device – and, as applicable, each package – will have a UDI composed of two parts: a device identifier, or UDI-DI, specific to a device, and a production identifier, or UDI-PI, to identify the unit producing the device. Manufacturers are also responsible for entering the necessary data on EUDAMED, which includes the UDI database, and for keeping it up to date. The obligations for registration in EUDAMED and other mandatory uses of the system will start when six months after the entire EUDAMED system (including all six modules) has been declared fully functional following an independent audit and an EU Commission notice to be published in the Official Journal and in accordance with the transitional provisions set out in the medical devices regulations. MDR. Until EUDAMED is fully functional, the corresponding provisions of the MDD continue to apply for the purpose of meeting the obligations laid down in the provisions regarding exchange of information, including, and in particular, information regarding registration of devices and economic operators.

All manufacturers placing medical devices into the market in the EU must comply with the EU medical device vigilance system. Under this system, serious incidents and Field Safety Corrective Actions, or FSCAs, must be reported to the relevant authorities of the EU member states. Manufacturers are required to take FSCAs, which are defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device.

The advertising and promotion of medical devices in the EU is subject to some general principles set forth in EU legislation. Under the MDR, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising of medical devices and contain general rules, for example, requiring that advertisements are evidenced, balanced, and not misleading. Specific requirements are defined at a national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices, in particular with respect to healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities, and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the US, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

The aforementioned EU requirements are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein, and Iceland.

Many other countries have specific requirements for classification, registration, and post-marketing surveillance that are independent of the countries discussed above. This landscape is constantly evolving. evolving and compliance with the regulatory requirements may require modifications to various systems, additional resources in certain functions, and updates to technical parameters, among other changes. Rafael Medical Devices could be found in violation if it interprets the laws incorrectly or fails to keep pace with changes in laws and regulations. In the event of either of these occurrences, Rafael Medical Devices could be instructed to recall any products that it is marketing, cease manufacturing and/or distribution, and/or be subject to civil or criminal penalties.

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 one of the Pharmaceutical Companies' product candidates is approved, sales of the Pharmaceutical Companies' products will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers, and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal, and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenue from product candidates that the Pharmaceutical Companies or Rafael Medical Devices may successfully develop and for which they may obtain regulatory 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 and medical devices, other supranational, national, regional, federal, state, and local laws concerning healthcare fraud and abuse, including false claims and anti-kickback laws, healthcare professional payment transparency laws, and privacy laws restrict business practices in the pharmaceutical and medical device industries. These laws have been subject to increased enforcement activities with respect to medical products product manufacturers and distributors in recent years. Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, fines, imprisonment and, within the US, exclusion from participation in government healthcare programs, including Medicare, Medicaid, Department of Defense, and Veterans Administration health programs. Restrictions under applicable federal and state and analogous foreign 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 protected health information, including breach notification regulations;

- new regulations adopted by the Securities and Exchange Commission, or SEC, effective December 18, 2023, that require greater disclosure regarding cybersecurity risk management, strategy and governance, as well as disclosure of material cybersecurity incidents, which may require reporting of a cybersecurity incident before its impact has been fully assessed or the underlying issue has been remediated, which could divert management's attention from incident response and could potentially reveal system vulnerabilities to threat actors, and for which failure to timely report such incidents under these or other similar rules could also result in monetary fines, sanctions or other forms of liability.
- analogous state data privacy and security laws and regulations that govern the collection, use, disclosure, transfer, storage, disposal, and protection of personal information, such as social security numbers, medical and financial information, and other information, including data breach laws that require timely notification to individuals, and at times regulators, the media or credit reporting agencies, if a company has experienced the unauthorized access or acquisition of personal information, as well as the California Consumer Privacy Act or CCPA, which, among other things, contains new disclosure obligations for businesses that collect personal information about California residents and affords those individuals numerous rights relating to their personal information that may affect companies' ability to use personal information or share it with business partners, and the California Privacy Rights Act, or CPRA, which expands the scope of the CCPA, imposes new restrictions on behavioral advertising, and establishes a new California Privacy Protection Agency that will enforce the law and issue regulations, and is scheduled to become became "operative" on January 1, 2023, with a 12-month "lookback provision," provision" applicable to personal data collected on or after January 1, 2022, and the various state laws and regulations may be more restrictive and not preempted by United States federal laws;

- analogous foreign data protection laws, including among others the EU General Data Protection Regulation, or the GDPR, and EU member states' implementing legislation, which imposes data protection requirements that include strict obligations and restrictions on the ability to collect, analyze, and transfer EU personal data, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances, and possible substantial fines for any violations (including possible fines for certain violations of up to the greater of 20 million Euros or 4% of total worldwide annual turnover of the preceding financial year), with legal requirements in foreign countries relating to the collection, storage, processing, and transfer of personal data continuing to evolve; evolve and varying widely across jurisdictions;

- the United States 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;

- 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; and

- 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.

In addition, our operations in foreign countries are subject to the extraterritorial application of the United States Foreign Corrupt Practices Act, or FCPA. Our global operations are also subject to foreign anti-corruption laws, such as the United Kingdom Bribery Act, among others. As part of our global compliance program, we seek to address anti-corruption risks proactively.

COMPETITION

We and the Investment Portfolio Companies operate in highly competitive segments. We and the Investment Portfolio Companies face competition from many different sources, including commercial pharmaceutical and biotechnology and medical device enterprises, academic institutions, government agencies, and private and public research institutions. Many of our and the Investment Portfolio Companies' competitors have significantly greater financial, product development, manufacturing and marketing resources than we and the Investment Portfolio Companies possess. Large pharmaceutical companies and medical device companies have extensive experience in development, clinical testing and obtaining regulatory approval for drugs and devices. In addition, many universities and private and public research institutes are active in research in direct competition with us and the Investment Portfolio Companies. We and the Investment Portfolio Companies also may compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our and the Investment Companies Portfolio Companies' competitors are pursuing the development and/or acquisition of pharmaceuticals, medical devices and over-the-counter ("OTC") products that target the same diseases, conditions and unmet needs that we and the Investment Portfolio Companies are targeting. If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our and the Investment Portfolio Companies' products can be subject to progressive price reductions or decreased volume of sales, or both. Most new products that we and the Investment Portfolio Companies would introduce must compete with other products already on the market or products that are later developed by competitors. The principal methods of competition for our and the Investment Portfolio Companies' products include quality, efficacy, market acceptance, price, and marketing and promotional efforts, patient access programs and product insurance coverage and reimbursement.

We face competition from other entities, including pharmaceutical and biotechnology companies and governmental institutions that are working on supporting orphan drug designations and clinical trials for the neurological manifestations of NPC. Some of these entities are well-funded, with more financial, technical and personnel resources than we have, and have more experience than we do in designing and implementing clinical trials. Two of our competitors were granted FDA approval of combination therapies for NPC on September 20, 2024 and September 24, 2024, and are each expected to be in the market in the second quarter of 2025. If we are unable to compete effectively against our current or future competitors, sales of our Trappsol® Cyclo™ product may not grow and our financial condition may suffer.

INTELLECTUAL PROPERTY

Licenses

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

Barer's subsidiary, Farber Partners, LLC ("Farber"), has formed agreements with Princeton University's Office of Technology Licensing for technology from the laboratory of Professor Joshua Rabinowitz, in the Department of Chemistry, Princeton University, for an exclusive worldwide license to its SHMT (serine hydroxymethyltransferase) inhibitor program and use of Methanol and prodrugs in therapy.

Cornerstone maintains an exclusive license agreement with the Research Foundation of the State University of New York at Stony Brook, or RF, granting Cornerstone the exclusive right to make, use and sell products covered under specified technology relating to lipoic acid derivatives with the right to grant sublicenses. This license agreement was subsequently amended in 2004, 2007 and 2017 and relates to Cornerstone's class of compounds. 2017. Cornerstone maintains a low single-digit royalty agreement with Altira Capital and Consulting, LLC (of which we own 66.66%)("Altira"), pursuant to which Cornerstone is granted sole ownership of certain patents directed to lipoic acid derivatives and other technology held by technology. Rafael possesses a 2/3 ownership interest in Altira.

Cornerstone maintains an exclusive license agreement with Ono Pharmaceutical Co., Ltd, or Ono, whereby Cornerstone 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 Cornerstone. Ono granted to Cornerstone 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 Cornerstone for material breach by Ono.

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Barer's subsidiary, Farber Partners, LLC ("Farber"), has formed agreements with Princeton University's Office of Technology Licensing for technology from the laboratory of Professor Joshua Rabinowitz, in the Department of Chemistry, Princeton University, for an exclusive worldwide license to its SHMT (serine hydroxymethyltransferase) inhibitor program and use of Methanol and prodrugs in therapy.

Patents

Cornerstone patents The designation of Trappsol® Cyclo™ as an orphan drug for the treatment of NPC1 by the FDA and European regulators would provide Cyclo with seven years, and 10 to 12 years, of market exclusivity, respectively, if it were to receive regulatory approval for its technology, inventions, designated orphan indication. Cyclo also protected its Trappsol® and improvements that it considers important Aquaplex® trademarks by registering them with the USPTO. In July 2024, Cyclo received a notice of decision from the European Patent Office 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 grant a patent is granted. As application regarding the methods to treat Alzheimer's Disease, with an effective date of September 2023, Cornerstone August 21, 2024.
LipoMedix owns or in-licenses more than one dozen several families of U.S. patents, more than thirty (30) foreign patents registered in various countries, and many pending U.S. and foreign patent applications. patents. Additional patent applications are anticipated to may be filed as studies progress. continue. Patents that Cornerstone LipoMedix has obtained for its platform technologies and patents that may issue in the future based on Cornerstone's LipoMedix's currently pending patent applications for its platform technologies are scheduled to expire in years 2028 2032 through 2042. 2040. These dates do not include potential patent term extensions. Cornerstone has obtained U.S. orphan drug designation for CPI-613® (devimistat) in the treatment of pancreatic cancer, AML, MDS, Burkitt's Lymphoma, Peripheral T-cell Lymphoma (PTCL), soft tissue sarcoma, and biliary cancer.

Cornerstone maintains U.S. Four patent applications covering the use of Promitil®, in combination with other chemotherapies and international trademarks covering its lead development compounds (CPI-613 with radiotherapy, targeting of Promitil® with a folate ligand, and a reformulation of Promitil® (devimistat) with co-encapsulated mitomycin prodrug and Telaglenastat (CB-839)). U.S. doxorubicin have been approved by the USPTO or EPO in 2018-2020. The patent portfolio is currently comprised of four granted families of patents and international trademarks are also maintained for potential brand names of devimistat in the event that it was to receive regulatory approval permitting commercialization. two applications under review.

Barer has filed patents for its novel inventions, and has entered into licensing agreements for other intellectual property. Patent applications have been filed in the name of Farber Partners, LLC (Barer's subsidiary) in the areas of T-cell nutrients to enhance checkpoint inhibition and one-carbon metabolism, and serine hydroxymethyltransferase (SHMT) inhibitors for therapies directed to treatment of cancer, autoimmune disease and fibrotic disease. In the area of T-cell nutrients, a Patent Cooperation Treaty Application (PCT) was filed on July 15, 2022, claiming priority to two US provisional applications that were filed in July and December of 2021. The PCT application entered the US national phase and the European regional phase in January of 2024. In the area of SHMT inhibitors, a US provisional application was filed on May 19, 2023 May 21, 2024. Pursuant to a Collaboration and Assignment Agreement between Farber and Ludwig Institute for Cancer Research Ltd. ("Ludwig"), Farber assigned its rights to these patents to Ludwig.

As Cornerstone patents its technology, inventions, and improvements that it considers important to the development of October 9, 2020, LipoMedix 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. Cornerstone owns or in-licenses several families dozens of U.S. patents. Additional and foreign patents and patent applications may be filed as studies continue. Patents that LipoMedix has obtained and patents that may issue in the future based on LipoMedix's currently pending patent applications for its platform technologies are scheduled to expire in years 2032 with expiration dates ranging from 2028 through 2035. These dates do 2042, not include including potential patent term extensions. Cornerstone also has obtained U.S. orphan drug designation for CPI-613® (devimistat) in the treatment of pancreatic cancer, AML, MDS, Burkitt's Lymphoma, Peripheral T-cell Lymphoma (PTCL), soft tissue sarcoma, and biliary cancer.

Four new patent applications Cornerstone maintains U.S. and international trademarks covering the use its lead development compounds (CPI-613® (devimistat) and Telaglenastat (CB-839)). U.S. and international trademarks are also maintained for potential brand names of Promitil®, in combination with other chemotherapies and with radiotherapy, targeting of Promitil with a folate ligand, and a reformulation of Promitil with co-encapsulated mitomycin prodrug and doxorubicin have been approved by the USPTO or EPO in 2018-2020. The patent portfolio is currently comprised of five granted families of patents and one application under review. devimistat that could be used if it were to receive regulatory approval permitting commercialization.

Rafael Medical Devices patents its technology, inventions, and improvements that it considers important to the development of its business and seeks to expand its intellectual property portfolio. As of September 16, 2023, Rafael Medical Devices had filed the following patent application related to its devices filed with the USPTO and PCT: Patent application entitled, Compression Anchor Systems, Devices, Instruments, Implants and Methods of Assembly and Use, Use; and patent application entitled Videoscopic Arthroscopic Instruments, Devices, and Systems and Methods of Use and Assembly.

The designation of Trappsol® Cyclo™ as an orphan drug for the treatment of NPC by the FDA and European regulators would provide Cyclo with seven years, and 10 to 12 years, of market exclusivity, respectively, following regulatory approval. Cyclo also protected its Trappsol® and Aquaplex® trademarks by registering them with the U.S. Patent and Trademark Office.

Day Three Labs Manufacturing, a majority-owned subsidiary of Day Three Labs, owns several families of US and international patents and patent applications related the service it provides to increased other third-party manufacturers to increase the bioavailability of cannabinoids. Day Three Labs Manufacturing has also filed for trademark protection over the use of the term UNLOKT, which it uses as the brand name for the other third-party manufacturers' cannabinoids processed using its technology.

Additional patent applications may be filed as development progresses across the Investment Portfolio Companies as deemed to be in its best interest.

MANUFACTURING

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

Cornerstone's compounds are organic compounds Cyclo is developing its lead product candidate, Trappsol® Cyclo™, for the proposed treatment of low molecular weight, generally called small molecules. They can be manufactured in reliable Niemann-Pick Disease, Type C1. The company owns all manufacturing and reproducible synthetic processes from readily available starting materials. The chemistry is amenable commercial rights to scale-up the product and does not require unusual equipment in the manufacturing process. Cornerstone expects to continue to develop drug candidates that can be produced relatively cost-effectively at manufactures using a validated, commercial-scale process using a team of contract manufacturing facilities. service providers.

LipoMedix's Promitil® and other pipeline candidates are based on an active pharmaceutical ingredient (API) referred to as MLP (abbreviation of mitomycin-C lipid-based prodrug) that is formulated into customized nanoparticles. These nanoparticles consist of lipids and a polyethylene-glycol (PEG) polymer and are known as pegylated liposomes. LipoMedix obtains bulk drug substance and drug product supplies from established contract manufacturers on a purchase order basis and does not have long-term supply arrangements in place. LipoMedix does not currently have arrangements in place for commercial supply or redundant supply for bulk drug substance or drug product.

Rafael Medical Devices optimizes supply chains and manufacturing on a device per device basis focusing on quality, time, and cost. At present, Rafael Medical Devices does not own or operate manufacturing facilities. Rafael Medical Devices management has relationships with top tier manufacturers that it leverages on an as-needed basis.

Cyclo is developing its lead product Trappsol® Cyclo™ for the treatment of Niemann-Pick Disease Type C. The company owns all manufacturing and commercial rights to the product and manufactures using a validated, commercial-scale process using a team of contract manufacturing service providers.

Day Three Labs Manufacturing, a majority-owned subsidiary of Day Three, Labs, provides a processing service to other third-party manufacturers for which it processes cannabinoids together with proteins using commercially available filtration equipment. Proteins used by Day Three Labs Manufacturing are obtained from established commercial manufacturers. Cannabinoids are acquired, owned, managed and held by the other third-party manufacturers for whom Day Three Labs Manufacturing provides processing services, and cannabinoids are obtained those manufacturers exclusively manage and control the process of obtaining and taking custody of the material from licensed state-licensed growers and extractors. extractors as well as controlling the overall process of manufacturing, marketing, and distributing their final products. All processing activities services take place at licensed other third-party manufacturers' state-licensed cannabis facilities, and Day Three Labs Manufacturing does not manage or take ownership, over custody or control of the cannabinoids being processed, but rather provides the processing their technology to other third-party manufacturers as a processing service.
Barer Institute, a wholly owned subsidiary of Rafael, does not own or operate manufacturing facilities.

Real Estate

Our current commercial real estate holdings consist of a portion of a building in Israel. Prior to its sale in August 2022, we also owned the 520 Property.

On August 22, 2022, the Company completed the sale of the 520 Property for a purchase price of $49.4 million.

The 520 Property was encumbered by a mortgage securing a $15 million loan which was paid off in this transaction. After repaying the loan, and paying commissions, taxes, and other costs, the Company received a net amount of approximately $33 million at closing.

The 520 Property serves as the headquarters of the Company and affiliated entities, IDT Corporation ("IDT"), and Genie Energy, Ltd. ("Genie"), who occupy the second through fourth floors.

Our 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 comprising approximately 12,400 gross square feet. feet including 24 indoor parking spaces. 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, 2023 July 31, 2024, the space is fully leased to two tenants; one of which is an IDT subsidiary.

Depreciation expense of property, plant and equipment was $137 thousand and $78 thousand as of July 31, 2024 and $72 thousand in fiscal 2023, respectively. Depreciation expense for the year ended July 31, 2024 includes depreciation of acquired assets from the Day Three Acquisition and fiscal 2022, respectively. Cornerstone Acquisition.

COMPETITION

With respect to our real estate business, we compete for commercial (office and retail) tenants in Jerusalem, Israel. 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.

OUR STRATEGY

Our strategy related to our real estate business is to continue to operate and maximize the value of our real estate holding in Israel.

EMPLOYEES

As of October 30, 2023 November 5, 2024, Rafael Holdings and its subsidiaries had 13 28 full-time employees, including 1 employee dedicated to the real estate group. and 3 part-time employees.

Item 1A. Risk Factors

RISK FACTORS

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

Risks Related to Our Financial Condition and Capital Needs

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

We may need to raise additional capital for operations and in order for stockholders to realize increased value on our securities. In the event the merger is consummated with Cyclo (the "Merger") and if the current *Phase III trial for Trappsol® Cyclo™* is successful, we may need to raise capital for the manufacturing, distribution and commercialization of *Trappsol® Cyclo™*. 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 or at all. 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 have only a limited operating history upon which our business and prospects can be evaluated. We expect to encounter risks and difficulties frequently encountered by early-stage companies in the industries in which we operate.

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

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

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

As of July 31, 2023 July 31, 2024, we held approximately $21.5 million $2.7 million in cash and cash equivalents, approximately $57.7 million $63.3 million in short-term available-for-sale securities, $2.5 million $0.4 million in third-party and related party receivables, and interest receivable (net of allowance for doubtful accounts), approximately $5.0 million $0.5 million in interests receivable, and $2.5 million in investment in hedge funds and approximately $0.1 million in securities in another entity that are not liquid. funds. Investments in hedge funds carry a degree of risk, as there can be no assurance that we will be able to redeem any hedge fund investments at any time or that our investment managers will be able to accurately predict the course of price movements of securities and other instruments and, in general, the securities markets have in recent years been characterized by great volatility and unpredictability. Our passive interests in other entities are not currently liquid, and we cannot assure that we will be able to liquidate them when we desire, or ever. As a result of these different market risks, our holdings of cash, cash equivalents, and investments could be materially and adversely affected.

We may not be able to consummate any investment, business combination or other transaction.

While we are actively seeking corporate development opportunities, we may not be able to find any suitable target businesses and consummate an investment, business combination or other transaction. Our ability to complete any such transactions may be negatively impacted by general market conditions, volatility in the debt and equity markets, decreased market liquidity, and third-party financing being unavailable on terms acceptable to us or at all.

Risks Related to our Pharmaceuticals Business

Our future success may depend significantly on prospects for Cornerstone's lead product candidate devimistat (CPI-613®) and results of Cyclo Therapeutics' Phase III trial for Trappsol®Cyclo™. If either company Cyclo is unable to successfully develop, gain regulatory approval for or commercialize its product candidates or experiences significant delays in doing so, our business will be materially harmed.

We have invested a significant amount of capital into Cornerstone's development program. All in Cyclo. Our dependence on the success of Cornerstone's current Trappsol® Cyclo™ and any future product candidates the need for additional capital will require preclinical increase if the merger is consummated and clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before Cornerstone can generate any revenue from product sales. the *Phase III trial for Trappsol® Cyclo*™ is successful.

The success of CPI-613® (devimistat) and Trappsol®Trappsol® Cyclo™ is beyond our Cornerstone's or and Cyclo's control, and the drug development and regulatory approval processes could cause significant delay or prevent Cornerstone and/or Cyclo from obtaining regulatory approval or commercializing CPI-613® (devimistat), Trappsol®Trappsol® Cyclo™ or any other product candidates. If either Cornerstone or Cyclo is unable to develop, obtain regulatory approval for, or, if approved, successfully commercialize its product candidates, we may not be able to generate sufficient revenue to continue our business.

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

Our business strategy includes elements for our subsidiaries and entities in which we invest to identify, create and test compounds, and to advance clinical testing of those and other compounds. A significant portion of the research that the Pharmaceutical Companies are conducting involves new compounds and drug discovery methods and suitable drug delivery systems, including the Pharmaceutical Companies' proprietary technology. The drug discovery that the Pharmaceutical Companies are conducting using the Pharmaceutical Companies' proprietary technology may not be successful in identifying compounds that are useful in treating cancer or other ailments. The Pharmaceutical Companies' research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying appropriate biomarkers, potential product candidates or effective carrier systems to confer a drug delivery advantage. 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 regulatory approval and achieve market acceptance.

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

If the Pharmaceutical Companies are unable to identify suitable compounds for preclinical and clinical development, and/or are unable to successfully secure regulatory approval for any such compounds, the Pharmaceutical Companies will not be able to obtain product revenue in future periods, which likely would result in significant harm to the Pharmaceutical Companies' financial position and adversely impact the Pharmaceutical Companies' valuation and our business.

We and the companies in which we hold interests may expend our and their limited resources to pursue a particular product candidate or an indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

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

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

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

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

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

- inability to generate sufficient nonclinical and preclinical or other in vivo or in vitro data to support the initiation of clinical studies;
- timely completion of nonclinical and preclinical laboratory tests, animal studies, and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- delays in reaching a consensus with regulatory agencies on study design and obtaining regulatory authorization to commence clinical trials;
- delays in reaching agreement on acceptable contractual terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;

- delays in recruiting eligible patients to participate in clinical trials;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of product candidates for use in clinical trials;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities;
- developments on trials conducted by competitors for related technology or medical products that raise FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting, screening and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by CROs, other third parties or the Pharmaceutical Companies to adhere to clinical trial protocols;

- failure by CROs, other third parties or the Pharmaceutical Companies to perform in accordance with the FDA's or any other regulatory authority's good laboratory practices, or GLPs, good clinical practice requirements, or GCP, or other applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in a clinical trial of the same class of agents conducted by other companies;
- changes to the clinical trial protocols;
- clinical sites deviating from trial protocols or dropping out of a trial;
- changes in regulatory requirements and guidance, or data from an ongoing or other studies, that require amending or submitting new clinical protocols;

- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- selection of inclusion and/or exclusion criteria that significantly inhibit the ability to recruit patients into clinical trials;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- the cost of clinical trials of the Pharmaceutical Companies' product candidates being greater than anticipated;
- interruptions of and/or delays in the clinical trials of the Pharmaceutical Companies' product candidates and the potential impact of such interruptions or delays on a product candidate's development program and the validity of clinical data result from a product candidate's development program;
- clinical trials of the Pharmaceutical Companies' product candidates producing negative or inconclusive results, which may result in our or their deciding, or regulators requiring us, to amend clinical trial protocols, conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization, or CMO, and delays or failure by CMOs or the Pharmaceutical Companies to properly implement or make any necessary changes to such manufacturing processes; and
- third parties being unwilling or unable to satisfy their contractual obligations to us or the Pharmaceutical Companies.

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

Further, conducting clinical trials in foreign countries, as the Pharmaceutical Companies may do for their product candidates, presents additional risks that may delay completion of clinical trials. These risks include the failure of patients enrolled patients in clinical trials in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, the utilization of alternative standards of care in foreign countries and the failure to conduct foreign clinical trials according to standards of care in foreign countries that FDA considers comparable to the standards of care in the US, failure of the Pharmaceutical Companies to persuade the FDA as to the scientific robustness and clinical acceptability of the data from any such foreign clinical trials, managing additional administrative burdens associated with foreign regulatory schemes, as well as political, economic, and economic public health risks relevant to such foreign countries.

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

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

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

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

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

Patient enrollment is also affected by other factors including:

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

These factors may make it difficult for the Pharmaceutical Companies to enroll enough patients to complete their clinical trials in a timely and cost-effective manner. The Pharmaceutical Companies' inability to enroll a sufficient number of patients for their clinical trials would result in significant delays or may require them to abandon one or more clinical trials altogether. Enrollment delays in clinical trials may result in increased development costs for the Pharmaceutical Companies' product candidates and jeopardize their ability to obtain regulatory approval. Furthermore, even if the Pharmaceutical Companies are able to enroll a sufficient number of patients for their clinical trials, they may have difficulty maintaining participation in their clinical trials through the treatment and any follow-up periods.

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

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

In addition, many compounds that initially showed promise in early-stage testing for treating cancer or other indications have later been found to cause side effects that prevented further development of the compound. Further, we expect that certain product candidates will be used in patients that have weakened immune systems, which may exacerbate any potential side effects associated with their use. Patients treated with oncology product candidates may also be undergoing surgical, radiation and and/or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to the product candidate but may still impact the risk-benefit profile of the product candidate and the success of clinical trials. The inclusion of critically ill patients in clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. It may be very challenging, or even impossible, for the Pharmaceutical Companies to demonstrate that any such deaths or other adverse events are traceable to other therapies or medications that such patients may be using or to the gravity of such patients' illnesses, in which case the FDA or analogous regulatory authorities may attribute any such deaths or other adverse events to the Pharmaceutical Companies' product candidate being studied in the clinical trial.

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

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

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including "boxed" warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- the Pharmaceutical Companies may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;

- the Pharmaceutical Companies may be required to develop and implement a risk evaluation and mitigation strategy, or REMS, which could include, among other things, a medication guide outlining the risks of such side effects for distribution to patients, and potentially limitations or even restrictions on prescribing, dispensing, and/or distribution;

- the Pharmaceutical Companies may be subject to fines, injunctions or the imposition of criminal penalties;

- we and/or the Pharmaceutical Companies could be sued and held liable for harm caused to patients; and

- our reputation may suffer.

Any of these events could prevent the Pharmaceutical Companies from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm the standing and reputation of the Pharmaceutical Companies among health-care providers and patients, and could seriously harm our business.

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

From time to time, we and/or the Pharmaceutical Companies may publicly disclose preliminary or top-line data from preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following study completion and a more comprehensive review of the data related to the particular study or trial. We and/or the Pharmaceutical Companies may also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we or they may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results reported may differ significantly from future results of the same studies, or different conclusions or considerations may qualify such results and/or limit the clinical significance and clinical conclusions that can be drawn from them, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Even complete data from an individual study or clinical trial may be evaluated different and result in different conclusions based upon subsequent data from a subsequently completed study. In addition, the full study results from all clinical trials are subject to FDA review, and the FDA may draw materially different conclusions than those reached by us or the Pharmaceutical Companies. As a result, top-line data should be viewed with caution until the final data are available, and then, until the full study results have been completely evaluated by the FDA.

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

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

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

The outcome of preclinical studies and early clinical trials may not be predictive of the success or failure of later preclinical studies or clinical trials, and interim results of preclinical studies or clinical trials do not necessarily predict success in future clinical trials. Many companies in the biopharmaceutical industries industry, including Cornerstone, have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and the Pharmaceutical Companies could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or even completed. We and the Pharmaceutical Companies have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support regulatory 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 regulatory approval for the product candidates. Even if we or the Pharmaceutical Companies, or future collaborators, believe that the results of clinical trials for the Pharmaceutical Companies' product candidates warrant regulatory approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant regulatory approval of the Pharmaceutical Companies' product candidates.

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

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

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

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

The FDA or any foreign regulatory bodies authorities can delay, limit or deny approval of the Pharmaceutical Companies' product candidates or require them to conduct additional nonclinical and preclinical or clinical testing or abandon a program for multiple reasons in their sole discretion, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of clinical trials;
- the Pharmaceutical Companies may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; indication(s);
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects experienced by participants in clinical trials or by individuals using drugs similar to the Pharmaceutical Companies' product candidates may result in negative regulatory conclusions regarding a product candidate's safety profile;
- the Pharmaceutical Companies may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with the Pharmaceutical Companies' interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of the Pharmaceutical Companies' product candidates may not be acceptable or sufficient to support the submission of a NDA or other comparable submission or to obtain regulatory approval in the United States or elsewhere, and the Pharmaceutical Companies may be required to conduct additional clinical studies;

- the FDA's FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling, manufacturing, and/or the specifications of the Pharmaceutical Companies' product candidates;

- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which the Pharmaceutical Companies contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering clinical data insufficient for approval.

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

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

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

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

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

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

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

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

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing and making available the drug will be recovered from sales in the United States. Cornerstone has received ODD for CPI-613 (devimistat) for the treatment of pancreatic cancer, acute myeloid leukemia, myelodysplastic syndrome, Burkitt's lymphoma, peripheral T-cell lymphomas, soft tissue sarcoma, and biliary cancer. Cyclo received orphan drug for the treatment of NPC NPC1 by the FDA for its Trappsol® Trappsol® product.

In the United States, ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has ODD subsequently receives the first FDA approval for a particular active ingredient for the rare disease for which it has such designation, the product is entitled to orphan drug exclusivity for that active ingredient for that rare disease. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA or other comparable submission, to market the same drug for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity, or if the FDA withdraws exclusive approval or revokes orphan drug designation, or if the marketing application (NDA or BLA) for the orphan drug is withdrawn for any reason, or if the FDA finds that the holder of the orphan exclusivity has not shown that it can ensure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the product was designated.

Even if the Pharmaceutical Companies obtain ODD for a product candidate, they may not be able to obtain or maintain orphan drug exclusivity for that product candidate. The Pharmaceutical Companies may not be the first to obtain regulatory approval of any product candidate for which they have obtained ODD for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. If one or more third-party sponsor is the first to receive approval for an alternative product(s) for the same orphan-designated indication as the Pharmaceutical Companies' product candidate, even if FDA were to conclude that the Pharmaceutical Companies' product candidate is not the "same drug" as the alternative product(s), the prior approval(s) of such alternative product(s) could result in a delay in the regulatory review of the Pharmaceutical Companies' product candidate and/or requests for the conduct of additional clinical trials that may further delay the prospects for any approval of the Pharmaceutical Companies' product candidate. In addition, exclusive marketing rights in the United States may be limited if the Pharmaceutical Companies seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if they are unable to ensure that they will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

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

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions, including a shutdown of the federal government. Average review times at the FDA have fluctuated in recent years. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the United States federal government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

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

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

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

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenue, warning letters, untitled letters or holds on clinical trials;

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us the Pharmaceutical Companies or suspension or revocation of approvals;

- product seizure or detention, or refusal to permit the import or export of our the Pharmaceutical Companies' products; and

- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

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

- the efficacy, safety profile, and any potential clinical advantages compared to alternative treatments;
- the approval, availability, market acceptance, and reimbursement for any companion diagnostic;
- the ability to offer the Pharmaceutical Companies' medicines for sale at competitive prices;

- convenience and ease of administration compared to alternative treatments;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- ensuring uninterrupted product supply;
- the strength of marketing and distribution support;
- sufficient third-party coverage and reimbursement; and
- the prevalence and severity of any side effects.

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

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

We and the Pharmaceutical Companies rely on third parties to perform a variety of functions. We are party to numerous agreements that place substantial responsibility on clinical research organizations, or CROs, contract manufacturing organizations, or CMOs, consultants, and other service providers for the development of the Pharmaceutical Companies' product candidates. We also rely on medical and academic institutions to perform aspects of the Pharmaceutical Companies' clinical trials of product candidates. In addition, an element of our research and development strategy has been to in-license technology and product candidates from academic and government institutions in order to minimize or eliminate investments in early research. We may not be able to enter new arrangements without undue delays or expenditures or on favorable terms, if at all, and these arrangements may not allow us to compete successfully. Moreover, if third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct clinical trials in accordance with regulatory requirements or applicable protocols, the Pharmaceutical Companies' product candidates may not be approved for marketing and commercialization or such approval and commercialization may be delayed. If that occurs, our collaborators will not be able, or may be delayed in their efforts, to seek regulatory approval for or commercialize the Pharmaceutical Companies' product candidates.

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

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

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

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

- the Pharmaceutical Companies' inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future medicines; medicines in accordance with approved labeling;

- 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;

- the Pharmaceutical Companies' inability to equip medical and sales personnel with compliant and effective materials, including medical and sales literature, to help them educate physicians and other healthcare providers regarding applicable diseases and any products that receive regulatory approval;

- the failure of the Pharmaceutical Companies, and/or any other third parties to whom sales, marketing, reimbursement and distribution services are outsourced, to develop and distribute compliant medical and sales literature in accordance with any labeling that is approved or to adhere to the scope of such literature when communicating with physicians and other health care professionals regarding any products that receive regulatory approval;
- the Pharmaceutical Companies' inability to develop or obtain sufficient operational functions to support our commercial activities; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

The companies in which we hold interests face substantial competition, and if competitors develop and market technologies or products more rapidly than those companies do or that are more effective, safer or less expensive than the product candidates that those companies develop, our commercial opportunities will be negatively impacted.

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

The Pharmaceutical Companies that are developing their product candidates for the treatment of cancer may compete against 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. professionals based upon their independent medical judgement and expertise. Some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic or biosimilar basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. The Pharmaceutical Companies expect that if their product candidates are approved, they will be priced at a significant premium over competitive generic or biosimilar products. This may make it difficult for the Pharmaceutical Companies to achieve their business strategy of using their product candidates in combination with existing therapies or replacing existing therapies with their product candidates following any regulatory approvals.

Cornerstone 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., Novo Nordisk, 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, Sagiment Biosciences, Eleison Pharmaceuticals, BioMarin Pharmaceutical Inc., and Takeda.

Cyclo is focused on a cure for NPC NPC1 and faces competition from Actelion, a subsidiary of Johnson & Johnson Orphazyme, a public company based in Denmark, Zevra Therapeutics, Inc., Mandos Health, azafaros Azafaros and IntraBio among others.

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

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

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

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

The commercial success of the Pharmaceutical Companies' product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of the Pharmaceutical Companies' product candidates will be covered and paid for, following regulatory approval, if any, by third-party payors, including government health administration authorities and private health coverage insurers. If coverage and reimbursement is not available, or reimbursement is available only to limited levels, the Pharmaceutical Companies, or any future collaborators, may not be able to successfully commercialize the Pharmaceutical Companies' product candidates in the event they receive regulatory approval. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, the Pharmaceutical Companies, or any future collaborators, to establish or maintain pricing sufficient to realize a sufficient return on our or the Pharmaceutical Companies' 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 us and or the Pharmaceutical Companies to provide scientific and clinical support for the use of their products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Regulatory 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 regulatory approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, the Pharmaceutical Companies, or any future collaborators, might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenue the Pharmaceutical Companies are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our or the Pharmaceutical Companies' ability or the ability of any future collaborators to recoup our or the Pharmaceutical Companies' or their investment in one or more product candidates, even if the Pharmaceutical Companies' product candidates obtain regulatory approval.

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

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

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

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

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

- decreased demand for any product candidates or medicines that the Pharmaceutical Companies may develop;
- injury to the Pharmaceutical Companies' reputation and significant negative media attention;

- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;

- reduced resources of the Pharmaceutical Companies' management to pursue the Pharmaceutical Companies' business strategy; strategy, and diverted time and attention from executing on that strategy; and

- the inability to commercialize any medicines that the Pharmaceutical Companies may develop.

Although we and the Pharmaceutical Companies plan to maintain product liability insurance coverage, it may not be adequate to cover all liabilities that the Pharmaceutical Companies and we may incur. We anticipate that we and the Pharmaceutical Companies will need to increase our and their insurance coverage as they continue to run clinical trials and if they successfully commercialize any medicine that receives regulatory approval. Insurance coverage in this setting is increasingly expensive. We and/or the Pharmaceutical Companies may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. In addition, if one of our or the Pharmaceutical Companies' 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 could potentially seek indemnification from us and/or the Pharmaceutical Companies, and therefore substantially limit the commercial potential of our and/or the Pharmaceutical Companies' products.

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

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

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

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

Current and future legislation may increase the difficulty and cost for us and the Pharmaceutical Companies and any future collaborators to obtain regulatory approval of the Pharmaceutical Companies' 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 development and/or regulatory approval of the Pharmaceutical Companies' product candidates, restrict or regulate post-approval activities and affect the Pharmaceutical Companies' ability, or the ability of any future collaborators, to profitably sell any products for which the Pharmaceutical Companies, or they, obtain regulatory approval. We and the Pharmaceutical Companies expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage and reimbursement criteria and additional downward pressure on the price that the Pharmaceutical Companies, or any future collaborators, may receive for any approved products.

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

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, or MDRP;
- a new methodology by which rebates owed by manufacturers under the MDRP are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to now offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- new requirements to report certain financial arrangements with physicians and teaching hospitals for eventual publication;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians for eventual publication;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and

- a Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models.

Since enactment of the ACA, there have been numerous executive and legal challenges and Congressional actions to repeal and replace provisions of the law. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden Administration or future Administrations or other efforts, if any, to challenge, repeal or replace the ACA, will impact the Pharmaceutical Companies' businesses. Nor is it clear whether other legislative changes will be adopted, if any, or how such changes would affect the demand for the Pharmaceutical Companies' products if they were to receive regulatory approval.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for drug products. Among other things, such scrutiny has led to enactment of a budget reconciliation measure known as the Inflation Reduction Act of 2022, or IRA, signed into law by President Biden on August 16, 2022, which makes wide-reaching changes to Medicare prescription drug coverage and more targeted changes to Medicaid, the State Children's Health Insurance Coverage Program, or CHIP, and private health insurance, and which includes several provisions to lower prescription drug costs for people with Medicare and reduce drug spending by the federal government. The prescription drug provisions included in the IRA will, among other things:

- require the federal government to negotiate prices for certain drugs covered under Medicare Part B (physician-administered drugs) and Part D (retail prescription drugs), starting with 10 high-spending, single-source drugs for 2026 and increasing to 20 by 2029;
- require manufacturers that sell drugs used by Medicare beneficiaries through Parts B and D to pay rebates to Medicare if they increase drug prices faster than consumer inflation, beginning in 2023;
- cap out-of-pocket spending for Medicare Part D enrollees and make other Part D benefit design changes, beginning in 2024;
- expand eligibility for full benefits under the Medicare Part D Low-Income Subsidy Program, beginning in 2024; and
- further delay implementation of the Trump Administration's drug rebate rule, beginning in 2027.

Pursuant to the IRA, the Centers for Medicare & Medicaid Services (CMS) selected ten drugs covered under Medicare Part D for the first cycle of negotiations for initial price applicability year 2026 and engaged in voluntary negotiations with the drug companies for the selected drugs. CMS negotiated prices for 10 drugs covered under Medicare Part D that will go into effect beginning January 1, 2026, based on negotiations and agreements reached between CMS and participating drug companies. In August 2024, CMS announced discounts ranging from 38% to 79% based upon negotiated price differences from the drugs' 2023 list price. Currently, CMS intends to announce the next set of 15 Part D drugs selected for negotiation by February 1, 2025. It is unclear exactly how the 2024 election will impact healthcare reform measures of the existing Administration or whether a new Administration could impose other reform efforts, including what, if any, impact such changes will have on our business.

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

We expect that healthcare reform measures that may be adopted in the future could have a material adverse effect on our and the Pharmaceutical Companies' industry generally and on our or their ability to maintain or increase sales of any of the Pharmaceutical Companies' product candidates that we are successfully develop, secure developed, receive regulatory approval for, and commercialize. are commercialized.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We and the Pharmaceutical Companies 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 regulatory 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 regulatory approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Additional Risks Related to our Medical Device Business

Rafael Medical Devices' device candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved or cleared devices or investigational or approved drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential, result in significant negative consequences, or potential product liability claims.

If Rafael Medical Devices' device candidates are associated with undesirable side effects or have unexpected characteristics in clinical trials when used alone or in combination with other approved or cleared devices or in combination with investigational or approved drugs, Rafael Medical Devices may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us Rafael Medical Devices from achieving or maintaining market acceptance of the affected device candidate and may adversely affect Rafael Medical Devices' and our business, financial condition, and prospects significantly.

In addition, many device candidates that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the device candidates. If significant adverse events or other side effects are observed in any of Rafael Medical Devices' current or future clinical trials, Rafael Medical Devices may have difficulty recruiting patients to the clinical trials, patients may drop out of such trials, or they may be required to abandon the trials or our their development efforts of a device candidate altogether. Rafael Medical Devices, the FDA, other comparable regulatory authorities or an IRB or ethics committee may suspend clinical trials of a device candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to inadequate clinical benefit and/or unacceptable health risks or adverse side effects.

Further, if any of Rafael Medical Devices' device candidates obtains regulatory approval, marketing authorization or clearance, toxicities or other serious adverse events associated with such device candidates previously not seen during clinical testing may also develop after such approval, marketing authorization, or clearance and lead to a number of potentially significant negative consequences, including, but not limited to:

- Regulatory authorities may suspend, limit or withdraw approvals, marketing authorizations or clearances of such device, if any, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including "boxed" warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- Rafael Medical Devices may be required to change the way the device is implanted or conduct additional clinical trials or post-approval studies;
- Rafael Medical Devices may be subject to fines, injunctions or the imposition of criminal penalties;
- we or Rafael Medical Devices could be sued and held liable for harm caused to patients; and
- Rafael Medical Devices and our reputation may suffer.

Any of these events could prevent Rafael Medical Devices from achieving or maintaining market acceptance of the particular device candidate, if approved, marketing authorized or cleared, as well as that of future device candidates, and could seriously harm their and our business.

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

From time to time, we and/or Rafael Medical Devices may publicly disclose preliminary or top-line data from preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following study completion and a more comprehensive review of the data related to the particular study or trial. We and/or Rafael Medical Devices may also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we or they may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results reported may differ significantly from future results of the same or future studies, or different conclusions or considerations may qualify such results and/or limit the clinical significance and clinical conclusions that can be drawn from them, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we and/or Rafael Medical Devices previously published. Even complete data from an individual study or clinical trial may be evaluated different and result in different conclusions based upon subsequent data from a subsequently completed study. In addition, the full study results from all clinical trials are subject to FDA review, and the FDA may draw materially different conclusions than those reached by us or Rafael Medical Devices. As a result, top-line data should be viewed with caution until the final data are available, and then, until the full study results have been completely evaluated by the FDA.

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

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

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

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

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same device candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in standards of care in different geographical locations, differences in the size and type of the patient populations, differences in the standard of care in different geographical locations, changes in and adherence to the treatment regimen and other elements of the clinical trial protocol, and the rate of dropout among clinical trial participants. If Rafael Medical Devices fails to receive positive results in clinical trials of Rafael Medical Devices' device candidates, the development timeline and regulatory approval, marketing authorization or clearance and commercialization prospects for Rafael Medical Devices' most advanced device candidates, and, correspondingly, our and Rafael Medical Devices' business and financial prospects, would be negatively impacted.

The regulatory approval, marketing authorization and clearance processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable, and if Rafael Medical Devices is ultimately unable to obtain regulatory approval or clearance for their device candidates, their business will be substantially harmed.

Before Rafael Medical Devices can market or sell a new medical device or a new use of or a claim for or significant modification to any medical device that has received approval or clearance, if any, in the United States, Rafael Medical Devices must obtain either clearance from the FDA under the 510(k) pathway, marketing authorization in response to a De Novo request, or approval of a PMA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed predicate device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. If FDA determines that the device is "not substantially equivalent," the device is automatically designated as a Class III device. The device sponsor then must either fulfill the more rigorous PMA requirements, or the sponsor can submit a De Novo request seeking a risk-based classification determination for the device in accordance with the FDA's De Novo classification process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. A sponsor also can submit a De Novo classification request directly, without first submitting a 510(k), if the sponsor determines that there is no legally marketed predicate device upon which to base a determination of substantial equivalence. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for products that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

The PMA approval, the De Novo classification, and the 510(k) clearance process can be expensive, lengthy, and uncertain. The FDA's 510(k) clearance process usually takes from three to twelve months, but can last longer, and the De Novo classification process generally can be comparable. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance and De Novo classification processes and generally takes from six to eighteen months, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort, and cost, we and Rafael Medical Devices cannot assure you that any particular device candidate will be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals, marketing authorizations, or clearances could harm our and Rafael Medical Devices' business.

Any modification to any 510(k)-cleared product, if any, that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of any such device, would require Rafael Medical Devices to obtain a new 510(k) marketing clearance and may even, in some circumstances, require the submission of a De Novo request or a PMA application, if the change raises complex or novel scientific issues or the product has a new intended use. The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. Rafael Medical Devices may make changes to a 510(k)-cleared product, if any, in the future that Rafael Medical Devices may determine does not require a new 510(k) clearance, De Novo marketing authorization, or PMA approval. If the FDA disagrees with Rafael Medical Devices' decision not to seek a new 510(k) clearance, De Novo marketing authorization, or PMA approval for changes or modifications to any existing devices and requires new clearances, marketing authorizations, or approvals, Rafael Medical Devices may be required to recall and stop marketing any products as modified, if any, which could require Rafael Medical Devices to redesign its products, conduct clinical trials to support any modifications, and pay significant regulatory fines or penalties. If there is any delay or failure in obtaining required clearances or approvals or if the FDA requires Rafael Medical Devices to go through a lengthier, more rigorous examination for future device candidates or modifications to existing devices, if any, than Rafael Medical Devices had expected, Rafael Medical Devices' ability to introduce new or enhanced devices in a timely manner would be adversely affected, which in turn would result in delayed or no realization of revenue from such device enhancements or new devices and could also result in substantial additional costs which could decrease our Rafael Medical Devices' profitability.

The FDA can delay, limit or deny approval, marketing authorization or clearance of a device for many reasons, including:

- Rafael Medical Devices may not be able to demonstrate to the FDA's satisfaction that the device or modification is substantially equivalent to the proposed predicate device or safe and effective for its intended use;
- The data from Rafael Medical Devices' preclinical studies and clinical trials may be insufficient to support approval or clearance, where required; and;
- The manufacturing process or facilities that Rafael Medical Devices use may not meet applicable requirements.

In addition, the FDA may change its approval, marketing authorization and clearance policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval, marketing authorization, or clearance of Rafael Medical Devices' future device candidates or impact Rafael Medical Devices' ability to modify approved, marketing authorized, or cleared devices, if any, on a timely basis. Even after approval, marketing authorization, or clearance for Rafael Medical Devices' products is obtained, they and the products are subject to extensive postmarket regulation by the FDA, including with respect to advertising, marketing, labeling, manufacturing, distribution, import, export, and clinical evaluation.

Rafael Medical Devices is also required to timely file various reports with regulatory agencies for any device that has received approval, marketing authorization, or clearance. If these reports are not timely filed, regulators may impose sanctions, and sales of Rafael Medical Devices' products may suffer, and they and we may be subject to product liability or regulatory enforcement actions, all of which could harm their and our business. In addition, if Rafael Medical Devices initiates a correction or removal for a device that receives approval, marketing authorization, or clearance, if any, issues a safety alert, or undertakes a field action or recall to reduce a risk to health posed by any such device, Rafael Medical Devices may be required to submit a report to the FDA, and in many cases, to other regulatory agencies. Such reports could lead to increased scrutiny by the FDA, other comparable regulatory agencies, and Rafael Medical Devices' customers regarding the quality and safety of their devices, and to negative publicity, including FDA alerts, press releases, or administrative or judicial actions. Furthermore, the submission of these reports has been and could be used by competitors against Rafael Medical Devices in competitive situations and cause customers to delay purchase decisions or cancel orders, which would harm their and our reputation and business.

The FDA, state, and foreign regulatory authorities have broad enforcement powers. Rafael Medical Devices' failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, untitled letters, fines, injunctions, consent decrees, and civil penalties;
- repair, replacement, refunds, recalls, termination of manufacturing and/or distribution, administrative detention or seizures of a device(s) that receives approval, marketing authorization or clearance, if any;
- operating restrictions, partial suspension or total shutdown of production;
- customer notifications or repair, replacement or refunds;
- refusing Rafael Medical Devices' requests for 510(k) clearance, De Novo classification or PMA approvals or foreign regulatory approvals of new device candidates, new intended uses or modifications to existing devices, if any;

- withdrawals of current 510(k) clearances, De Novo classifications or PMAs or foreign regulatory approvals, resulting in prohibitions on sales of any Rafael Medical Devices' device(s) that receives approval, marketing authorization or clearance, if any;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could also result in higher than anticipated costs or lower than anticipated sales of any Rafael Medical Devices' device(s) that receives approval, marketing authorization, or clearance and adversely affect their and our business, results of operations, and financial condition.

Even if Rafael Medical Devices receives regulatory approval, marketing authorization, or clearance for any device candidate, they will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

Any regulatory approvals, marketing authorizations, or clearances that Rafael Medical Devices may receive for their device candidates will require the regular submission of reports to regulatory authorities and surveillance to monitor the safety and effectiveness of the medical device, may contain significant limitations related to use restrictions for specified age groups or patient populations, warnings, precautions or contraindications, and may include burdensome post-approval study requirements. If the FDA or a comparable foreign regulatory authority approves, issues a marketing authorization for, or clears a device candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, and recordkeeping for Rafael Medical Devices' devices, if any, will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, maintenance of cGMP compliance at and registrations for all manufacturing facilities, as well as continued compliance with cGMP and GCP requirements for any clinical trials that are conducted post-approval. Manufacturers of approved devices and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. Later discovery of previously unknown problems with marketed devices, including adverse events of unanticipated severity or frequency, or with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of any Rafael Medical Devices' device that receives approval, marketing authorization or clearance, if any, withdrawal of the device from the market or voluntary or mandatory device recalls;
- requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenue, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve or clear pending applications or supplements to approved, marketing authorized or cleared applications filed by Rafael Medical Devices or suspension or revocation of approvals, if any;
- product seizure or detention, or refusal to permit the import or export of Rafael Medical Devices' devices; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit Rafael Medical Devices' ability to commercialize their device candidates and generate revenue and could require Rafael Medical Devices to expend significant time and resources in response and could generate negative publicity.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval, marketing authorization, or clearance of Rafael Medical Devices' device candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, the results of the 2020 United States Presidential Election impacted our business and industry. Namely, the Trump Administration took several Executive Actions, including the issuance of a number of Executive Orders, that imposed significant burdens on, or otherwise materially delayed, the FDA's ability to engage in routine oversight activities, such as implementing statutes through rulemaking, issuance of guidance, and review and approval of applications seeking approval, marketing authorization, or clearance of device candidates. It is difficult to predict whether or how these orders will be rescinded and replaced under the Biden Administration. Administration or future Administrations. The policies and priorities of any administration Administration and the U.S. Congress are unknown and could materially impact the regulations governing our Rafael Medical Devices' device candidates. If we or Rafael Medical Devices are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or they are not able to maintain regulatory compliance as a result of a changing regulatory landscape or otherwise, we or they may be subject to enforcement action, may lose any regulatory approval(s), marketing authorization(s), or clearance(s) that we or they obtain, if any, or fail to obtain new regulatory approvals, marketing authorizations, or clearances, and we and they may not be able to achieve or sustain profitability, which would adversely affect our business, prospects, financial condition, and results of operations.

Rafael Medical Devices is dependent upon third parties for a variety of functions. These arrangements may not provide Rafael Medical Devices with the benefits they expect.

Rafael Medical Devices relies on third parties to perform a variety of functions. Rafael Medical Devices is party to numerous agreements that place substantial responsibility on clinical research organizations, contract manufacturing organizations, consultants, and other service providers for the development of Rafael Medical Devices' device candidates. Rafael Medical Devices also relies on medical and academic institutions to perform aspects of its clinical trials of device candidates. In addition, an element of Rafael Medical Devices' research and development strategy has been to in-license technology and device candidates from academic and government institutions in order to minimize or eliminate investments in early research. Rafael Medical Devices may not be able to enter new arrangements without undue delays or expenditures or on favorable terms, and these arrangements may not allow Rafael Medical Devices to compete successfully. Moreover, if third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct clinical trials in accordance with regulatory requirements or applicable protocols, Rafael Medical Devices' device candidates may not be approved, receive marketing authorization, or be cleared for marketing and commercialization or such approval, marketing authorization, or clearance may be delayed. If that occurs, Rafael Medical Devices or its collaborators will not be able, or may be delayed in their efforts, to commercialize Rafael Medical Devices' device candidates.

Product liability lawsuits against Rafael Medical Devices or their collaborators or us could cause substantial liabilities and could limit commercialization of any medical devices that Rafael Medical Devices or their collaborators may develop.

Rafael Medical Devices and their collaborators and we face an inherent risk of product liability exposure related to the testing and manufacturing of Rafael Medical Devices' device candidates in human clinical trials and will face an even greater risk if Rafael Medical Devices or they commercially sell any medical devices that Rafael Medical Devices or they may develop that secure regulatory approval, marketing authorization, or clearance. Rafael Medical Devices' device candidates are designed to affect, and any future devices will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with Rafael Medical Devices' device candidates or devices could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot assure you that we and Rafael Medical Devices will not face product liability claims. We and Rafael Medical Devices may be subject to product liability claims if Rafael Medical Devices' device candidates or devices cause, or merely appear to have caused, patient injury or death, even if such injury or death was as a result of supplies or components that are produced by third-party suppliers. Product liability claims may be brought against us by consumers, healthcare providers or others selling or otherwise coming into contact with our Rafael Medical Devices' products, among others. If Rafael Medical Devices or their collaborators, or we, cannot successfully defend themselves or ourselves against product liability claims that Rafael Medical Devices' device candidates or devices caused injuries, Rafael Medical Devices and we could incur substantial liabilities and reputational harm. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any device candidates or devices that Rafael Medical Devices may develop;
- injury to Rafael Medical Devices' 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;
- product recalls or withdrawals from the market;
- reduced resources of Rafael Medical Devices' management to pursue Rafael Medical Devices' business strategy, and diverted time and attention from executing on that strategy; and
- the inability to commercialize any devices that Rafael Medical Devices may successfully develop, if any.

Although Rafael Medical Devices and we maintain product liability and/or clinical study liability insurance coverage that they and we believe is appropriate, this insurance is subject to deductibles and coverage limitations, and it may not be adequate to cover all liabilities that Rafael Medical Devices may incur. Rafael Medical Devices' and our current product liability insurance may not continue to be available to them or us on acceptable terms, if at all. If Rafael Medical Devices or we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, they or we could be exposed to significant liabilities. We anticipate that Rafael Medical Devices will need to increase their insurance coverage as they continue to run clinical trials and if they successfully commercialize any device that receives regulatory approval, marketing authorization, or clearance. Insurance coverage in this setting is increasingly expensive. Rafael Medical Devices or we may not be able to maintain insurance coverage at a reasonable cost, if at all, or in an amount adequate to protect them or us against any product liability claim that may arise. In addition, if one of Rafael Medical Devices' 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 could potentially seek indemnification from Rafael Medical Devices, and therefore substantially limit the commercial potential of Rafael Medical Devices' device candidates. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could adversely affect our and Rafael Medical Devices' business, results of operations, and financial condition.

If Rafael Medical Devices fails 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.

Rafael Medical Devices is 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. Rafael Medical Devices' operations involve the use of hazardous materials, including chemical materials. Rafael Medical Devices' operations also produce hazardous waste products. Rafael Medical Devices generally contracts with third parties for the disposal of these materials and wastes. Rafael Medical Devices 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, Rafael Medical Devices could be held liable for any resulting damages, and any liability could exceed their resources. Rafael Medical Devices also could incur significant costs associated with civil or criminal fines and penalties.

Although Rafael Medical Devices maintains 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. Rafael Medical Devices may not maintain adequate insurance for environmental liability or toxic tort claims that may be asserted against them in connection with their storage or disposal of hazardous materials.

In addition, Rafael Medical Devices 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 Rafael Medical Devices' research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Reliance on Third Parties

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

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

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

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

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

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

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

The facilities used by contract manufacturers to manufacture product candidates or approved products must also be approved by the FDA or other comparable foreign regulatory authorities following inspections for any such approved products that generally will be conducted after the Pharmaceutical Companies or Rafael Medical Devices submit an application to the FDA or other comparable foreign regulatory authorities. Such inspections also could occur, for other products being manufactured by contract manufacturers, before the Pharmaceutical Companies or Rafael Medical Devices submit an application to the FDA or other comparable foreign regulatory authorities, and any adverse regulatory findings from such inspections could adversely impact a contract manufacturer's ability to be a contract manufacturer for the Investment Portfolio Companies. The Investment Portfolio Companies may not directly control the manufacturing process of, and may be completely dependent on, contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of product candidates and device candidates and of any products that receive regulatory approval or clearance. Beyond periodic audits, the Investment Portfolio Companies have no direct control over the ability of their contract manufacturers to maintain adequate quality control, quality assurance, and qualified personnel. Nevertheless, the Portfolio Companies are responsible for ensuring that all manufacturing is conducted in accordance with the applicable cGMP or QSR and other legal and regulatory requirements and scientific standards, and the Portfolio Companies' reliance on third parties does not relieve them of their regulatory responsibilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of any approved or cleared products or if they withdraw any approval in the future, the Investment Portfolio Companies may need to find alternative manufacturing facilities, which would require the incurrence of significant additional time and costs and materially adversely affect the ability to develop, obtain regulatory approval or clearance for or market any product candidates or device candidates, if approved or cleared. Similarly, if any third-party manufacturers on which the Pharmaceutical Companies or Rafael Medical Devices will rely fail to manufacture quantities of their product candidates or device candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows them to achieve profitability, their and our business, financial condition, and prospects could be materially and adversely affected.

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

- the Pharmaceutical Companies and Rafael Medical Devices may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited, and the FDA must inspect any manufacturers for applicable cGMP and QSR compliance as part of our the Pharmaceutical Companies' and Rafael Medical Devices' marketing applications;

- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of the Pharmaceutical Companies' product candidates and Rafael Medical Devices' device candidates;

- third-party manufacturers might be unable to timely manufacture Pharmaceutical Companies' product candidates and Rafael Medical Devices' device candidates or produce the quantity and quality required to meet their clinical and commercial needs, if any;

- contract manufacturers may not be able to execute the Pharmaceutical Companies' and Rafael Medical Devices' manufacturing procedures and other logistical support requirements appropriately;

- future contract manufacturers may not perform as agreed, may not devote sufficient resources to the Pharmaceutical Companies Companies' product candidates or Rafael Medical Devices' device candidates, or may not remain in the contract manufacturing business for the time required to supply clinical trials or to successfully produce, store, and distribute approved or cleared products, if any;

- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies and foreign regulatory authorities to ensure strict compliance with cGMP and QSR and other government regulations and corresponding foreign standards, and the Healthcare Portfolio Companies have no direct control over third-party manufacturers' compliance with these regulations and standards; standards, although the Portfolio Companies' reliance on third parties does not relieve them of their regulatory responsibilities;

- the Healthcare Portfolio Companies may not own, or may have to share, the intellectual property rights to any improvements made by any third-party manufacturers in the manufacturing process for the Pharmaceutical Companies' product candidates and Rafael Medical Devices' device candidates;

- third-party manufacturers could breach or terminate their agreements with us, the Pharmaceutical Companies or Rafael Medical Devices;

- raw materials and components used in the manufacturing process, particularly those for which the Healthcare Portfolio Companies have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;

- contract manufacturers and critical reagent suppliers may be subject to public health emergencies, inclement weather, as well as natural or man-made disasters; and

- contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and the Pharmaceutical Companies and Rafael Medical Devices will have no direct control over contract manufacturers' ability to maintain adequate quality control, quality assurance, and qualified personnel. personnel, although the Pharmaceutical Companies' and Rafael Medical Devices' reliance on third parties does not relieve them of their regulatory responsibilities.

Our The Portfolio Companies' business could be materially adversely affected by business disruptions caused by third-party providers that could materially adversely affect their and our potential future revenue and financial condition and increase their and our costs and expenses. Each of these risks could delay or prevent the completion of the Pharmaceutical Companies' and Rafael Medical Devices' clinical trials or the approval of any of the Pharmaceutical Companies' product candidates or Rafael Medical Devices' device candidates by the FDA or comparable foreign regulatory authorities, result in higher costs, or adversely impact commercialization of any product candidates in the event that they were to receive regulatory approval or clearance.

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

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

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

Further, collaborations involving our the Portfolio Companies' product candidates and device candidates are subject to numerous risks, which may include the following:

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

- a collaborator with marketing and distribution rights to one or more product candidates or device candidates may not commit sufficient resources to their marketing and distribution in the event that they were to receive regulatory approval or clearance;

- collaborators may not properly maintain or defend our or the Portfolio Companies' intellectual property rights or may use our or their intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our or their intellectual property or proprietary information or expose us or them to potential liability;

- disputes may arise between us and/or the Portfolio Companies and a collaborator that cause the delay or termination of the research, development or commercialization of a product candidate or device candidate, or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates or device candidates; and

- collaborators may own or co-own intellectual property covering our or the Portfolio Companies' products that results from our or their collaborating with them, and in such cases, we and they would not have the exclusive right to commercialize such intellectual property.

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

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

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

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

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

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

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

- new regulations adopted by the Securities and Exchange Commission, or SEC, effective December 18, 2023, that require greater disclosure regarding cybersecurity risk management, strategy and governance, as well as disclosure of material cybersecurity incidents, which may require reporting of a cybersecurity incident before its impact has been fully assessed or the underlying issue has been remediated, which could divert management's attention from incident response and could potentially reveal system vulnerabilities to threat actors, and for which failure to timely report such incidents under these or other similar rules could also result in monetary fines, sanctions or other forms of liability.
- analogous state data privacy and security laws and regulations that govern the collection, use, disclosure, transfer, storage, disposal, and protection of personal information, such as social security numbers, medical and financial information, and other information, including data breach laws that require timely notification to individuals, and at times regulators, the media or credit reporting agencies, if a company has experienced the unauthorized access or acquisition of personal information, as well as the California Consumer Privacy Act or CCPA, which, among other things, contains new disclosure obligations for businesses that collect personal information about California residents and affords those individuals numerous rights relating to their personal information that may affect companies' ability to use personal information or share it with business partners, and the California Privacy Rights Act, or CPRA, which expands the scope of the CCPA, imposes new restrictions on behavioral advertising, and establishes a new California Privacy Protection Agency that will enforce the law and issue regulations, and is scheduled to become became "operative" on January 1, 2023, with a 12-month "lookback provision," provision" applicable to personal data collected on or after January 1, 2022, and the various state laws and regulations may be more restrictive and not preempted by United States federal laws;

- analogous foreign data protection laws, including among others the EU General Data Protection Regulation, or the GDPR, and EU member states' implementing legislation, and the UK GDPR, which imposes data protection requirements that include strict obligations and restrictions on the ability to collect, analyze, and transfer EU EEA or UK personal data, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances, and possible substantial fines for any violations (including possible fines for certain violations of up to the greater of 20 million Euros or 4% of total worldwide annual turnover of the preceding financial year), with legal requirements in foreign countries relating to the collection, storage, processing, and transfer of personal data continuing to evolve; evolve and varying widely across jurisdictions; and

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

The Investment Portfolio Companies may also be subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope. scope and vary significantly from the federal laws. For example, we they may be subject to the following: state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, or that apply regardless of payor; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug and device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing; state and local laws requiring the registration of pharmaceutical and device sales and medical representatives; and state and foreign laws, such as the GDPR governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Additionally, we they may be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our the Portfolio Companies' business activities, or our their arrangements with physicians, could be subject to challenge under one or more of such laws. It is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we and the Portfolio Companies take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us or them from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our and their business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our or their business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If the Pharmaceutical Companies or Rafael Medical Devices or their respective employees, independent contractors, consultants, commercial partners, and vendors violate these laws, they and we may be subject to investigations, enforcement actions and/or significant penalties, including the imposition of significant civil, criminal, and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if they or we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of the Pharmaceutical Companies' and Rafael Medical Devices' operations, any of which could adversely affect their ability to operate their business and their and our results of operations. In addition, the approval or clearance, if any, and commercialization of any of the Pharmaceutical Companies' product candidates or Rafael Medical Devices' device candidates outside the United States will also likely subject them and us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Risks Related to our Commercial Real Estate Business

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 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. There are number of competitive office properties the areas in which our property is located, which may be newer or better located than our property and could have a material adverse effect on our ability to lease office space at our property, and on the effective rents we are able to charge.

Risks Related to Intellectual Property

If we or the companies in which we hold interests are unable to adequately maintain or protect their our proprietary technology and product candidates and device candidates and services, if the scope of the patent protection obtained is not sufficiently broad, or if the terms of patents are insufficient to protect product candidates, device candidates, services or technologies for an adequate amount of time, competitors could develop and commercialize technology and products similar or identical to that technology or those product candidates, device candidates and the services, and our ability to successfully commercialize technology or product candidates, device candidates or services may be materially impaired.

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

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

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

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

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

Third parties may challenge any existing patent or future patent we own that is owned or license licensed by us through adversarial proceedings in the issuing offices or in court proceedings, including as a response to any assertion of our patents against them. In any of these proceedings, a court or agency with jurisdiction may find our patents invalid and/or unenforceable, or, even if valid and enforceable, insufficient to provide protection against competing products and services sufficient to achieve our business objectives. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or reexamination by the USPTO if a third party asserts a substantial question of patentability against any claim of a U.S. patent we own or license. The adoption of the Leahy-Smith America Invents Act, or the Leahy-Smith Act, in September 2011 established additional opportunities for third parties to invalidate U.S. patent claims, including inter partes review and post-grant review proceedings. Outside of the United States, patents we own or license may become subject to patent opposition or similar proceedings, which may result in loss of scope of some claims or the entire patent. In addition, such proceedings are very complex and expensive and may divert our management's attention from our core business. If any of our patents are challenged, invalidated, or circumvented by third parties or otherwise limited or expire prior to the commercialization of our products, services or technologies, and if we do not own or have exclusive rights to other enforceable patents protecting our products, services or other technologies, competitors and other third parties could market products and use processes that are substantially similar, or superior, to ours and theirs, and our business would suffer.

The entities in which we hold interests or in which we may invest may not make necessary payments or take other actions to protect intellectual property or other rights that they own, license or have acquired from third parties, which could result in the loss or impairment of those rights and the reduction of the value of our interests.

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

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

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

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

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

We and the companies in which we hold interests may not be able to prevent, alone or with our licensees or any future licensors, infringement, misappropriation or other violations of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us or them alleging that we infringe their patents. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party or a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. candidates or device candidates, services or technologies. Such a loss of patent protection could harm our business. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from exploiting the claimed subject matter at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from exploiting its technology on the grounds that our patents do not cover such technology. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making, using, importing, and selling similar or competitive products. products, services, or technologies. Any of these occurrences could adversely affect our competitive business position, business prospects, and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question or has not infringed them. In this case, we could ultimately be forced to cease use of such trademarks.

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

Our commercial success and that of the companies in which we hold interests depends significantly on our ability to operate without infringing upon the intellectual property rights of third parties.

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

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

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

- we or and our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our product candidates, device candidates, or processes do not infringe those third parties' patents;

- we or and our collaborators may participate at substantial cost in International Trade Commission proceedings to abate importation of third-party products that would compete unfairly with our products;

- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;

- if third parties initiate litigation claiming that our processes or product candidates or those of the companies in which we hold interests, infringe their patent or other intellectual property rights, we, they and our collaborators will need to defend against such proceedings;

- if third parties initiate litigation or other proceedings, including inter partes reviews, oppositions or other similar agency proceedings, seeking to invalidate patents owned by or licensed to us or the companies in which we hold interests, or to obtain a declaratory judgment that their products, services, or technologies do not infringe our patents or patents licensed to us or them, we will need to defend against such proceedings;

- we may be subject to ownership disputes relating to intellectual property, including disputes arising from conflicting obligations of consultants or others who are involved in developing our product candidate; and

- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or product candidates or those of the companies in which we hold interests infringe or misappropriate its patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

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

- incur substantial monetary liability for infringement or other violations of intellectual property rights, which we may have to pay if a court decides that the product candidate, service, or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay up to treble damages and the third party's attorneys' fees;

- pay substantial damages to our customers or end users and those of the companies in which we hold interests to discontinue use or replace infringing technology with non-infringing technology;

- stop manufacturing, offering for sale, selling, using, importing, exporting or licensing the product or technology incorporating the allegedly infringing technology or stop incorporating the allegedly infringing technology into such product, service, or technology;

- obtain from the owner of the infringed intellectual property right a license, which may require us to pay substantial upfront fees or royalties to sell or use the relevant technology and which may not be available on commercially reasonable terms, or at all;

- redesign our product candidates, services, and technology and those of the companies in which we hold interests so they do not infringe or violate the third party's intellectual property rights, which may not be possible or may require substantial monetary expenditures and time;

- enter into cross-licenses with our competitors and those of the companies in which we hold interests, which could weaken our overall intellectual property position;
- lose the opportunity to license our technology that of the companies in which we hold interests to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others;
- find alternative suppliers for non-infringing products and technologies, which could be costly and create significant delay; or
- relinquish rights associated with one or more of our patent claims or those of the companies in which we hold interests, if our those claims are held invalid or otherwise unenforceable

Some of our competitors and those of the companies in which we hold interests may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they those competitors have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us or them from manufacturing, marketing or otherwise commercializing our products, services, and technology. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information and that of the companies in which we hold interests could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a material adverse effect on the price of our common stock. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. The occurrence of any of these events may have a material adverse effect on our business, results of operation, financial condition or cash flows.

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

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

Changes in patent law could diminish the value of patents in general, thereby impairing our the ability of us and the companies in which we hold interests to protect our respective existing and future product candidates, device candidates and processes.

As is the case with other biopharmaceutical companies, our success and that of the companies in which we hold interests is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industries industry involves both technological and legal complexity, and is therefore costly, time consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith Act was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switched the United States patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had conceived or reduced to practice the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

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

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

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

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection and that of the companies in which we hold interests could be reduced or eliminated for non-compliance with these requirements.

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

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

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

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

We and the companies in which we hold interests may not be able to adequately protect our intellectual property rights throughout the world.

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

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

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

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

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

Patent terms may be inadequate to protect our competitive position and that of the companies in which we hold interests on our product candidates or device candidates for an adequate amount of time.

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

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

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

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

- others may be able to develop and/or practice technology processes or technologies that is are similar to our technology processes or technologies or aspects of our technology, processes or technologies, but that are not covered by the claims of the patents that we own or control, assuming such patents have issued or do issue;

- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;

- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;

- others may independently develop similar or alternative processes or technologies or duplicate any of our processes or technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our product candidates or device candidates, including our processes and technologies, could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may have an adverse effect on our business.

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

We and the companies in which we hold interests may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

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

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

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

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

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

We and the companies in which we hold interests may not be successful in obtaining necessary intellectual property rights to future products through acquisitions and in-licenses.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Similar impacts could be experienced by Rafael Medical Devices in response to the COVID-19 pandemic, subsequent variants or comparable public health emergencies.
We have implemented a number of measures to protect the health and safety of our workforce, including a mandatory work-from-home policy for our workforce who can perform their jobs from home as well as restrictions on business travel and workplace and in-person meetings. We will maintain these as necessary and appropriate in response to the COVID-19 pandemic, subsequent variants or comparable public health emergencies.

As a result of the COVID-19 pandemic, subsequent variants or comparable public health emergencies, we and the Pharmaceutical Companies and Rafael Medical Devices may experience further disruptions that could severely impact our or their business, preclinical studies, and clinical trials, including:

- difficulties or delays in initiating, enrolling, conducting or completing any planned and ongoing nonclinical and preclinical studies and clinical trials;
- delays in receiving approval from local regulatory authorities to initiate our the Pharmaceutical Companies' and Rafael Medical Devices' planned clinical trials;
- delays or difficulties in enrolling patients in our the Pharmaceutical Companies' and Rafael Medical Devices' clinical trials;
- limits or halts imposed on clinical trials and clinical trial sites, including hospitals and medical centers, among others;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of the Pharmaceutical Companies' and Rafael Medical Devices' clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- risk that participants enrolled in our clinical trials or staff involved in or related staff to clinical trials will acquire COVID-19 or subsequent variants while the clinical trial is ongoing, which could impact the duration and results of the clinical trial, including by increasing the number of observed adverse events;

- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;

- prolonged government shutdowns or global health concerns preventing the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities;

- interruption or delays in the operations of the FDA, which may impact review and approval timelines;

- interruption of, or delays in receiving, supplies of our the Pharmaceutical Companies' product candidates and Rafael Medical Devices' device candidates from our their contract manufacturing organizations due to staffing or supply shortages, production slowdowns, global shipping delays or stoppages and disruptions in delivery systems;

- limitations on employee resources that would otherwise be focused on the conduct of our the Pharmaceutical Companies' and Rafael Medical Devices' preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;

- refusal of the FDA or comparable foreign regulatory authorities to accept data from clinical trials in affected geographies;

- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our, the Pharmaceutical Companies' and Rafael Medical Devices' business continuity plans; and

- delays or difficulties with equity offerings due to disruptions and uncertainties in the securities market.

Any inability by the Pharmaceutical Companies or Rafael Medical Devices to successfully initiate or complete nonclinical and preclinical studies or clinical trials could result in additional costs or impair our ability to generate revenue from future product sales of any product candidates or device candidates that were thought to be on track to receive regulatory approval or clearance.

The COVID-19 pandemic, subsequent variants or comparable public health emergencies could also negatively impact our real estate business in a number of ways, including:

- the financial condition of our tenants and their ability or willingness to pay rent in full on a timely basis;

- the impact on rents and demand for office and retail space;

- a complete or partial closure of operations resulting from government action;

- the impact of new regulations or norms on physical space needs and expectations;

- the effectiveness of governmental measures aimed at slowing and containing the spread;

- the extent and terms associated with governmental relief programs;

- the ability of debt and equity markets to function and provide liquidity;

- the ability to avoid delays or cost increases associated with building materials or construction services necessary for development, redevelopment and tenant improvements; and

- our tenants' ability to ensure business continuity in the event a continuity of operations plan is not effective or improperly implemented.

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

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and to disclose any changes and material weaknesses in those internal controls. A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

We cannot be certain that we will continue to maintain an effective system of internal controls over our financial reporting in future periods. Any failure to maintain such internal controls could adversely impact our ability to report our financial results on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis as required by the Securities and Exchange Commission and The New York Stock Exchange, we could face severe consequences from those authorities. In either case, there could result a material adverse effect on our business. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We have identified material weaknesses in our internal controls over financial reporting.

Maintaining effective internal controls over financial reporting is necessary for us to produce reliable financial statements.

In the past, we have identified material weaknesses in our internal controls over financial reporting which have since been remediated.

If additional material weaknesses in our internal controls over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results.

Conditions in Israel, including the recent terrorist attack by ongoing war between Israel and Hamas, and other terrorist organizations from conflicts in the Gaza Strip and Israel's war against them, region, may adversely affect our real estate holding and operations of our Investment Portfolio Companies, which would lead to a decrease in revenues.

On October 7, 2023, In October 2023, Hamas terrorists and members of other terrorist organizations infiltrated Israel's southern border from the Gaza Strip and conducted a series of terror attacks on civilian and military targets. Thereafter, these terrorists Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along the Israeli Israel's border with the Gaza Strip. Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers, as well as evacuations of tens of thousands of civilians from their homes. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Furthermore, hostilities along Israel's northern border with Hezbollah located in Lebanon and Iran have accelerated, and each of these clashes may escalate in the future into a greater regional conflict.

It The intensity and duration of Israel's current war against Hamas is possible that other terrorist organizations will join difficult to predict, as are such war's economic implications on our business and operations and on Israel's economy in general. These events may be intertwined with wider macroeconomic indications of a deterioration of Israel's economic standing, for instance, a downgrade in Israel's credit rating by rating agencies (such as the hostilities recent downgrade by Moody's of its credit rating of Israel from A1 to A2, as well including Hezbollah in Lebanon, as the downgrade of its outlook rating from "stable" to "negative" and Palestinian military organizations in the West Bank. S&P Global lowered its long-term credit rating from AA- to A+, as well as a downgrade of its short-term credit ratings from A-1+ to A-1, with an outlook on the long-term ratings "negative", as well as the recent downgrade by Fitch Ratings of its credit rating of Israel from A+ to A, with an outlook rating of "negative"). which may have a material adverse effect on our company and our ability to effectively conduct its operations.

Our real estate holding in Jerusalem and operations of Lipomedix LipoMedix and Day Three in Jerusalem and Rosh Haayin, respectively, are not only within the range of rockets from the Gaza Strip, but also within the range of rockets that can be fired from Lebanon, Syria or elsewhere in the Middle East. Our lone real estate holding can be damaged as a result of hostile action or hostilities or the ongoing operations of Lipomedix LipoMedix and Day Three may be disrupted.

Our commercial insurance does not cover losses that may occur as a result of events associated with war and terrorism. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained or that it will sufficiently cover our potential damages. Any losses or damages incurred by us could have a material adverse effect on our business.

As a result of the Israeli security cabinet's decision to declare war against Hamas, several hundred thousand Israeli reservists were drafted to perform immediate military service. Certain of our employees and consultants in Israel, in addition to employees of our service providers located in Israel, have been called for service in the current war with Hamas as of the date of this registration statement, annual report, and such persons are expected may be absent for an extended period of time. As a result, operations of Lipomedix LipoMedix and Day Three may be disrupted by such absences, which may materially and adversely affect their business and results of operations.

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

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

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

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

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

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and, during certain periods, including currently, we may utilize alternatives for such coverage, accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security cybersecurity incidents, could harm our ability to operate our business and that of the companies in which we hold interests effectively.

We and the Portfolio Companies and our and their other third-party vendors and collaborators receive, collect, process, use and store a large amount of information, including personal information, intellectual property, protected health and other sensitive and confidential information. This data is often accessed through transmissions over public and private networks, including the internet. The secure transmission of such information over the internet and other mechanisms is essential to maintain confidence in our and their information technology systems yet is vulnerable to unauthorized access and disclosure. We have implemented security measures, technical controls and contractual precautions designed to identify, detect and prevent unauthorized access, alteration, use or disclosure of data. We may face increased cybersecurity risks due to our reliance on internet technology and the number of employees who are working remotely, which may create additional opportunities to exploit vulnerabilities. Beyond external activity, systems that access or control access to services and databases may be compromised as a result of human error, fraud or malice on the part of employees or third parties, or may result from accidental technological failure. Because the techniques used to circumvent security systems can be highly sophisticated and change frequently, often are not recognized until launched against a target, and may originate from less regulated and remote areas around the world, we may be unable to proactively address all possible threats or implement adequate preventive measures for all situations.

Despite the implementation of security measures, our and the Investment Portfolio Companies' internal computer systems and those of other third parties with which we and the Investment Portfolio Companies collaborate and contract are vulnerable to attempted breaches of security, unauthorized disclosure of information, attacks which reduce availability of systems such as denial of service, damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. failures, and the perception that personal and/or other sensitive or confidential information in our possession is not secure. System failures, accidents or security breaches could cause interruptions in our and the Investment Portfolio Companies' operations and could result in a material disruption of our and 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 inf in the Investment Portfolio Companies' regulatory approval and clearance efforts and significantly increase their costs to recover or reproduce the data. data and pursue regulatory approval or clearance. To the extent that any disruption or security breach were to result in a loss of, or damage to, our or the Investment Portfolio Companies' data or applications, or inappropriate disclosure of confidential or proprietary information, we and the Investment Portfolio Companies could incur substantial legal liability or significant harm to our reputation, and our and their product research, development, and commercialization efforts could be delayed.

We face risks related to the protection of information that we maintain—or for which a third-party engaged to maintain information security on our behalf— including unauthorized access, acquisition, use, disclosure, or modification of such information. Cyberattacks are increasing in their frequency, sophistication and intensity and have become increasingly difficult to detect and respond to. Cyberattacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. The techniques used in these attacks change frequently and may be difficult to detect for periods of time, and we may face difficulties in anticipating and implementing adequate preventative measures. A material cyberattack or security incident could cause interruptions in our or their operations and could result in a material disruption of our or their business operations, damage to our or their reputation, financial condition, results of operations, cash flows and prospects.

Furthermore, we, the Portfolio Companies and our third-party providers and business partners rely on electronic communications and information systems to conduct our operations. We and our third-party providers have been, and may continue to be, targeted by parties using fraudulent e-mails and other communications in attempts to misappropriate bank accounting information, passwords, or other personal information or to introduce viruses or other malware to our information systems. In October 2021, we experienced a cybersecurity incident where a related party's email was hacked which led to payment of two invoices. As of the date of this filing, one of the invoice payments had been recovered by the Company. We continue to explore a range of steps to enhance our security protections and prevent future unauthorized activity.

Although we endeavor to mitigate these threats, such cyber-attacks against us, the Portfolio Companies or our third-party providers and business partners remain a serious issue. The pervasiveness of cybersecurity incidents in general and the risks of cyber-crime are complex and continue to evolve. Although we are making significant efforts to maintain the security and integrity of our information systems and are exploring various measures to manage the risk of a security breach or disruption, there can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions would not be successful or damaging.

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

FailureRisks Related to complete the merger Merger with Cyclo

The Exchange Ratio used in the Merger will be determined in accordance with a formula and is not yet knowable. The actual Exchange Ratio could subject be materially different than currently anticipated.

At the First Effective Time (as defined in the Notes to the consolidated financial statements), outstanding shares of Cyclo Common Stock will be automatically cancelled and retired and cease to exist, and will entitle a holder of shares of Cyclo common stock to receive shares of our Class B Common Stock in exchange for the holder's Cyclo Common Stock equal to the Exchange Ratio. The Merger Agreement contains an illustration of the calculation of the Exchange Ratio based on the assumptions described therein. Those assumptions will likely not reflect the actual metrics as of the Closing. The actual Exchange Ratio will be based upon a price for Cyclo common stock of $.95 per share and the sum of (i) our cash, cash equivalents and marketable securities as of the Closing Date, (ii) certain other of our assets and (iii) the amounts loaned by us to litigation. Cyclo prior to closing of the Merger, less our current liabilities, divided by the total number of shares of our capital stock outstanding as of the Closing Date, including any shares issuable upon exercise or conversion of our outstanding securities with exercise or conversion prices not exceeding 150% of the then-current market price of our Class B Common Stock issued to Cyclo stockholders. Accordingly, the Exchange Ratio could be significantly higher or lower than in the illustration provided. This will impact the value of the deal to the Cyclo stockholders and the number of shares of our Class B Common Stock to be issued to the Cyclo stockholders.

Uncertainty about the Merger may adversely affect our business and stock price whether or not the Merger is completed.

We are subject to risks in connection with the announcement and pendency of the Merger, including the pendency and outcome of any legal proceedings against us, our directors and others relating to the Merger and the risks from possibly foregoing opportunities we might otherwise pursue absent the proposed Merger.

In addition, in response to the announcement of the proposed Merger, our existing or prospective suppliers or collaboration partners may:

- delay, defer or cease providing goods or services to us;
- delay or defer other decisions concerning us, or refuse to extend credit terms to us;
- cease further joint development activities; or
- otherwise seek to change the terms on which they do business with us.

While we are attempting to address these risks, our existing and prospective customers, suppliers or collaboration partners may be reluctant to purchase our products, supply us with goods and services or continue collaborations due to the potential uncertainty about the direction of our product offerings and the support and service of our products after the completion of the Merger.

While the Merger is pending, we are subject to contractual restrictions that could harm our business, operating results, and stock price.

The Merger Agreement includes restrictions on our conduct prior to the completion of the Merger, generally requiring us to conduct our businesses in the ordinary course, consistent with past practice, and restricting us from taking certain specified actions absent prior written consent from the other party. We may find that these and other obligations in the Merger Agreement may delay or prevent us from or limit our ability to respond effectively to competitive pressures, industry developments and future business opportunities that may arise during such period, even if our management or Board think they may be advisable. The Merger Agreement also contains restrictions on the conduct of our business prior to the completion of the Merger, prohibiting our ability to acquire another business or restructure, reorganize or completely or partially liquidate absent the other's prior written consent. These restrictions could adversely impact our business, operating results and stock price and the perceived acquisition value, regardless of whether the Merger is completed.

The Merger will involve substantial costs.

We have incurred and expect to continue to incur substantial costs and expenses relating to the Merger and the issuance of our Class B common stock in connection with the Merger, including, as applicable, fees and expenses payable to financial advisors, other professional fees and expenses, insurance premium costs, SEC filing fees, printing and mailing costs and other transaction-related costs, fees and expenses. We may also incur significant costs relating to the acquisition of Cyclo, including the payment to certain holders of Cyclo's warrants who have the right to elect to receive cash payment as a result of the Merger as well as ongoing liabilities of Cyclo that remain in the business after the Merger is completed. We continue to assess the magnitude of these costs, and additional unanticipated costs may be incurred in connection with the Merger. In addition, if the Merger is not completed, we will have incurred substantial expenses for which no ultimate benefit will have been received by either company.

We will incur significant transaction and Merger-related transaction costs in connection with the Merger.

We expect that we will incur significant, non-recurring and operating costs in connection with consummating the Merger and funding the operations of Cyclo during the pendency of the Merger and post-closing. We will also incur additional costs to retain key employees of Cyclo under employee agreements with the merged company. We will also incur significant fees and expenses relating to legal services (including any costs that would be incurred in defending against any potential class action lawsuits and derivative lawsuits in connection with the Merger if any such proceedings are brought), accounting and other fees and costs associated with consummating the Merger. We will also incur costs in connection with the payment to certain holders of Cyclo Warrants as a result of the Merger. Some of these costs are payable regardless of whether the Merger is completed. We continue to assess the magnitude of these costs, additional unanticipated costs may be incurred in the Merger and the operation of the business of Cyclo following the Merger.

We or Cyclo may waive one or more of the closing conditions to the Merger without re-soliciting approval from our respective stockholders.

To the extent permitted by law, we or Cyclo may determine to waive, in whole or part, one or more of the conditions to our or their respective obligations to consummate the Merger. We and Cyclo expect to evaluate the materiality of any waiver and its effect on Cyclo or our stockholders in light of the facts and circumstances at the time to determine whether any amendment the Registration Statement or any re-solicitation of proxies is required in light of such waiver. Any determination as to whether to waive any condition to the consummation of the Merger, and as to whether to re-solicit the stockholders' approval as a result of such waiver, will be made by us and Cyclo at the time of such waiver based on the facts and circumstances as they exist at that time.

We may be targets of securities class action and derivative lawsuits which could result in substantial costs and may delay or prevent the Merger from being completed.
Securities class action lawsuits and derivative lawsuits are often brought against public companies that have entered into merger agreements. Even if the lawsuits are without merit, defending against these claims could result in substantial costs and divert management time and resources. An adverse judgment could result in monetary damages, which could have a negative impact on our liquidity and financial condition. Additionally, if a plaintiff is successful in obtaining an injunction prohibiting completion of the Merger, then that injunction may delay or prevent the Merger from being completed, or from being completed within the expected timeframe, which may adversely affect our business, financial position and results of operations.
Changes in the market prices of our Class B Common Stock may result from a variety of factors that are beyond our control.
The market value of our Class B Common Stock has fluctuated since the date of the announcement of the Merger and will continue to fluctuate to the Closing Date and following the completion of the Merger. The market value of our Class B Common Stock at the time of the closing of the Merger may vary significantly from the price of our Class B Common Stock on the date of the Merger Agreement, the date of the Registration Statement or the date of our Special Meeting. Changes in the market prices of our Class B Common Stock may result from a variety of factors that are beyond our control, including changes in our business, operations and prospects, general market conditions, regulatory considerations, governmental actions, and legal proceedings and developments.
We may not realize the anticipated benefits and cost savings of the Merger.
While we will continue to operate independently following the completion of the merger, the success of the merger will depend, in part, on our ability to realize the anticipated benefits and cost savings from Cyclo's businesses as a wholly owned subsidiary of ours following the Merger. Our ability to realize these anticipated benefits and cost savings is subject to certain risks, including, among others:

- our ability to successfully operate the businesses following the closing of the Merger;
- the risk that our businesses will not perform as expected;
- the extent to which we will be able to realize the expected synergies, which include realizing potential savings from eliminating duplication and redundancy in overhead, adopting an optimized operating model between our company and Cyclo's company and leveraging scale, our funding the merged company following the completion of the Merger, and creating value resulting from the Merger;
- the reduction of cash available for operations and other uses by us;
- the possibility of costly litigation challenging the Merger.

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

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

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

- We may experience negative reactions from the financial markets, including negative impacts on trading prices of our Class B Common Stock and from our customers, vendors, regulators and employees;
- We may be required to pay certain expenses incurred in connection with the Merger, whether or not the Merger is completed including the payment of up to $250,000 of expenses of the other party in certain circumstances involving a breach of the representations, warranties and covenants in the Merger Agreement;
- the Merger Agreement places certain restrictions on the operation of our business prior to the closing of the Merger, and such restrictions, the waiver of which is subject to the consent of Cyclo, may prevent us from making certain acquisitions, taking certain other specified actions or otherwise pursuing business opportunities during the pendency of the Merger that we would have made, taken or pursued if these restrictions were not in place; and
- matters relating to the Merger will require substantial commitments of time and resources by our management and the expenditure of significant funds in the form of fees and expenses, which would otherwise have been devoted to day-to-day operations and other opportunities that may have been beneficial to us.

In addition, we could be subject to litigation related to any failure to complete the proposed merger with Cornerstone Merger or related to any proceeding to specifically enforce our obligations under the merger agreement. Merger Agreement. If any of these risks materialize, they may materially and adversely affect our business, financial condition, financial results and stock prices.

Third parties may terminate or alter existing contracts or relationships with us.

We have contracts with customers, vendors and other business partners which may require us, as applicable to obtain consents from these other parties in connection with the Merger. If these consents cannot be obtained, the counterparties to these contracts and other third parties with which we currently have relationships may have the ability to terminate, reduce the scope of or otherwise materially adversely alter their relationships with us in anticipation of the Merger, or with us following the Merger. The pursuit of such rights may result in our suffering additional losses, a loss of potential future revenue, incurring liabilities in connection with a breach of such agreements or losing rights that are material to our business. Any such disruptions could limit our ability to achieve the anticipated benefits of the Merger. The adverse affect of such disruptions could also be exacerbated by a delay in the completion of the Merger or the termination of the Merger.

The NYSE may not list our shares of Class B Common Stock, which could limit investors' ability to make transactions in the shares of our Class B Common Stock and subject our Class B Common Stock to additional trading restrictions.

In connection with the Merger, in order to continue to maintain the listing of our Class B Common Stock on the NYSE, we will be required to demonstrate compliance with the NYSE's listing requirements. We will use reasonable best efforts to cause the shares of our Class B Common Stock issuable, and required to be reserved for issuance, in connection with the Merger to be approved for listing on the NYSE, subject to official notice of issuance, prior to the Closing. We cannot provide assurance that we will be able to meet all listing requirements. Even if the shares of our Class B Common Stock are listed on the NYSE, we may be unable to maintain the listing of our securities in the future.

If we fail to meet the listing requirements and the NYSE does not list our securities on its exchange, Cyclo would not be required to consummate the Merger. In the event that Cyclo elected to waive this condition, and the Merger was consummated without our securities being listed on the NYSE or on another national securities exchange, we would face significant material adverse consequences, including:

- a limited availability of market quotations for our Class B Common Stock;
- reduced liquidity for our Class B Common Stock;
- a determination that the shares of our Class B Common Stock are a "penny stock" which will require brokers trading in our Class B Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our Class B Common Stock;
- a limited amount of news and analyst coverage; and;
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or pre-empts the states from regulating the sale of certain securities, which are referred to as "covered securities" If the shares of our Class B Common Stock are not listed on the NYSE, such securities would not qualify as covered securities and we would be subject to regulation in each state in which we offer our securities because states are not pre-empted from regulating the sale of securities that are not covered securities.

Risks Related to Ownership of our Common Stock

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

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

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 Executive Chairman, controls a majority of the voting power of our capital stock. As of October 27, 2023 October 29, 2024, 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 665,247 821,374 shares of our Class B common stock, representing approximately 51% 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.

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

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

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

We are considered a "smaller reporting company." We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock prices may be more volatile.

General Risk Factors

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

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

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

Investors may suffer dilution.

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

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

Our stock price is likely to remain volatile. The stock market in general and the market for Investment the Portfolio 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 healthcare industries;
- announcements by us or our competitors of preliminary or interim data from or the results of clinical trials, new product or service offerings, or significant acquisitions;
- strategic collaborations or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- additions or departures of key personnel; and
- sales of our common stock, including sales by our directors and officers or specific stockholders. In addition, in the past, stockholders have initiated class action lawsuits against companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources

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

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

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

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

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

Item 1B. Unresolved Staff Comments. Comments

None.

Item 1C. Cybersecurity

Cybersecurity risk management and strategy

Our cybersecurity risk management is based on recognized cybersecurity industry frameworks and standards, including those of the National Institute of Standards and Technology, the Center for Internet Security Controls, and the International Organization for Standardization. We use these frameworks, together with information collected from internal assessments, to develop policies for the use of our information assets (for example, TI business information and information resources such as mobile phones, computers and workstations), access to specific intellectual property or technologies, and protection of personal information. We protect these information assets through industry-standard techniques, such as multifactor authentication and malware defenses. We also work with internal stakeholders across the company to integrate foundational cybersecurity principles throughout our organization's operations, including the employment of multiple layers of cybersecurity defenses, restricted access based on business needs, and integrity of our business information. Throughout the year, we also regularly train our employees on cybersecurity awareness, confidential information protection and simulated phishing attacks.

Our cybersecurity risk management extends to risks associated with our use of third-party service providers. For instance, we conduct risk and compliance assessments of third-party service providers that request access to our information assets.
Our cybersecurity risk management is an important part of our comprehensive business continuity program and enterprise risk management. Our global information security team periodically engages with a cross-functional group of subject matter experts and leaders to assess and refine our cybersecurity risk posture and preparedness. For example, we regularly evaluate and update contingency strategies for our business in the event that a portion of our information resources were to be unavailable due to a cybersecurity incident. We practice our response to potential cybersecurity incidents through regular tabletop exercises, threat hunting and red team exercises.
Governance of cybersecurity risk management
The board of directors, as a whole, has oversight responsibility for our strategic and operational risks. The audit committee assists the board of directors with this responsibility by reviewing and discussing our risk assessment and risk management practices, including cybersecurity risks, with members of management. The audit committee, in turn, periodically reports on its review with the board of directors.
Management is responsible for day-to-day assessment and management of cybersecurity risks and reports regularly to the audit committee.
Item 2. Properties. 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 Nano-Oncology research center either directly from LipoMedix or indirectly through the Israel Innovation Authority Fund (Israel Chief Scientist Office). This arrangement has been in place since 2012, and the grant support is negotiable and renewed on an annual basis. However, there can be no guarantees that Shaare Zedek will continue this agreement in the future.

LipoMedix leased an administrative office in Giv'at Ram Hi-Tech Park from the Hebrew University. Rent was $3,600 annually, and the lease agreement ran through September 30, 2022.
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

Legal proceedings disclosure is presented in Note 19 21 to our Consolidated Financial Statements and included in Item 8 to Part II of this Annual Report.

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. Disclosures

Not applicable.

Part II

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

PRICE RANGE OF COMMON STOCK

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

On October 27, 2023 November 5, 2024, there were 262 249 holders of record of our Class B common stock and one holder of record of our Class A common stock. Howard Jonas has voting and dispositive power over all shares of Class A common stock. 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 27, 2023 November 5, 2024, the last sales price reported on the NYSE for the Class B common stock was $1.55 $1.81 per share.

We do not anticipate paying dividends on our common stock unless and 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, 2023 July 31, 2024, and which is incorporated by reference herein.

Performance Graph of Stock

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

Issuer Repurchases of Equity Securities

None.

Item 6. [Reserved].

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

FOREIGN CURRENCY RISK

Revenue from tenants located in Israel represented 44% and 53% of our consolidated revenues, inclusive of revenue from discontinued operations, for the years ended July 31, 2024 and 2023, 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. Investments in hedge funds carry a degree of risk and depend to a great extent on correct assessments of the future course of price movements of securities and other instruments. There can be no assurance that our investment managers will be able to accurately predict these price movements. The securities markets have in recent years been characterized by great volatility and unpredictability. Our passive interests in other entities are not currently liquid and we cannot assure that we will be able to liquidate them when we desire, or ever. Accordingly, the value of our investments may go down as well as up and we may not receive the amounts originally invested upon redemption.

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

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

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

Overview

Rafael Holdings, Inc. (NYSE:RFL), ("Rafael Holdings", "Rafael", "we" or the "Company"), a Delaware corporation, is a holding company with interests in clinical and early-stage pharmaceutical companies (the "Pharmaceutical Companies"), including an investment in Cornerstone Pharmaceuticals, (and planned merger with) Cyclo Therapeutics Inc. (Nasdaq: CYTH), formerly known as Rafael Pharmaceuticals Inc. ("Cyclo Therapeutics" or "Cyclo"), a cancer metabolism-based therapeutics clinical stage biotechnology company dedicated to developing Trappsol® Cyclo™, which is being evaluated in clinical trials for the potential treatment of Niemann-Pick Disease Type C1 ("NPC1"), a rare, fatal and progressive genetic disorder, a majority equity interest in LipoMedix Pharmaceuticals Ltd. ("LipoMedix"), a clinical stage pharmaceutical company, the Barer Institute Inc. ("Barer"), a wholly-owned preclinical cancer metabolism research operation, an investment and a majority interest in Cyclo Therapeutics, Cornerstone Pharmaceuticals, Inc. (Nasdaq: CYTH) ("Cyclo Therapeutics" or "Cyclo) Cornerstone"), formerly known as Rafael Pharmaceuticals Inc., a clinical-stage biotechnology company dedicated to developing life-changing medicines for patients and families living with challenging diseases through its lead therapeutic asset, Trappsol® Cyclo™., an investment in Day Three Labs, Inc. ("Day Three"), a company which reimagines existing cannabis offerings with pharmaceutical-grade technology and innovation like Unlokt™ to bring to market better, cleaner, more precise and predictable products in the cannabis industry, and cancer metabolism-based therapeutics company. We also hold a majority interest in Rafael Medical Devices, LLC, LLC. ("Rafael Medical Devices"), an orthopedic-focused medical device company developing instruments to advance minimally invasive surgeries, ("Rafael Medical Devices" and a majority interest in Day Three Labs, Inc. ("Day Three"), a company which empowers third-party manufacturers to reimagine their existing cannabis offerings enabling them to bring to market better, cleaner, more precise and predictable versions by utilizing Day Three's pharmaceutical-grade technology and innovation like Unlokt™. Day Three and Rafael Medical Devices, together with the Pharmaceutical Companies, represent our "Investment "Portfolio Companies"). In November 2022, the Company resolved to curtail its early-stage development efforts, including pre-clinical research at Barer. The decision was taken to reduce spending as the Company focuses on exploring strategic opportunities. Since then, the Company has sought partners for programs at Farber and has entered into a license agreement for one of its technologies. The Company's primary focus is to expand our investment portfolio through opportunistic and strategic investments including therapeutics, which address high unmet medical needs.

The Company holds debt and equity investments in Cornerstone, that include preferred and common equity interests and a warrant to purchase additional equity. On June 17, 2021, Upon closing of the planned merger with Cyclo, the Company entered into a merger agreement intends to acquire full ownership of Cornerstone in exchange for issuing Company Class B common stock to the other stockholders of Cornerstone ("Merger Agreement" or "Merger"). On October 28, 2021, the Company announced that the AVENGER 500 Phase 3 clinical trial for CPI-613 focus its efforts on making Trappsol® (devimistat), Cornerstone's Cyclo™ its lead product candidate, did not meet its primary endpoint of significant improvement in overall survival in patients with metastatic adenocarcinoma of the pancreas. In addition, following a pre-specified interim analysis, the independent data monitoring committee for the ARMADA 2000 Phase 3 study for devimistat recommended the trial to be stopped due to a determination that it was unlikely to achieve the primary endpoint (the "Data Events"). In light of the Data Events, the Company concluded that the prospects for CPI-613 were uncertain and fully impaired in its financial statements for the year ended July 31, 2022, the value of its loans, receivables, and investment in Cornerstone based upon its valuation of Cornerstone.

On September 24, 2021, the Company entered into a Line of Credit Loan Agreement (the "Line of Credit Agreement") with Cornerstone under which Cornerstone borrowed $25 million from the Company. Due to the Data Events, the Company recorded a full reserve on the $25 million due the Company from Cornerstone.

On February 2, 2022, the Company terminated the Merger Agreement with Cornerstone Pharmaceuticals, effective immediately, in accordance with its terms. Subsequently, on February 2, 2022, the Company withdrew its Registration Statement on Form S-4 related to the proposed Merger. clinical program.

On March 21, 2023, the Company loaned $2.0 million to Cornerstone which debt is represented by a Promissory Note made by Cornerstone (the "Promissory Note" or "Note"). The Note, which bears interest at a rate of seven and one-half percent (7.5%) per annum, was originally due and payable on May 22, 2023. On May 22, 2023, the Promissory Note was amended to extend the maturity date to November 30, 2023 and to waive any increase in the interest rate provided for in the Note, provided that the entire principal amount and all accrued interest thereon is repaid in cash or converted into equity securities of Cornerstone no later than November 30, 2023.

Cornerstone is in the process of a comprehensive restructuring transaction including, an equity investment by the Company of $1.5 million with other stockholders having the right to invest amounts on the same terms to avoid dilution, the conversion and modification of other Cornerstone debt obligations, the extension of the Cornerstone debt held by RP Finance, a reverse stock split, the conversion of all outstanding preferred stock of Cornerstone into common stock and the adoption of certain governance measures. This transaction is subject to a number of conditions which are beyond the Company's control.

In 2019, the Company established the Barer Institute Inc., an early-stage small molecule research operation focused on developing a pipeline of novel therapeutic compounds, including compounds to regulate cancer metabolism with potentially broader application in other indications beyond cancer. Barer was led by a team of scientists and academic advisors considered to be among the leading experts in cancer metabolism, chemistry, and drug development. In addition to its own internal discovery efforts, Barer pursued collaborative research agreements and in-licensing opportunities with leading scientists from top academic institutions. Farber Partners, LLC ("Farber") was formed to support agreements with Princeton University's Office of Technology Licensing for technology from the laboratory of Professor Joshua Rabinowitz, in the Department of Chemistry, Princeton University, including an exclusive worldwide license to its SHMT (serine hydroxymethyltransferase) inhibitor program. The Company also holds a majority equity interest in LipoMedix, a clinical stage oncological pharmaceutical company based in Israel. In addition, the Company has invested in other early-stage pharmaceutical ventures.

In 2016, the Company first invested in LipoMedix Pharmaceuticals Ltd. ("LipoMedix"), a clinical stage pharmaceutical company. On February 9, 2023, the Company entered into a Share Purchase Agreement with LipoMedix in which LipoMedix sold 70,000,000 ordinary shares to the Company at a price per share of $0.03 and an aggregate sale price of approximately $2.1 million. Subsequent to this transaction, the Company owns 95% of LipoMedix.

On April 7, 2023, the Company entered into a Common Stock Purchase Agreement (the "Day Three Purchase Agreement") with Day Three. Day Three is a cannabinoid ingredient manufacturer specializing in the development and commercialization of novel cannabis product solutions. Pursuant to the Day Three Purchase Agreement, the Company purchased 4,302,224 shares of common stock representing 38% of the outstanding shares of common stock of Day Three (33.333% on a fully diluted basis), for a purchase price of $3.0 million. The Company also received a warrant exercisable for 7,528,893 shares of common stock at an aggregate purchase price of $3.0 million, which expires five years from the date of issuance or earlier based on the occurrence of certain events as defined in the Day Three Purchase Agreement As of July 31, 2023, the Company had not exercised the warrant. Refer to Note 8 to our accompanying consolidated financial statements for further detail.

On May 2, 2023, the Company entered into a Securities Purchase Agreement (the "Cyclo SPA") with Cyclo. Cyclo is a clinical stage biotechnology company, whose common stock is listed on the Nasdaq Capital Market under the symbol CYTH, that develops cyclodextrin-based products for the treatment of neurodegenerative diseases. The Company purchased from Cyclo (i) 2,514,970 common shares (the "Purchased Shares") and (ii) a warrant to purchase 2,514,970 common shares with an exercise price of $0.71 per share (the "Cyclo Warrant"), at a combined purchase price equal to $0.835 per Purchased Share and Cyclo Warrant to purchase one share, for an aggregate purchase price of $2.1 million. The Cyclo Warrant is exercisable for a period of seven years from the date of issuance.

On August 1, 2023, the Company purchased an additional 4,000,000 shares of common stock (the "Cyclo II Shares"), and a warrant to purchase an additional 4,000,000 Shares (the "Cyclo II Warrant"), for an aggregate purchase price of $5,000,000. The Cyclo II Warrant has an exercise price of $1.25 per share and is exercisable until July 31, 2030. The August 1, 2023 investment increased the Company's percentage ownership of Cyclo common stock to 34%.

On October 20, 2023, the Company exercised the Cyclo Warrant to purchase 2,514,970 common shares at an exercise price of $0.71 per share, pursuant to a Securities Purchase Agreement dated October 20, 2023, and in consideration received a new warrant to purchase an additional 2,766,467 common shares at an exercise price of $0.95 per share which are exercisable for a period of four years following the issuance date (the "Cyclo III Warrant"), for an aggregate purchase price of $1,785,629.

During the fourth quarter of fiscal 2023, Rafael Medical Devices received $825 thousand as a deposit from outside third party investors for the purchase of membership units. On August 1, 2023, the Company received an additional $100 thousand. Following these investments, the Company holds 53.4% (on a fully diluted basis) of the ownership interests in Rafael Medical Devices. As of July 31, 2023, the Company recorded the funds received within prepaid expenses and other current assets and other current liabilities within the consolidated balance sheets.

Historically, the Company owned real estate assets. In 2020, the Company sold an office building located in Piscataway, New Jersey and, on August 22, 2022, the Company sold the building at 520 Broad Street in Newark, New Jersey that serves as headquarters for the Company and several tenants and an associated public garage. Currently, garage (the "520 Property"). As of July 31, 2024, the Company holds a portion of a commercial building in Jerusalem, Israel as its remaining owned real estate asset.

On July 1, 2022 In May 2023, the Company first invested in Cyclo Therapeutics. Cyclo is a clinical-stage biotechnology company that develops cyclodextrin-based products for the potential treatment of neurodegenerative diseases. Cyclo's lead drug candidate is Trappsol® Cyclo™ (hydroxypropyl beta cyclodextrin), a treatment for Niemann-Pick Disease, type C1 ("NPC1"). NPC1 is a rare and fatal autosomal recessive genetic disease resulting in disrupted cholesterol metabolism that impacts the brain, lungs, liver, spleen, and other organs. In January 2017 the FDA granted Fast Track designation to Trappsol® Cyclo™ for the treatment of NPC1. Initial patient enrollment in the U.S. Phase I study commenced in September 2017, and in May 2020 Cyclo announced Top Line data demonstrating Trappsol® Cyclo™ was well tolerated in this study. Cyclo is currently conducting a Phase III Clinical Trial Evaluating Trappsol® Cyclo™ in Pediatric and Adult Patients with Niemann-Pick Disease, Type C1. See Notes 11 and 12 to the Consolidated Financial Statements for more information on the Company's investments in Cyclo.

As discussed in more detail below, on August 21, 2024, the Company determined entered into a merger agreement with Cyclo. In the event the merger is consummated, the Company intends to fund the TransportNPC phase III clinical trial, evaluating Trappsol® Cyclo™ in Niemann Pick C, to its interim analysis in the middle of 2025 and focus its efforts on Trappsol® Cyclo™ as its lead clinical program. At that point, the 520 Property met Company will make a determination as to whether or not to file an NDA for Trappsol® Cyclo™.

LipoMedix is a clinical stage Israeli company focused on the held-for-sale criteria development of a product candidate that holds the potential to be an innovative, safe, and effective cancer therapy based on liposome delivery. As of July 31, 2024, the Company's ownership interest in LipoMedix was approximately 95%. LipoMedix has completed various clinical stages of Promitil® including Phase 1A (solid tumors) and 1B (as single agent and in combination with capecitabine and/or bevacizumab in colorectal cancer). Another phase 1B testing Promitil® as radiosensitizer is ongoing and near completion. A total of 149 patients have been treated with Promitil® as a single agent, or in combination with other anticancer drugs or radiotherapy, under the framework of a phase 1A and two 1B clinical studies and under named patient approval for compassionate use.

In 2019, the Company established Barer, a preclinical cancer metabolism research operation, to focus on developing a pipeline of novel therapeutic compounds, including compounds designed to regulate cancer metabolism with potentially broader application in other indications beyond cancer. Barer has been comprised of scientists and academic advisors that are experts in cancer metabolism, chemistry, and drug development. In addition to its own internal discovery efforts, Barer pursued collaborative research agreements and in-licensing opportunities with leading scientists from top academic institutions. Barer's majority owned subsidiary, Farber Partners, LLC ("Farber"), was formed around one such agreement with Princeton University's Office of Technology Licensing ("Princeton") for technology from the laboratory of Professor Joshua Rabinowitz, in the Department of Chemistry, Princeton University, for an exclusive worldwide license to its SHMT (serine hydroxymethyltransferase) inhibitor program. In November 2022, the Company resolved to curtail its early-stage development efforts, including pre-clinical research at Barer Institute. Since then, the Company has therefore classified the 520 Property as held-for-sale sought partners for Farber programs and has entered into a license agreement for one of its technologies.

The Company owns a 37.5% equity interest in the consolidated balance sheet at July 31, 2022. The sale RP Finance LLC ("RP Finance"), which was, until March 13, 2024 (the date of the 520 Property also represents a significant strategic shift that will have a major effect on RP Finance Consolidation, as described in Note 3 to the Company's operations Consolidated Financial Statements), accounted for under the equity method. RP Finance is an entity associated with members of the family of Howard Jonas (Executive Chairman, Chairman of the Board, and financial results. Therefore, controlling stockholder of the Company has classified the Company) which holds 37.5% equity interest of RP Finance. RP Finance holds debt and equity investments in Cornerstone. In October 2021, Cornerstone received negative results of operations related its Avenger 500 Phase 3 study for Devimistat in pancreatic cancer as well as a recommendation to stop its ARMADA 2000 Phase 3 study due to a determination that the trial would unlikely achieve its primary endpoint (the "Data Events"). Due to the 520 Property as discontinued operations Data Events, RP Finance fully impaired its then debt and equity investments in the consolidated statements Cornerstone.

On March 13, 2024, Cornerstone consummated a restructuring of operations its outstanding debt and comprehensive loss. Depreciation on the 520 Property ceased effective July 1, 2022, as equity interests (the "Cornerstone Restructuring"). As a result of the 520 Property being classified Cornerstone Restructuring, Rafael became a 67% owner of the issued and outstanding common stock of Cornerstone (the "Cornerstone Acquisition"), and Cornerstone became a consolidated subsidiary of Rafael. The Cornerstone Acquisition is accounted for as held-for-sale. an acquisition of a variable interest entity that is not a business in accordance with U.S. GAAP. The Company was determined to be the accounting acquirer for financial reporting purposes. See Note 3 to our accompanying consolidated financial statements the Consolidated Financial Statements for further additional information regarding discontinued operations. the transaction. In conjunction with the Cornerstone Restructuring and Cornerstone Acquisition, the Company reassessed its relationship with RP Finance, and as a result determined that RP Finance is still a variable interest entity and that the Company became the primary beneficiary of RP Finance as the Company now holds the ability to control repayment of the RP Finance Line of Credit which directly impacts RP Finance's economic performance. Therefore, following the Cornerstone Restructuring and Cornerstone Acquisition, the Company consolidated RP Finance (the "RP Finance Consolidation"). See Note 3 to the Consolidated Financial Statements for additional information on the Consolidation.

As of July 31, 2023, the Company's commercial real estate holdings consisted of a portion of a commercial building in Israel. On August 22, 2022, In May 2021, the Company completed the sale of the building at 520 Broad Street in Newark, New Jersey that serves as headquarters for formed Rafael Medical Devices, an orthopedic-focused medical device company developing instruments to advance minimally invasive surgeries. In August 2023, the Company raised $925,000 from third parties in exchange for a purchase price 31.6% ownership of approximately $49.4 million and realized net proceeds of approximately $33 million. Rafael Medical Devices.

In April 2023, the Company first invested in Day Three, a company which empowers third-party manufacturers to reimagine their existing cannabis offerings enabling them to bring to market better, cleaner, more precise and predictable versions by utilizing Day Three's pharmaceutical-grade technology and innovation like Unlokt™. In January 2024, the Company entered into a series of transactions with Day Three and certain shareholders, acquiring a controlling interest of Day Three and subsequently consolidating Day Three's results (the "Day Three Acquisition").

Results of Operations

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

Healthcare Segment

Our consolidated expenses for our Healthcare segment were as follows:

	Year Ended July 31,		Change	
	2023	2022	$	%
	(in thousands)			
General and administrative	$ (8,794)	$ (16,818)	8,024	48 %
Research and development	(6,312)	(8,742)	2,430	28 %
Depreciation	(15)	(3)	(12)	— %
Provision for loss on receivable from Cornerstone Pharmaceuticals pursuant to line of credit	—	(25,000)	25,000	(100)%
Provision for losses on related party receivables	—	(10,095)	10,095	(100)%
Loss from operations	$ (15,121)	$ (60,658)	45,537	75 %

	Year Ended July 31,		Change	
	2024	2023	$	%
	(in thousands)			
General and administrative	$ (8,338)	$ (8,794)	$ 456	5 %
Research and development	(3,668)	(6,312)	2,644	42 %
IPR&D expense	(89,861)	—	(89,861)	100 %
Depreciation and amortization	(165)	(15)	(150)	(1000)%
Loss from operations	$ (102,032)	$ (15,121)	$ (86,911)	(575)%

To date, the Healthcare segment has not generated any revenues. The entirety of the expenses in the Healthcare segment relate to the activities of Barer, LipoMedix, Barer, Farber, Cornerstone, and Rafael Medical Devices. As of July 31, 2023 July 31, 2024, we held a 100% interest in Barer, a 95% interest in LipoMedix, a 93% interest in Farber, a 67% interest in Cornerstone, and a 100% 68% interest in Rafael Medical Devices.

On August 1, 2023, the Rafael Medical Devices closed on the sale of membership units in exchange of for $925,000, and following that sale, the Company holds 53.4% (on a fully diluted basis) of 68% voting interest based on the outstanding equity interests in Rafael Medical Devices, on a fully-diluted basis. Devices. As of July 31, 2023, the Company recorded $825,000 of the funds received related to the sale within prepaid expenses and other current assets and other liabilities of $825,000 within the consolidated balance sheets.

General and administrative expenses. General and administrative expenses consist mainly of payroll, stock-based compensation expense, benefits, facilities, consulting and professional fees. The Company operations have been scaled to meet the current needs which has led to reduced overall general and administrative expenses. The decrease in general and administrative expenses during the year ended July 31, 2023 July 31, 2024 compared to the year ended July 31, 2022 July 31, 2023 is primarily due to comprised of a net decrease in severance insurance expense of approximately $5.0 million $0.9 million, a decrease in payroll severance pay expense of approximately $3.4 million $0.4 million, a decrease in legal expense of approximately $1.1 million, a decrease in professional licenses and fees of approximately $1.2 million $0.3, and a decrease in other general and administrative payroll expenses of approximately $0.7 million $0.2 million, partially offset by a net increase in stock-based compensation expense professional fees of approximately $3.6 million due to a material forfeiture of granted equity interests in the year ended July 31, 2022 $1.1 million.

Research and development expenses. Research and development expenses decreased for the year ended July 31, 2023 July 31, 2024 as compared to the corresponding period in fiscal 2022. year ended July 31, 2023. Research and development expenses are derived from activity at Barer, LipoMedix, Farber, Cornerstone, Day Three, and Rafael Medical Devices. In The decrease for the year ended July 31, 2024 stems from the November 2022 the Company resolved decision to curtail its the Company's early-stage development efforts, including pre-clinical research at Barer, net of increases attributable to the Barer Institute. The decision was taken to reduce spending as the Company focuses on exploring strategic opportunities.acquisitions of Cornerstone and Day Three.

Loss on line of credit. In-process research and development ("IPR&D") expenses. Due to the Data Events, in IPR&D expenses during the year ended July 31, 2022, July 31, 2024 compared to the Company recorded a full reserve on the $25 million year ended July 31, 2023 increased by $89.9 million due to the Company from Cornerstone Pharmaceuticals related Acquisition. See Note 3 to our accompanying consolidated financial statements for more information on the Line of Credit Agreement.transaction.

*Loss on related party receivables. Infusion Technology*Due to the Data Events, in

	Year Ended July 31,		Change	
	2024	2023	$	%
	(in thousands)			
Infusion Technology revenue	$ 355	$ —	$ 355	—%
Cost of Infusion Technology revenue	(154)	—	(154)	—%
General and administrative	(374)	—	(374)	—%
Research and development	(502)	—	(502)	—%
Loss from operations	$ (675)	$ —	$ (675)	—%

Infusion Technology revenue. Infusion Technology revenue increased by $355 thousand during the year ended July 31, 2022, July 31, 2024 compared to the Company recorded a loss year ended July 31, 2023 due to the acquisition of approximately $10.1 million Day Three in January 2024.

Cost of Infusion Technology revenue. Cost of Infusion Technology revenue increased by $154 thousand during the year ended July 31, 2024 compared to the year ended July 31, 2023 due to the acquisition of Day Three in January 2024. The specific costs are related to the full reserve recorded on the RP Finance receivable of $9.375 million, an equity method investment (see Note 6), supplies, materials, production labor, and a full reserve recorded on the Cornerstone Pharmaceuticals receivable, see (Note 4) of $720 thousand. travel costs.

General and administrative expenses. General and administrative expenses consist mainly of payroll, insurance, software, and licenses. General and administrative expenses increased by $374 thousand during the year ended July 31, 2024 compared to the year ended July 31, 2023 due to the acquisition of controlling interest in Day Three, and subsequent consolidation of its results, in January 2024.

Research and development expenses. Research and development expenses increased by $502 thousand during the year ended July 31, 2024 compared to the year ended July 31, 2023 due to the acquisition of Day Three in January 2024.

Real Estate Segment

The revenue and expenses of the 520 Property have been excluded from the real estate segment in the figures below due to its classification of held-for-sale and discontinued operations, and the sale of the 520 Property on August 22, 2022. The Real Estate segment consists of a portion of a commercial building in Israel. Consolidated income (loss) and expenses for our Real Estate segment were as follows:

	Year Ended July 31,		Change	
	2023	2022	$	%
	(in thousands)			
Rental – Third Party	$ 171	$ 179	(8)	(4)%
Rental – Related Party	108	111	(3)	(3)%
Other – Related Party	—	120	(120)	(100)%
General and administrative	(138)	(160)	22	14%
Depreciation and amortization	(63)	(69)	6	9%
Income from operations	$ 78	$ 181	(103)	57%

	Year Ended July 31,		Change	
	2024	2023	$	%
	(in thousands)			
Rental – Third Party	$ 174	$ 171	$ 3	2%
Rental – Related Party	108	108	—	—%
General and administrative	(142)	(138)	(4)	(3)%
Depreciation and amortization	(60)	(63)	3	5%
Income from operations	$ 80	$ 78	$ 2	3%

Other - Related Party. Other – related party revenues decreased by approximately $120 thousand during the year ended July 31, 2023, compared to the year ended July 31, 2022. During the year ended July 31, 2022, the Company only billed Cornerstone Pharmaceuticals $120 thousand for the first quarter of 2022 for administrative, finance, accounting, tax, and legal services. As of July 31, 2023 and 2022, Cornerstone Pharmaceuticals owed the Company $720 thousand which relates to administrative and back-office services, for which a full allowance for uncollectibility has been recorded.

General and administrative expenses. General and administrative expenses consist mainly of payroll, benefits, facilities, consulting and professional fees. The decrease in general and administrative expenses of approximately $22 thousand during the year ended July 31, 2023 compared to the year ended July 31, 2022 is primarily due to a decrease in professional fees.

Consolidated Operations

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

	Year Ended July 31,		Change	
	2023	2022	$	%
	(in thousands)			
Loss from continuing operations	$ (15,043)	$ (60,477)	45,434	75%
Interest expense	—	(6)	6	100%
Interest income	3,253	201	3,052	(1518)%
Impairment of investments - Other Pharmaceuticals	(334)	—	(334)	(100)%
Impairment of cost method investment - Cornerstone Pharmaceuticals	—	(79,141)	79,141	(100)%
Realized gain (loss) on available-for-sale securities	154	(45)	199	(442)%
Realized gain on investment in equity securities	309	—	309	(100)%
Unrealized gain on investment in equity securities	33	—	33	(100)%
Unrealized gain on investments - Cyclo Therapeutics Inc.	2,663	—	2,663	(100)%
Unrealized gain (loss) on investments - Hedge Funds	220	(504)	724	(144)%
Loss from continuing operations before income taxes	(8,745)	(139,972)	131,227	94%
Benefit from income taxes	255	—	255	(100)%
Equity in loss of Day Three Labs Inc.	(203)	—	(203)	100%
Equity in loss of RP Finance	—	(575)	575	(100)%
Consolidated net loss from continuing operations	(8,693)	(140,547)	131,854	94%
Income (loss) from discontinued operations related to 520 Property	6,478	(1,830)	8,308	454%
Net loss attributable to noncontrolling interests	(339)	(17,719)	17,380	98%
Net loss attributable to Rafael Holdings, Inc.	$ (1,876)	$ (124,658)	$ 122,782	98%

	Year Ended July 31,		Change	
	2024	2023	$	%
	(in thousands)			
Loss from operations	$ (102,627)	$ (15,043)	$ (87,584)	(582)%
Interest income	2,383	3,253	(870)	(27)%
Impairment of investments - Other Pharmaceuticals	—	(334)	334	100%
Loss on initial investment in Day Three upon acquisition	(1,633)	—	(1,633)	(100)%
Realized gain on available-for-sale securities	1,772	154	1,618	1051%
Realized gain (loss) on investment in equity securities	(46)	309	(355)	(115)%
Realized gain on investment - Cyclo	424	—	424	(100)%
Unrealized gain on equity securities	—	33	(33)	(100)%
Unrealized gain on investment - Cyclo	37	2,663	(2,626)	100%
Unrealized gain on convertible notes receivable, due from Cyclo	1,191	—	1,191	100%
Unrealized gain on investment - Hedge Funds	63	220	(157)	(71)%
Recovery of receivables from Cornerstone	31,305	—	31,305	100%
Interest expense	(248)	—	(248)	(100)%
Other income	118	—	118	100%
Loss from continuing operations before income taxes	(67,261)	(8,745)	(58,516)	(669)%
Benefit from income taxes	2,680	255	2,425	951%
Equity in loss of Day Three	(422)	(203)	(219)	108%
Consolidated net loss from continuing operations	(65,003)	(8,693)	(56,310)	(648)%
Income from discontinued operations related to 520 Property	—	6,478	(6,478)	100%
Net loss attributable to noncontrolling interests	(30,593)	(339)	(30,254)	(8924)%
Net loss attributable to Rafael Holdings, Inc.	$ (34,410)	$ (1,876)	$ (32,534)	(1734)%

Interest income. income and realized gains on available-for-sale securities. Interest income was $3.3 million $2.4 million and $201 thousand $3.3 million for the years ended July 31, 2023 July 31, 2024 and 2022, 2023, respectively. The increase decrease is primarily due to the interest income earned maturity and accretion sales activity which resulted in an increase of the discount realized gains on the face value of our investments in available-for-sale securities whose balance increased to $57.7 million at July 31, 2023 from $36.7 million at July 31, 2022 of $1.6 million for the year ended July 31, 2024.

Impairment of investments - Other Pharmaceuticals. We recorded an impairment loss losses of $0 and $334 thousand for the year ended July 31, 2023, related to an our investment in securities in another entity Nanovibronix using the measurement alternative.alternative for the years ended July 31, 2024 and 2023, respectively.

Impairment of cost method investment - Cornerstone Pharmaceuticals. In connection with the Data Events, during the year ended July 31, 2022, we recorded a full impairment charge to our cost method investment in Cornerstone Pharmaceuticals in the amount of $79 million.

Realized gain (loss) on available-for-sale securities. We recorded a realized gain of approximately $154 thousand related to the sale of available-for-sale securities for the year ended July 31, 2023. We recorded a realized loss of approximately $45 thousand related to the sale of available-for-sale securities for the year ended July 31, 2022.

Realized gain on investment in equity securities. - Cyclo. We recorded a realized gain of approximately $309 $424 thousand related to the sale exercise of equity securities the May Warrants in connection with our October 2023 investment in Cyclo for the year ended July 31, 2023 July 31, 2024.

Unrealized gain on investment - Cyclo. We recorded an unrealized gain of approximately $37 thousand and $2.7 million related to the change in fair value in our investment in Cyclo for the years ended July 31, 2024 and 2023, respectively.
Unrealized gain on convertible notes receivable, due from Cyclo. We recorded an unrealized gain of $1.2 million related to the convertible note receivable due from Cyclo for the year ended July 31, 2023 July 31, 2024.

Unrealized gain (loss) on investments investment - Hedge Funds. We recorded an unrealized gains gain of approximately $220 $63 thousand and losses an unrealized gain of approximately $504 $220 thousand for the years ended July 31, 2023 July 31, 2024 and 2022, 2023, respectively.
Recovery of receivables from Cornerstone. We recorded an increase in recovery of receivables from Cornerstone of approximately $31.3 million for the year ended July 31, 2024. See Note 3 to our accompanying consolidated financial statements for more information related to this matter.
Benefit from income taxes. In accordance with the State of New Jersey's Technology Business Tax Certificate Transfer Program, which allowed certain high technology and biotechnology companies to sell unused net operating loss carryforwards ('NOLs') to other New Jersey-based corporate taxpayers based in New Jersey, the Company received approximately $2.6 million for the sale of the Company's prior period NOLs totaling $31.6 million in the year ended July 31, 2024. The Company received proceeds of approximately $274 thousand from the sale of the Company's prior period NOLs totaling $3.3 million in the year ended July 31, 2023.

Benefit from income taxes. Our benefit from income taxes was approximately $255 thousand and $0 for the years ended July 31, 2023 and 2022, respectively. The increase is primarily attributed to approximately $274 thousand in proceeds for the sale of the Company's 2018 and 2019 New Jersey tax credits. These benefits were realized by utilizing the New Jersey Technology Business Tax Certificate Transfer Program whereby the State of New Jersey allows us to sell a portion of our state net operating loss carryforwards.

Equity in loss of Day Three Labs, Inc. Three. We recognized a loss of approximately $422 and $203 thousand from our ownership interest in Day Three due to operating results for the year years ended July 31, 2023. July 31, 2024 and 2023, respectively. As of July 31, 2023 January 2, 2024, the equity method investment in Day Three on is a majority-owned subsidiary which is consolidated. See Note 10 to our balance sheet is approximately $2.8 million. accompanying consolidated financial statements for further information regarding the acquisition.

Equity in loss of RP Finance. We recognized a loss of $575 thousand from our ownership interest in RP Finance due to operating results for the year ended July 31, 2022. As of July 31, 2022, the equity method investment in RP Finance on our balance sheet was $0, and no additional equity loss of RP Finance was recorded subsequent to the year ended July 31, 2022.

Income (loss) from discontinued operations related to 520 Property. Discontinued operations include: (i) rental and parking revenues, (ii) payroll, benefits, facilities, consulting and professional fees dedicated to 520 Property, (iii) depreciation and amortization expenses, (iv) interest (including amortization of debt issuance costs) on the note payable that was secured by a mortgage on the 520 Property, and (v) gain on the disposal of the 520 Property. The operating results of these items are presented in our consolidated statements of operations and comprehensive loss as discontinued operations for all periods presented. The increase decrease in the net income attributable to discontinued operations for the year ended July 31, 2023 July 31, 2024 as compared to the year ended July 31, 2022 July 31, 2023 was due to a gain on the sale of the 520 Property of $6.8 million, an approximate $1.4 million decrease in interest expense, partially offset by a $3.3 million decrease in rental revenue, a $2.2 million decrease in general and administrative expenses (which is primarily comprised of a decrease in real estate taxes, utilities other building related repairs, maintenance expenses, and other expenses totaling approximately $2.4 million, slightly offset by a $129 thousand increase in expense related to the write-off of deferred rental income), and a $1.3 million decrease in depreciation and amortization expense due to no depreciation expense during the year ended July 31, 2023 as depreciation stopped as of July 1, 2022 when the 520 Property was classified as held-for-sale..

See Note 3 14 to our accompanying consolidated financial statements for further information regarding discontinued operations.

Net loss attributable to noncontrolling interests. The change in the net loss attributable to noncontrolling interests was due to an approximate $17.3 million loss related is primarily attributed to the net loss of Cornerstone Pharmaceuticals impairment loss (the total impairment loss was approximately $79 million) which was applicable to noncontrolling interests includes $89.9 million in certain of the Company's subsidiaries and was allocated to the holders of interests in CS Pharma and Pharma Holdings in the approximate amounts of $10.4 million and $6.9 million, respectively, for the year ended July 31, 2022.IPR&D expenses.

Liquidity and Capital Resources

	As of July 31,		Change		As of July 31,		Change	
	2023	2022	$	%	2024	2023	$	%
	(in thousands)				(in thousands)			
Balance Sheet Data:								
Cash and cash equivalents	$ 21,498	$ 26,537	(5,039)	(19)%	$ 2,675	$ 21,498	$ (18,823)	(88)%
Convertible note receivable, related party	1,921	—	1,921	100%	—	1,921	(1,921)	(100)%
Convertible note receivable					1,146	—	1,146	100%
Installment note payable					1,700	—	1,700	100%
Working capital	80,796	87,321	(6,525)	(7)%	64,988	80,796	(15,808)	(20)%
Total assets	98,829	118,320	(19,491)	(16)%	96,832	98,829	(1,997)	(2)%
Note payable, net of debt issuance costs, held-for-sale	—	15,000	(15,000)	(100)%				
Total equity attributable to Rafael Holdings, Inc.	100,293	100,515	(222)	—%	82,185	100,293	(18,108)	(18)%
Noncontrolling interests	(3,664)	(3,309)	(355)	11%	4,073	(3,664)	7,737	211%
Total equity	96,629	97,206	(577)	(1)%	86,258	96,629	(10,371)	(11)%

	For the Years Ended July 31,		Change		Year Ended July 31,		Change	
	2023	2022	$	%	2024	2023	$	%
	(in thousands)				(in thousands)			
Cash flows (used in) provided by								
Cash flows used in								
Operating activities of continuing operations	$ (10,247)	$ (26,038)	15,791	(61)%	$ (7,802)	$ (10,247)	$ 2,445	24%
Investing activities of continuing operations	(26,960)	(63,683)	36,723	(58)%	(10,820)	(26,960)	16,140	60%
Financing activities of continuing operations	(218)	103,864	(104,082)	(100)%	(179)	(218)	39	18%
Effect of exchange rates on cash and cash equivalents	(146)	(306)	160	(52)%	(22)	(146)	124	85%
Operating, investing, and financing activities of discontinued operations	32,532	(154)	32,686	(21,224)%	—	32,532	(32,532)	(100)%
(Decrease) increase in cash and cash equivalents	$ (5,039)	$ 13,683	(18,722)	(137)%				
Decrease in cash and cash equivalents					$ (18,823)	$ (5,039)	(13,784)	274%

Capital Resources

As of July 31, 2023 July 31, 2024, we held cash and cash equivalents of approximately $21.5 million, $2.7 million and available-for-sale securities valued at approximately $57.7 million $63.3 million. On August 22, 2022, the Company received net proceeds of approximately $33 million in connection with the sale of the 520 Property (see Note 3 14 to our accompanying consolidated financial statements for further details). The Company expects its balance of cash and cash equivalents, and available-for-sale-securities, available-for-sale securities, to be sufficient to meet our obligations for at least the next 12 months from the filing of this Annual Report on Form 10-K.

Operating Activities

The decrease in cash Cash used in operating activities decreased by $2.4 million from cash used of $10.2 million for the year ended July 31, 2023 to cash used of $7.8 million for the year ended July 31, 2024, as the increase in the loss from continuing operations was more than offset by the impact from non-cash items, such as $89.9 million in in-process research and development expense, $31.3 million from the recovery of receivables from Cornerstone, and changes in assets and liabilities.

Investing Activities

Cash used in investing activities for the year ended July 31, 2023 as compared to the year ended July 31, 2022 July 31, 2024 was primarily related to the lower loss from continuing operations of $8.7 million in fiscal 2023 as compared to the corresponding period in fiscal 2022 due to an impairment purchases of cost method available-for-sale securities of approximately $155.7 million, purchase of $4.0 million in convertible notes receivable from Cyclo, and the investment in Cornerstone Pharmaceuticals Cyclo common stock and warrants of approximately $79 million, a provision for loss on receivable from Cornerstone Pharmaceuticals of $25 million, and a provision for losses on related party receivables of approximately $10 million in fiscal 2022, coupled with the impact from non-cash items, primarily $1.2 million in accretion of discount on available-for-sale securities, $0.2 million in net unrealized (gain) loss on investments - Hedge Funds, $0.2 million in realized (gain) loss on available-for-sale securities, offset by impairment of investments - other pharmaceuticals of $0.3 million and stock-based compensation of $2.2 million. The decrease was also impacted by a decrease in prepaid expenses and other current assets of $0.4 million and a decrease in accounts payable and accrued expenses of $0.8 million, as well as other changes in assets and liabilities.

Cash used in operating activities for the year ended July 31, 2022 was primarily related to the loss from continuing operations of $140.5 million and an increase in prepaid expenses and other current assets of $3.5 million $6.8 million, partially offset by the impact proceeds of $153.4 million from noncash items included sales and maturities of available-for-sale securities and $2.5 million in the loss proceeds from operations, principally the impairment of the Company's cost method investment in Cornerstone Pharmaceuticals of $79 million, the reserve on the amounts due the Company from Cornerstone Pharmaceuticals related to the Line of Credit Agreement of $25 million, the reserve on receivables due from Cornerstone Pharmaceuticals totaling $10.1 million, changes in other current liabilities of $3.6 million, as well as other changes in assets and liabilities.hedge funds.

Investing Activities

Cash used in investing activities for the year ended July 31, 2023 was primarily due to purchases of available-for-sale securities of approximately $204.8 million, the investment in Day Three of $3.0 million, the purchase of investment in Cyclo common stock and warrants of $2.1 million, the loan of $2.0 million to Cornerstone and the purchase of equity securities of $1.6 million. This is partially offset by proceeds of $185.1 million from the sale and maturities of available-for-sale securities and proceeds of $1.3 million from the sale of equity securities.

Financing Activities

Cash used in investing financing activities for the year ended July 31, 2022 July 31, 2024 was primarily related to purchases a principal payment of available-for-sale securities of approximately $65 million, amounts loaned to Cornerstone Pharmaceuticals of approximately $25 million pursuant to $0.8 million on the Line of Credit Agreement and installment note acquired during the payments to fund our portion of advances under the line of credit between RP Finance and Cornerstone Pharmaceuticals in the amount of approximately $1.9 million, Day Three Acquisition, partially offset by the proceeds from sale of $28.5 million from the maturities RMD membership units of available-for-sale securities. $0.9 million.

Financing Activities

Cash used in financing activities for the year ended July 31, 2023 was primarily related to repayment of the $15 million $15.0 million note payable in connection with the sale of 520 Property and for payment of taxes related to shares withheld for employee taxes on vesting of shares granted to employees.

Cash provided by financing activities for the year ended July 31, 2022 was primarily related to proceeds of approximately $110 million related to the sale of our common stock to investors and a related party, partially offset by payment of transaction costs of $6.2 million.

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.

Operating, Financing, and Investing Activities of Discontinued Operations

The cash flows from discontinued operations - 520 Property represents for the year ended July 31, 2023 represent the net income excluding non-cash depreciation and amortization, as well as the net proceeds from the sale of the 520 Property. For the year ended July 31, 2023, net cash used in operating activities of discontinued operations totaled $0.6 million. Net cash provided by investing activities of discontinued operations of $48.2 million related to proceeds from sale of the 520 Property of $49.4 million, slightly offset by payment of transaction costs of $1.2 million. Net cash used in financing activities of discontinued operations of $15.0 million related to the payment of the Note Payable in connection with sale of the 520 Property. For the year ended July 31, 2022, net cash used in operating activities of discontinued operations totaled $41 thousand, and net cash used in investing activities of discontinued operations totaled $113 thousand.

Critical Accounting Estimates

We have chosen accounting policies that we believe are appropriate to accurately and fairly report our operating results and financial condition in conformity with U.S. GAAP. We apply these accounting policies in a consistent manner. Our significant accounting policies are discussed in Note 2, “Summary of Significant Accounting Policies,” in our accompanying consolidated financial statements.

The application of critical accounting policies requires that we make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. These estimates and assumptions are based on historical and other factors believed to be reasonable under the circumstances. We evaluate these estimates and assumptions on an ongoing basis and may retain outside consultants to assist in our evaluation. If actual results ultimately differ from previous estimates, the revisions are included in results of operations in the period in which the actual amounts become known. The critical accounting policies that involve the most significant management judgments and estimates used in preparation of our consolidated financial statements, or are the most sensitive to change from outside factors, are discussed below.

Corporate Bonds

Investments Measured at Fair Value

We have elected the fair value option to account for our investment in and convertible notes due from Cyclo. over which we have significant influence. The fair value option is irrevocable once elected. We measure our investment in Cyclo at fair value and record all subsequent changes in fair value in earnings in the consolidated statement of operations. We believe the fair value option best reflects the underlying economics of the investment.

We hold convertible notes receivable that are classified as available-for-sale as defined under Accounting Standards Codification ("ASC") 320, *Investments - Debt and Equity Securities*, and are recorded at fair value. Subsequent changes in fair value are recorded in accumulated other comprehensive income (loss). The fair value of these convertible note receivables are estimated using a scenario-based analysis based on the probability-weighted present value of future investment returns, considering each of the possible outcomes available to us, including cash repayment, equity conversion, and collateral transfer scenarios. Estimating the fair value of the convertible notes requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors.

The Company recognizes the fair value of the Cyclo Warrants utilizing a Black-Scholes model at acquisition and each reporting date. The application of the Black-Scholes model utilizes significant assumptions, including expected volatility, expected life, marketability discount, and risk-free interest rate. In order to determine the volatility, we measured expected volatility based on several inputs, including considering a peer group of publicly traded companies and the implied volatility of the Company's publicly-traded warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. Both of the Cyclo Warrants and the underlying shares of common stock are subject to volume restrictions in accordance with SEC Rule 144 for which a discount to the stock price of Cyclo was applied. The Black-Scholes model further incorporated a discount for the overall lack of marketability for the Cyclo Warrants.

Certain inputs utilized in our Black-Scholes model may fluctuate in future periods based upon factors which are outside of the Company's control. A significant change in one or more of these inputs used in the calculation of the fair value may cause a significant change to the fair value of our warrant liability which could also result in material non-cash gain or loss being reported in our consolidated statements of operations and comprehensive loss.

The Company's marketable securities are also considered to be available-for-sale as defined under ASC 320, *Investments - Debt and Equity Securities*, and are recorded at fair value based on the quoted price in active markets for similar assets and inputs that are observable for the asset. Unrealized gains or losses are included in accumulated other comprehensive income. Realized gains or losses are released from accumulated other comprehensive income and into earnings on the consolidated statements of operations and comprehensive loss. loss operations of acquired businesses are included in the consolidated financial statements from the acquisition date.

Convertible Note Receivable, Related Party

The Convertible Note Receivable is classified as available-for-sale as defined under We account for our investments in hedge funds in accordance with ASC 320, 321, *Investments - Debt and – Equity Securities*, . Unrealized gains and is recorded at fair value. Subsequent changes losses resulting from the change in fair value are recorded of these securities is included in accumulated unrealized (loss) gain on investments – Hedge Funds in the consolidated statements of operations and comprehensive loss. Hedge funds classified as Level 3 include investments and securities for which fair value may not be based on readily observable data inputs. The availability of observable inputs can vary from security to security and is affected by a wide variety of factors, including, for example, the type of security, whether the security is new and not yet established in the marketplace, the liquidity of markets, and other comprehensive loss.

characteristics particular to the security. The fair value of the Convertible Note Receivable these assets is estimated using a scenario-based analysis based on information provided by the probability-weighted present fund managers or the general partners. Therefore, these assets are classified as Level 3.

Business Combinations

Amounts paid for acquisitions are allocated to the assets acquired and liabilities assumed based on their estimated fair value at the date of acquisition. The fair value of identifiable intangible assets is based on detailed valuations that use information and assumptions provided by management, including expected future investment returns, considering each of the possible outcomes available to the Company, including cash repayment, equity conversion, and collateral transfer scenarios. Estimating flows. We allocate any excess purchase price over the fair value of the Convertible Note Receivable requires identifiable net assets and liabilities acquired to goodwill. Identifiable intangible assets with finite lives are amortized over their useful lives. Acquisition-related costs, including advisory, legal, accounting, valuation, and other costs, are expensed in the development periods in which the costs are incurred. The results of significant and subjective estimates that may, and operations of acquired businesses are likely to, change over included in the duration of consolidated financial statements from the instrument with related changes in internal and external market factors. acquisition date.

Stock-based Compensation Goodwill

The Company assesses goodwill for impairment on an annual basis or more frequently when events and circumstances occur indicating that the recorded goodwill may be impaired. The Company regularly monitors current business conditions and other factors including, but not limited to, adverse industry or economic trends and lower projections of profitability that may impact future operating results. The process of evaluating the potential impairment of goodwill requires significant judgement. In performing the Company's annual goodwill impairment test, the Company is permitted to first assess qualitative factors to determine whether it is more likely than not the fair value of the Company's reporting unit is less than its carrying amount, including goodwill. In performing the qualitative assessment, the Company considers certain events and circumstances specific to the reporting unit and the entity as a whole, such as macroeconomic conditions, industry and market considerations, overall financial performance and cost factors when evaluating whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. The Company is also permitted to bypass the qualitative assessment and proceed directly to the quantitative test. If the Company chooses to undertake the qualitative assessment and concludes that it is more likely than not that the fair value of the reporting unit is less than its carrying amount, the Company would then proceed to the quantitative impairment test. In the quantitative assessment, the Company compares the fair value of the reporting unit to its carrying amount, which includes goodwill. If the fair value exceeds the carrying value, no impairment loss exists. If the fair value is less than the carrying amount, a goodwill impairment loss is measured and recorded.

The Company assesses goodwill for impairment on an annual basis as of May 31 or more frequently when events and circumstances occur indicating that recorded goodwill may be impaired. The Company did not record an impairment charge during the year ended July 31, 2024.

Stock-based Compensation

We record stock-based compensation for options granted and restricted stock units awarded to employees, non-employees, and to members of the board of directors for their services on the board of directors based on the grant date fair value of awards issued, and the expense is recorded on a straight-line basis over the requisite service period. Forfeitures are recognized when they occur.

The fair value of restricted stock units is determined by the grant date market price of our common shares. We use the Black-Scholes-Merton option pricing model to determine the fair value of stock options. The use of the Black-Scholes-Merton option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. We have concluded that its historical share option exercise experience does not provide a reasonable basis upon which to estimate expected term. Therefore, the expected term was determined according to the simplified method, which is the average of the vesting tranche dates and the contractual term. Due to the lack of Company-specific historical and implied volatility data, the estimate of expected volatility is primarily based on the historical volatility of a group of similar companies that are publicly traded. For these analyses, companies with comparable characteristics are selected, including enterprise value and position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of its stock-based awards. The risk-free interest rate is determined by reference to U.S. Treasury zero-coupon issues with remaining maturities similar to the expected term of the options. We have not paid, and do not anticipate paying, cash dividends on shares of our common stock.

Investments – Hedge Funds In-Process Research and Development

We account hold acquired in-process research and development ("IPR&D") intangible assets pursuant to a business combination. These IPR&D assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. These IPR&D assets are not amortized but reviewed for our investments impairment at least annually, or when events or changes in hedge funds in accordance with ASC 321, *Investments – Equity Securities*. Unrealized gains the business environment indicate the carrying value may be impaired.

IPR&D acquired as part of the Cornerstone Acquisition represents the R&D asset of Cornerstone which was in-process, but not yet completed, and losses resulting from which had no alternative use. To value the change in fair IPR&D acquired as part of the Cornerstone Acquisition, the Company utilized the Multi-Period Excess Earnings Method ("MPEEM"), under the Income Approach. The method reflects the present value of these securities is included in unrealized (loss) gain on investments – Hedge Funds the projected operating cash flows generated by Cornerstone's assets after taking into account the cost to realize the revenue, and an appropriate discount rate to reflect the time value and risk associated with the invested capital. IPR&D acquired represents Cornerstone's research and development activities related to oncology-focused pharmaceuticals which seeks to exploit the metabolic differences between normal cells and cancer cells. The IPR&D acquired as part of the Cornerstone Acquisition, accounted for as an asset acquisition, was expensed immediately as a component of in-process research and development expense in the consolidated statements of operations and comprehensive loss. Hedge funds classified as Level 3 include investments and securities which may not be based on readily observable data inputs. The availability of observable inputs can vary from security to security and is affected by a wide variety of factors, including, for example, the type of security, whether the security is new and not yet established in the marketplace, the liquidity of markets, and other characteristics particular to the security. The fair value of these assets is estimated based on information provided by the fund managers or the general partners. Therefore, these assets are classified as Level 3.

Investments – Cost Method

We periodically evaluate our investments for impairment due to declines considered to be other than temporary. If we determine that a decline in fair value is other than temporary, then a charge to earnings is recorded in the accompanying consolidated statements statement of operations and comprehensive loss and a new basis in the investment is established.as it had no alternative future use.

Investments – Fair Value Method

The method of accounting applied to long-term investments in equity securities 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 include the identification of any variable interests in which the Company is the primary beneficiary. The consolidated financial statements include the Company's controlled affiliates. All significant intercompany accounts and transactions between the consolidated affiliates are eliminated.

Investments in equity securities may be accounted for using (i) the fair value option if elected, (ii) fair value through earnings if fair value is readily determinable or (iii) for equity investments without readily determinable fair values, the measurement alternative to measure at cost adjusted for any impairment and observable price changes, as applicable. The election to use the measurement alternative is made for each eligible investment.

The Company has elected the fair value option to account for its investment in Cyclo Therapeutics Inc. over which the Company has significant influence. The fair value option is irrevocable once elected. The Company measured its initial investment in Cyclo at fair value and shall record all subsequent changes in fair value in earnings in the consolidated statement of operations. The Company believes the fair value option best reflects the underlying economics of the investment. See Note 9, "Investments," in our accompanying consolidated financial statements for further details.

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.

Discontinued Operations

In accordance with the Financial Accounting Standards Board, ASC 205-20, *Presentation of Financial Statements - Discontinued Operations*, the results of operations of a component of an entity or a group or component of an entity that represents a strategic shift that has, or will have, a major effect on the reporting company's operations that has either been disposed of or is classified as held-for-sale are required to be reported as discontinued operations in a company's consolidated financial statements. In order to be considered a discontinued operation, both the operations and cash flows of the discontinued component must have been (or will be) eliminated from the ongoing operations of the Company and the Company will not have any significant continuing involvement in the operations of the discontinued component after the disposal transaction. As a result of the agreement to sell the 520 Property, the accompanying consolidated financial statements reflect the activity related to the sale of the 520 Property as discontinued operations. See Note 3 to our consolidated financial statements for additional information regarding the results, major classes of assets and liabilities, significant non-cash operating items, and capital expenditures of discontinued operations.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

FOREIGN CURRENCY RISK

Revenue from tenants located in Israel represented 53% and 7% of our consolidated revenues, inclusive of revenue from discontinued operations, for the years ended July 31, 2023 and 2022, respectively. The entirety of these revenues is in currencies other than the U.S. Dollar. Our foreign currency exchange risk is somewhat mitigated by our ability to offset a portion of these non-U.S. Dollar-denominated revenues with operating expenses that are paid in the same currencies. While the impact from fluctuations in foreign exchange rates affects our revenues and expenses denominated in foreign currencies, the net amount of our exposure to foreign currency exchange rate changes at the end of each reporting period is generally not material.

INVESTMENT RISK

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

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

An evaluation was performed under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) promulgated under the Securities and Exchange Act of 1934, as amended) as of July 31, 2023 July 31, 2024. Based on that evaluation, the Company's management, including the President and Chief Executive Officer and Chief Financial Officer, concluded that the Company's disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

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

Management conducted an assessment of the effectiveness of the Company's internal control over financial reporting as of July 31, 2023 July 31, 2024 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, 2023 July 31, 2024 is effective.

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

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

Changes in Internal Control over Financial Reporting

There were no significant changes made in the Company's internal control over financial reporting during the fourth quarter of the year ended July 31, 2023 July 31, 2024 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Attestation Report of the Independent Registered Public Accounting Firm

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

Item 9B. Other Information.

None.

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

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance.

The following is a list of our directors and executive officers as of October 27, 2023 November 6, 2024, along with the specific information required by Rule 14a-3 of the Securities Exchange Act of 1934:

Executive Officers

Executive Officers

Howard S. Jonas — Executive Chairman
William Conkling — Chief Executive Officer
David Polinsky — Chief Financial Officer
John Goldberg — Chief Medical Officer

Directors

Directors

Howard S. Jonas — Jonas—Chairman of the Board
Susan Bernstein
Stephen Greenberg
Dr. Mark McCamishStein
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, 2023 July 31, 2024, 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, 2023 July 31, 2024, 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, 2023 July 31, 2024, 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, 2023 July 31, 2024, 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, 2023 July 31, 2024, and which is incorporated by reference herein.

Part IV

Item 15. Exhibits, Financial Statement Schedules.

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

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

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

2 Financial Statement Schedules.

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

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

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

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

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

(b) Exhibits.

Exhibit Number	Description
3.1(1) 2.1(1)	Agreement and Plan of Merger, dated as of August 21, 2024, by and among Rafael, Cyclo, First Merger Sub and Second Merger Sub.
3.1(2)	Amended and Restated Certificate of Incorporation of Rafael Holdings, Inc.
3.2(3) 3.2(2)	Third Amended and Restated By-Laws of Rafael Holdings, Inc.
4.2*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
10.1(4) 10.1(3)	2021 Equity Incentive Plan, as amended and restated
10.2(3) 10.2(2)	Employment Agreement dated as of June 13, 2022, between the Company and Howard S. Jonas.

10.3(5)	
10.3(4)	Letter Agreement dated January 20, 2022, between the Company and William Conkling.
10.4*	Letter Agreement dated November 16, 2023, between the Company and John Goldberg
10.5(6)	
10.6(5)	Securities Purchase Agreement, dated August 19, 2021, by and among Rafael Holdings, Inc. and the Investors named therein.
10.6(6)	
10.7(5)	Securities Purchase Agreement, dated August 19, 2021, by and among Rafael Holdings, Inc. and I9 Plus, LLC.
10.7(6)	
10.8(5)	Registration Rights Agreement, dated August 19, 2021, by and among Rafael Holdings, Inc. and the Investors named therein.
10.9(6)	Contract of Sale between Broad Atlantic Associates LLC and 520 Broad Street Propco LLC, dated February 18, 2022. (schedules, exhibits and similar attachments to the Contract of Sale that are not material have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish supplementally a copy of any omitted schedule, exhibit or similar attachment to the Securities and Exchange Commission upon request).
21.01*	Subsidiaries of the Registrant
23.1*	Consent of CohnReznick LLP, Independent Registered Public Accounting Firm
31.01*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.02*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.01*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.02*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97*	Compensation Clawback Policy
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* * Filed or furnished herewith.

(1) (1)Incorporated by reference to Form 8-K, filed August 22, 2024.

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

(3) (2) Incorporated by reference to Form 8-K, filed June 14, 2022.

(4) (3) Incorporated by reference to Exhibit A of the Company's Definitive Proxy Statement, filed with the Commission on November 28, 2022.

(5) (4) Incorporated by reference to Form 8-K, filed January 21, 2022.

(6) (5) Incorporated by reference to Form 8-K, filed August 24, 2021.

(7) (6) Incorporated by reference to Form 8-K, filed May 9, 2022.

Item 16. Form 10-K Summary

None.

Signatures

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

Rafael Holdings, Inc.

By: **/s/ William Conkling**

William Conkling

Chief Executive Officer

Date: October 30, 2023November 6, 2024

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

Signature	Titles	Date
/s/ William Conkling **William Conkling**	President and Chief Executive Officer (Principal Executive Officer) (Principal Executive Officer)	October 30, 2023 November 5, 2024
/s/ David Polinsky **David Polinsky**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) (Principal Financial Officer and Principal Accounting Officer)	October 30, 2023 November 5, 2024
/s/ Howard S. Jonas **Howard S. Jonas**	Director, Chairman of the Board and Executive Chairman	October 30, 2023 November 5, 2024
/s/ Stephen GreenbergSusan Y. Bernstein **Susan Y. Bernstein**	Director	November 5, 2024
/s/ October 30, 2023 Stephen Greenberg **Stephen Greenberg**	Director	November 5, 2024
/s/ Dr. Mark McCamish Stein **Mark McCamish** **Dr. Mark Stein**	Director	October 30, 2023 November 5, 2024
/s/Dr. Michael J. Weiss **Dr. Michael J. Weiss**	Director	October 30, 2023 November 5, 2024

Rafael Holdings, Inc.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Rafael Holdings, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Rafael Holdings, Inc. as of July 31, 2023 July 31, 2024 and 2022, 2023, and the related consolidated statements of operations and comprehensive loss, equity and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Rafael Holdings, Inc. as of July 31, 2023 July 31, 2024 and 2022, 2023, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (i) related to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communications of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of Intangible Assets and Purchase Price Consideration in the Cornerstone Pharmaceuticals, Inc. Restructuring and Acquisition

Description of the matter

As described in Note 3 to the consolidated financial statements, the Company, Cornerstone Pharmaceuticals, Inc. ("Cornerstone"), and other holders of debt and equity securities of Cornerstone agreed to various transactions which effected a recapitalization and restructuring of the outstanding debt and equity interests in Cornerstone. The recapitalization resulted in the Company becoming the primary beneficiary of Cornerstone, a variable interest entity, and consolidating Cornerstone. The Company was determined to be the accounting acquiror and treated the restructuring as an asset acquisition resulting in the recording of an in-process research and development asset of approximately $89,861,000. The purchase consideration resulting from the restructuring included the forgiveness of a line of credit and a promissory note in exchange for Cornerstone common stock valued at $37,845,000 and $2,663,000, respectively. The fair value of this consideration and the in-process research and development asset were calculated by management using a blend of a discounted cash flow and comparable companies valuations. The methods used to estimate the fair value of acquired intangible assets and purchase consideration utilizing a discounted cash flow involve significant assumptions. The significant assumptions applied by management in estimating the fair value of acquired intangible assets and purchase consideration included income projections and discount rates.

Significant judgment is exercised by the Company in determining the valuation of the intangible assets and purchase price consideration.

Given these factors, the related audit effort in evaluating management's judgments in determining the valuation of the intangible assets and purchase price consideration was challenging, subjective, and complex and required a high degree of auditor judgment.

How our Audit Addressed the Critical Audit Matter

Our principal audit procedures related to this critical audit matter included the following:

- We gained an understanding of and evaluated the design and implementation of the Company's controls that address the risk of material misstatement related to developing fair value estimates and management projections.
- We evaluated management's significant accounting policies related to estimating the fair value of intangible assets and purchase consideration.
- We tested the reasonableness of the underlying data used to determine the forecasted discounted future cash flows.
- We evaluated the reasonableness of the discounted future cash flows utilized in the discounted cash flow model by comparing forecasted discounted cash flows to market information.
- We evaluated the reasonableness of the probability weighting of the discounted cash flows based upon the likelihood of approval of the acquired research and development projects by comparing the probabilities to historical market information and industry data.
- Professionals with specialized skill and knowledge were used to assist in evaluating the reasonableness of the discount rates utilized.

/s/ CohnReznick LLP

We have served as Company's auditor since 2019.

New York, New York

October 30, 2023 November 6, 2024

PART I. FINANCIAL INFORMATION
RAFAEL HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	Year Ended July 31,		Year Ended July 31,	
	2023	2022	2024	2023
ASSETS				
CURRENT ASSETS				
Cash and cash equivalents	$ 21,498	$ 26,537	$ 2,675	$ 21,498
Available-for-sale securities	57,714	36,698	63,265	57,714
Interest receivable	387	140	515	387
Convertible note receivables, due from Cyclo			5,191	—
Accounts receivable, net of allowance for credit losses of $245 at July 31, 2024 and July 31, 2023			426	213
Prepaid expenses and other current assets			430	914
Convertible note receivable, related party	1,921	—	—	1,921
Accounts receivable, net of allowance for doubtful accounts of $245 and $197 at July 31, 2023 and July 31, 2022, respectively	213	157		
Prepaid expenses and other current assets	914	4,621		
Assets held-for-sale	—	40,194		
Investment in equity securities	294	—	—	294
Total current assets	82,941	108,347	72,502	82,941
Property and equipment, net	1,695	1,770	2,120	1,695
Investments – Cyclo			12,010	4,763
Investments – Hedge Funds			2,547	4,984
Investment – Day Three			—	2,797
Investments – Other Pharmaceuticals	65	477	—	65
Investments – Hedge Funds	4,984	4,764		
Investment - Day Three Labs Inc.	2,797	—		
Investments - Cyclo Therapeutics Inc.	4,763	—		
In-process research and development and patents	1,575	1,575		
Convertible note receivable			1,146	—
Goodwill			3,050	—
Intangible assets, net			1,847	—
In-process research and development			1,575	1,575
Other assets	9	1,387	35	9
TOTAL ASSETS	$ 98,829	$ 118,320	$ 96,832	$ 98,829
LIABILITIES AND EQUITY				
CURRENT LIABILITIES				
Accounts payable	$ 333	$ 564	$ 2,556	$ 333
Accrued expenses	763	1,875	1,798	763
Convertible notes payable			614	—
Other current liabilities	1,023	3,518	113	1,023
Due to related parties	26	69	733	26
Note payable, net of debt issuance costs, held-for-sale	—	15,000		
Installment note payable			1,700	—
Total current liabilities	2,145	21,026	7,514	2,145
Accrued expenses, noncurrent			2,982	—
Convertible notes payable, noncurrent			73	—
Other liabilities	55	88	5	55

TOTAL LIABILITIES	*2,200*	*21,114*	*10,574*	*2,200*
COMMITMENTS AND CONTINGENCIES				
EQUITY				
Class A common stock, $0.01 par value; 35,000,000 shares authorized, 787,163 shares issued and outstanding as of July 31, 2023 and July 31, 2022, respectively	*8*	*8*		
Class B common stock, $0.01 par value; 200,000,000 shares authorized, 23,635,709 issued and 23,490,527 outstanding as of July 31, 2023, and 23,712,449 shares issued and 23,687,964 shares outstanding as of July 31, 2022	*236*	*237*		
Class A common stock, $0.01 par value; 35,000,000 shares authorized, 787,163 shares issued and outstanding as of July 31, 2024 and July 31, 2023			*8*	*8*
Class B common stock, $0.01 par value; 200,000,000 shares authorized, 24,142,535 issued and 23,819,948 outstanding (excluding treasury shares of 101,487) as of July 31, 2024, and 23,635,709 shares issued and 23,490,527 shares outstanding as of July 31, 2023			*238*	*236*
Additional paid-in capital	*264,010*	*262,023*	*280,048*	*264,010*
Accumulated deficit	*(167,333)*	*(165,457)*	*(201,743)*	*(167,333)*
Accumulated other comprehensive loss related to unrealized loss on available-for-sale securities	*(353)*	*(63)*		
Treasury stock, at cost; 101,487 and 0 Class B shares as of July 31, 2024 and July 31, 2023, respectively			*(168)*	*—*
Accumulated other comprehensive income (loss) related to unrealized income on available-for-sale securities			*111*	*(353)*
Accumulated other comprehensive income related to foreign currency translation adjustment	*3,725*	*3,767*	*3,691*	*3,725*
Total equity attributable to Rafael Holdings, Inc.	*100,293*	*100,515*	*82,185*	*100,293*
Noncontrolling interests	*(3,664)*	*(3,309)*	*4,073*	*(3,664)*
TOTAL EQUITY	*96,629*	*97,206*	*86,258*	*96,629*
TOTAL LIABILITIES AND EQUITY	*$ 98,829*	*$ 118,320*	*$ 96,832*	*$ 98,829*

See accompanying notes to the consolidated financial statements.

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

	Year Ended July 31,	
	2023	**2022**
REVENUE		
Rental – Third Party	$ 171	$ 179
Rental – Related Party	108	111
Other – Related Party	—	120
Total revenue	279	410
COSTS AND EXPENSES		
General and administrative	8,932	16,978
Research and development	6,312	8,742
Depreciation and amortization	78	72
Provision for loss on receivable from Cornerstone Pharmaceuticals pursuant to line of credit	—	25,000
Provision for losses on related party receivables	—	10,095
Loss from operations	(15,043)	(60,477)
Interest expense	—	(6)
Interest income	3,253	201
Impairment of investments - Other Pharmaceuticals	(334)	—
Impairment of cost method investment - Cornerstone Pharmaceuticals	—	(79,141)
Realized gain (loss) on available-for-sale securities	154	(45)
Realized gain on investment in equity securities	309	—
Unrealized gain on investment in equity securities	33	—
Unrealized gain on investments - Cyclo Therapeutics Inc.	2,663	—
Unrealized gain (loss) on investments - Hedge Funds	220	(504)
Loss from continuing operations before income taxes	(8,745)	(139,972)
Benefit from income taxes	255	—
Equity in loss of Day Three Labs Inc.	(203)	—
Equity in loss of RP Finance	—	(575)
Consolidated net loss from continuing operations	(8,693)	(140,547)
Discontinued Operations (Note 3)		
Loss from discontinued operations related to 520 Property	(306)	(1,830)
Gain on disposal of 520 Property	6,784	—
Income (loss) from discontinued operations	6,478	(1,830)
Consolidated net loss	(2,215)	(142,377)
Net loss attributable to noncontrolling interests	(339)	(17,719)
Net loss attributable to Rafael Holdings, Inc.	$ (1,876)	$ (124,658)
OTHER COMPREHENSIVE LOSS		
Consolidated net loss	$ (2,215)	$ (142,377)
Unrealized loss on available-for-sale securities	(290)	(63)
Foreign currency translation adjustment	(42)	(5)
Total comprehensive loss	(2,547)	(142,445)
Comprehensive loss attributable to noncontrolling interests	(336)	(17,746)
Total comprehensive loss attributable to Rafael Holdings, Inc.	$ (2,211)	$ (124,699)
Loss per share attributable to common stockholders		
Basic and diluted:		
Continuing operations	$ (0.36)	$ (6.22)
Discontinued operations	0.28	(0.09)
Total basic and diluted loss per share	$ (0.08)	$ (6.31)
Weighted average number of shares used in calculation of loss per share		
Basic and diluted	23,263,211	19,767,342

See accompanying notes to the consolidated financial statements.

RAFAEL HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF EQUITY
(in thousands, except share data)

	Year Ended July 31, 2023								
	Common Stock, Series A		Common Stock, Series B		Additional paid-in-capital	Accumulated deficit	Accumulated other comprehensive income	Noncontrolling interests	Total Equity
	Shares	Amount	Shares	Amount					
Balance at August 1, 2022	**787,163**	**$ 8**	**23,687,964**	**$ 237**	**$ 262,023**	**$ (165,457)**	**$ 3,704**	**$ (3,309)**	**$ 97,206**
Net loss for the year ended July 31, 2023	—	—	—	—	—	(1,876)	—	(339)	**(2,215)**
Stock-based compensation	—	—	220,019	2	3,089	—	—	—	**3,091**
Forfeiture of restricted stock	—	—	(296,759)	(2)	(901)	—	—	—	**(903)**
Shares withheld for payroll taxes	—	—	(120,697)	(1)	(217)	—	—	—	**(218)**
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	(290)	—	**(290)**
Acquisition of additional ownership interest in LipoMedix	—	—	—	—	16	—	—	(16)	**—**
Foreign currency translation adjustment	—	—	—	—	—	—	(42)	—	**(42)**
Balance at July 31, 2023	787,163	$ 8	23,490,527	$ 236	$ 264,010	$ (167,333)	$ 3,372	$ (3,664)	$ 96,629

See accompanying notes to the consolidated financial statements.

RAFAEL HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF EQUITY
(in thousands, except share data)

	Year Ended July 31, 2022								
	Common Stock, Series A		Common Stock, Series B		Additional paid-in-capital	Accumulated deficit	Accumulated other comprehensive income	Noncontrolling interests	Total Equity
	Shares	Amount	Shares	Amount					
Balance at August 1, 2021	**787,163**	**$ 8**	**16,936,864**	**$ 169**	**$ 159,136**	**$ (40,799)**	**$ 3,772**	**$ 14,418**	**$ 136,704**
Net loss for the year ended July 31, 2022	—	—	—	—	—	(124,658)	—	(17,719)	**(142,377)**
Stock-based compensation	—	—	1,533,311	16	18,045	—	—	—	**18,061**
Forfeiture of restricted stock	—	—	(943,305)	(9)	(18,969)	—	—	—	**(18,978)**
Common stock sold to investors	—	—	2,833,425	28	99,142	—	—	—	**99,170**
Transaction costs incurred in connection with sale of common stock	—	—	—	—	(6,228)	—	—	—	**(6,228)**
Common stock sold to related party	—	—	3,338,307	33	10,964	—	—	—	**10,997**
Acquisition of additional ownership interest in LipoMedix	—	—	—	—	8	—	—	(8)	**—**
Shares withheld for payroll taxes	—	—	(10,638)	—	(75)	—	—	—	**(75)**
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	(63)	—	**(63)**
Foreign currency translation adjustment	—	—	—	—	—	—	(5)	—	**(5)**
Balance at July 31, 2022	787,163	$ 8	23,687,964	$ 237	$ 262,023	$ (165,457)	$ 3,704	$ (3,309)	$ 97,206

See accompanying notes to the consolidated financial statements.

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

	Year Ended July 31,	
	2023	**2022**
Operating activities		
Consolidated net loss	$ (2,215)	$ (142,377)
Less: Income (loss) from discontinued operations	6,478	(1,830)
Loss from continuing operations	(8,693)	(140,547)
Adjustments to reconcile consolidated net loss to net cash used in operating activities		
Depreciation and amortization	78	72
Net unrealized (gain) loss on investments - Hedge Funds	(220)	504
Unrealized gain on equity securities	(33)	—
Unrealized gain in equity investments - Cyclo Therapeutics Inc.	(2,663)	—
Realized (gain) loss on available-for-sale securities	(154)	45
Amortization of discount on available-for-sale securities	(1,195)	—
Impairment of investments - Other Pharmaceuticals	334	—
Impairment of cost method investment - Cornerstone Pharmaceuticals	—	79,141
Provision for loss on receivable from Cornerstone Pharmaceuticals pursuant to line of credit	—	25,000
Equity in loss of RP Finance	—	575
Equity in loss of Day Three Labs Inc.	203	—
Provision for losses on related party receivables	—	10,095
Provision for doubtful accounts	—	4
Stock-based compensation, net	2,188	(917)
Change in assets and liabilities, net of effects from discontinued operations:		
Trade accounts receivable	(117)	74
Interest receivable	(247)	(140)
Prepaid expenses and other current assets	373	(3,545)
Other assets	(27)	130
Accounts payable and accrued expenses	(827)	52
Other current liabilities	781	3,566
Due to related parties	(43)	(67)
Due from Cornerstone Pharmaceuticals	—	(120)
Other liabilities	15	40
Net cash used in continuing operations	(10,247)	(26,038)
Net cash used in discontinued operations	(639)	(41)
Net cash used in operating activities	(10,886)	(26,079)
Investing activities		
Payment to Cornerstone Pharmaceuticals pursuant to Line of Credit	—	(25,000)
Purchases of property and equipment	—	(2)
Payment to fund RP Finance Line of Credit	—	(1,875)
Purchases of available-for-sale securities	(204,798)	(65,306)
Proceeds from the sale and maturities of available-for-sale securities	185,121	28,500
Issuance of convertible note receivable, related party	(2,000)	—
Proceeds from investments - Other Pharmaceuticals	78	—
Purchases of equity securities	(1,586)	—
Proceeds from sales of equity securities	1,325	—
Purchase of Investment in Day Three Labs Inc.	(3,000)	—
Purchase of Investment in Cyclo Therapeutics Inc.	(2,100)	—
Net cash used in investing activities of continuing operations	(26,960)	(63,683)
Net cash provided by (used in) investing activities of discontinued operations	48,171	(113)
Net cash provided by (used in) investing activities	21,211	(63,796)
Financing activities		
Proceeds from issuance of common stock	—	99,170
Proceeds from issuance of common stock from related party	—	10,997
Payment of transaction costs incurred in connection with sale of common stock	—	(6,228)
Payments for taxes related to shares withheld for employee taxes	(218)	(75)
Net cash (used in) provided by continuing operations	(218)	103,864
Net cash used in financing activities of discontinued operations	(15,000)	—

Net cash (used in) provided by financing activities	(15,218)	103,864
Effect of exchange rate changes on cash and cash equivalents	(146)	(306)
Net (decrease) increase in cash and cash equivalents	(5,039)	13,683
Cash and cash equivalents, beginning of year	26,537	12,854
Cash and cash equivalents, end of year	$ 21,498	$ 26,537
Non-cash supplemental disclosure		
Acquisition of additional ownership interest in LipoMedix	$ 16	$ 8

See accompanying notes to the consolidated financial statements.

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

	Year Ended July 31,	
	2024	2023
REVENUE		
Infusion Technology	$ 355	$ —
Rental – Third Party	174	171
Rental – Related Party	108	108
Total revenue	637	279
COSTS AND EXPENSES		
Cost of Infusion Technology revenue	154	—
General and administrative	8,854	8,932
Research and development	4,170	6,312
In-process research and development expense	89,861	—
Depreciation and amortization	225	78
Loss from operations	(102,627)	(15,043)
Interest income	2,383	3,253
Impairment of investments - Other Pharmaceuticals	—	(334)
Loss on initial investment in Day Three upon acquisition	(1,633)	—
Realized gain on available-for-sale securities	1,772	154
Realized gain (loss) on investment in equity securities	(46)	309
Unrealized gain on investment in equity securities	—	33
Realized gain on investment - Cyclo	424	—
Unrealized gain on investment - Cyclo	37	2,663
Unrealized gain on convertible notes receivable, due from Cyclo	1,191	—
Unrealized gain on investment - Hedge Funds	63	220
Recovery of receivables from Cornerstone	31,305	—
Interest expense	(248)	—
Other income	118	—
Loss from continuing operations before income taxes	(67,261)	(8,745)
Benefit from income taxes	2,680	255
Equity in loss of Day Three	(422)	(203)
Consolidated net loss from continuing operations	(65,003)	(8,693)
Discontinued Operations (Note 14)		
Loss from discontinued operations related to 520 Property	—	(306)
Gain on disposal of 520 Property	—	6,784
Income from discontinued operations	—	6,478
Consolidated net loss	(65,003)	(2,215)
Net loss attributable to noncontrolling interests	(30,593)	(339)
Net loss attributable to Rafael Holdings, Inc.	$ (34,410)	$ (1,876)
OTHER COMPREHENSIVE LOSS		
Consolidated net loss	$ (65,003)	$ (2,215)
Unrealized (loss) gain on available-for-sale securities	464	(290)
Foreign currency translation adjustment	(53)	(42)
Comprehensive loss	(64,592)	(2,547)
Comprehensive loss attributable to noncontrolling interests	(30,595)	(336)
Comprehensive loss attributable to Rafael Holdings, Inc.	$ (33,997)	$ (2,211)
Income (loss) per share attributable to common stockholders		
Basic and diluted:		
Continuing operations	$ (1.45)	$ (0.36)
Discontinued operations	—	0.28

Total basic and diluted loss per share	$ (1.45)	$ (0.08)
Weighted average number of shares used in calculation of income (loss) per share		
Basic and diluted	23,745,516	23,263,211

See accompanying notes to the consolidated financial statements.

RAFAEL HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF EQUITY
(in thousands, except share data)

	Year Ended July 31, 2024										
	Common Stock, Series A		Common Stock, Series B		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income	Noncontrolling interests	Treasury Stock		Total Equity
	Shares	Amount	Shares	Amount					Class B Shares	Amount	
Balance at August 1, 2023	**787,163**	**$ 8**	**23,490,527**	**$ 236**	**$ 264,010**	**$ (167,333)**	**$ 3,372**	**$ (3,664)**	**—**	**$ —**	**$ 96,629**
Net loss	—	—	—	—	—	(34,410)	—	(30,593)	—	—	**(65,003)**
Stock-based compensation	—	—	506,826	3	2,293	—	—	—	—	—	**2,296**
Shares withheld for payroll taxes	—	—	(75,918)	(1)	(135)	—	—	—	—	—	**(136)**
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	464	—	—	—	**464**
Sale of Rafael Medical Devices membership units	—	—	—	—	869	—	—	56	—	—	**925**
Noncontrolling interest in Day Three acquisition	—	—	—	—	—	—	—	1,151	—	—	**1,151**
Purchases of treasury stock	—	—	(101,487)	—	—	—	—	—	101,487	(168)	**(168)**
Gain on RP Finance consolidation	—	—	—	—	7,600	—	—	—	—	—	**7,600**
Paid-in capital arising from Cornerstone Acquisition	—	—	—	—	7,260	—	—	—	—	—	**7,260**
Noncontrolling interest arising from Cornerstone Acquisition	—	—	—	—	—	—	—	27,501	—	—	**27,501**
Noncontrolling interest arising from RP Finance Consolidation	—	—	—	—	—	—	—	12,667	—	—	**12,667**
Elimination of RP Finance investment in Cornerstone	—	—	—	—	(1,849)	—	—	(3,082)	—	—	**(4,931)**
Dissolution of Levco	—	—	—	—	—	—	19	37	—	—	**56**
Foreign currency translation adjustment	—	—	—	—	—	—	(53)	—	—	—	**(53)**
Balance at July 31, 2024	787,163	$ 8	23,819,948	$ 238	$ 280,048	$ (201,743)	$ 3,802	$ 4,073	101,487	$ (168)	$ 86,258

See accompanying notes to the consolidated financial statements.

RAFAEL HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF EQUITY
(in thousands, except share data)

	Year Ended July 31, 2023								
	Common Stock, Series A		Common Stock, Series B		Additional paid-in	Accumulated	Accumulated other comprehensive	Noncontrolling	Total
	Shares	Amount	Shares	Amount	capital	deficit	income	interests	Equity
Balance at August 1, 2022	**787,163**	**$ 8**	**23,687,964**	**$ 237**	**$ 262,023**	**$ (165,457)**	**$ 3,704**	**$ (3,309)**	**$ 97,206**
Net loss	—	—	—	—	—	(1,876)	—	(339)	**(2,215)**
Stock-based compensation	—	—	220,019	2	3,089	—	—	—	**3,091**
Forfeiture of restricted stock	—	—	(296,759)	(2)	(901)	—	—	—	**(903)**
Shares withheld for payroll taxes	—	—	(120,697)	(1)	(217)	—	—	—	**(218)**
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	(290)	—	**(290)**
Acquisition of additional ownership interest in LipoMedix	—	—	—	—	16	—	—	(16)	**—**
Foreign currency translation adjustment	—	—	—	—	—	—	(42)	—	**(42)**
Balance at July 31, 2023	787,163	$ 8	23,490,527	$ 236	$ 264,010	$ (167,333)	$ 3,372	$ (3,664)	$ 96,629

See accompanying notes to the consolidated financial statements.

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

	Year Ended July 31,	
	2024	2023
Operating activities		
Consolidated net loss	$ (65,003)	$ (2,215)
Less: Income from discontinued operations	—	6,478
Loss from continuing operations	(65,003)	(8,693)
Adjustments to reconcile consolidated net loss to net cash used in operating activities		
Depreciation and amortization	225	78
Gain on sale of property and equipment	(27)	—
Net unrealized gain on investment - Hedge Funds	(63)	(220)
Unrealized gain on equity securities	—	(33)
Realized loss on investment in equity securities	46	—
Realized gain on available-for-sale securities	(1,772)	(154)
Amortization of discount on available-for-sale securities	(1,891)	(1,195)
Impairment of investments - Other Pharmaceuticals	—	334
Loss on initial investment in Day Three upon acquisition	1,633	—
Realized gain in equity investments - Cyclo	(424)	—
Unrealized gain in equity investments - Cyclo	(37)	(2,663)
Unrealized gain on convertible notes receivable, due from Cyclo	(1,191)	—
Recovery of receivables from Cornerstone	(31,305)	—
In-process research and development expense	89,861	—
Gain on dissolution of a business	18	—
Equity in loss of Day Three	422	203
Bad debt expense	20	—
Stock-based compensation	2,296	2,188
Change in assets and liabilities, net of effects from acquisitions and discontinued operations:		
Trade accounts receivable	(150)	(117)
Interest receivable	(139)	(247)
Prepaid expenses and other current assets	673	373
Other assets	22	(27)
Accounts payable and accrued expenses	(146)	(827)
Other current liabilities	(938)	781
Due to related parties	138	(43)
Other liabilities	(70)	15
Net cash used in continuing operations	(7,802)	(10,247)
Net cash used in discontinued operations	—	(639)
Net cash used in operating activities	(7,802)	(10,886)
Investing activities		
Purchase of property and equipment	(143)	—
Purchases of available-for-sale securities	(155,657)	(204,798)
Proceeds from the sale and maturities of available-for-sale securities	153,352	185,121
Proceeds from Day Three patent sale	270	—
Purchase of intangible assets	(35)	—
Proceeds from sales of equity securities	271	1,325
Issuance of Convertible Notes, Due from Cyclo	(4,000)	—
Issuance of convertible note receivable, related party	—	(2,000)
Purchase of Investment in Day Three	—	(3,000)
Purchase of Investment in Cyclo	(6,786)	(2,100)
Issuance of convertible note receivable	(1,000)	—
Issuance of Day Three Promissory Notes	(1,989)	—
Proceeds from investments - Other Pharmaceuticals	42	78
Purchases of equity securities	—	(1,586)
Cash acquired in acquisition of Day Three, net of cash payments	1,099	—
Cash acquired in the Cornerstone Acquisition, net of cash payments	1,256	—
Proceeds from hedge funds	2,500	—
Net cash used in investing activities of continuing operations	(10,820)	(26,960)
Proceeds from sale of 520 Property - discontinued operations	—	49,400
Payment of transaction costs for sale of 520 Property - discontinued operations	—	(1,229)

Net cash provided by investing activities of discontinued operations	—	48,171
Net cash (used in) provided by investing activities	(10,820)	21,211
Financing activities		
Principal payments on installment note payable	(800)	—
Payments for taxes related to shares withheld for employee taxes	(136)	(218)
Purchases of treasury stock	(168)	—
Proceeds from sale of Rafael Medical Devices membership units	925	—
Net cash used in financing activities of continuing operations	(179)	(218)
Payment of Note Payable in connection with sale of 520 Property - discontinued operations	—	(15,000)
Net cash used in financing activities of discontinued operations	—	(15,000)
Net cash used in financing activities	(179)	(15,218)
Effect of exchange rate changes on cash and cash equivalents	(22)	(146)
Net decrease in cash and cash equivalents	(18,823)	(5,039)
Cash and cash equivalents, beginning of year	21,498	26,537
Cash and cash equivalents, end of year	$ 2,675	$ 21,498
Non-cash supplemental disclosure		
Acquisition of additional ownership interest in LipoMedix	$ —	$ 16
Conversion of RFL Line of Credit into Cornerstone Common Stock	$ 37,845	$ —
Conversion of 2023 Promissory Note into Cornerstone Common Stock	$ 2,663	$ —
Recognition of noncontrolling interest in the Cornerstone Acquisition	$ 27,501	$ —
Recognition of noncontrolling interest in the RP Finance Consolidation, net of elimination	$ 9,585	$ —
Gain on RP Finance Consolidation recorded as an adjustment to additional paid-in capital due to related party nature of transaction, net of elimination	$ 5,751	$ —
Noncash consideration received in exchange for equipment	$ 34	$ —
Elimination of principal and accrued interest on the Day Three Promissory Notes included in consideration for acquisition of Day Three	$ 2,000	$ —

See accompanying notes to the consolidated financial statements.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – DESCRIPTION OF BUSINESS

Description of Business

Rafael Holdings, Inc. (NYSE:RFL), ("Rafael Holdings", "Rafael", "we" or the "Company"), a Delaware corporation, is a holding company with interests in clinical and early-stage pharmaceutical companies (the "Pharmaceutical Companies"), including an investment in (and planned merger with) Cyclo Therapeutics Inc. (Nasdaq: CYTH), ("Cyclo Therapeutics" or "Cyclo"), a clinical stage biotechnology company dedicated to developing Trappsol® Cyclo™, which is being evaluated in clinical trials for the potential treatment of Niemann-Pick Disease Type C1 ("NPC1"), a rare, fatal and progressive genetic disorder, a majority equity interest in LipoMedix Pharmaceuticals Ltd. ("LipoMedix"), a clinical stage pharmaceutical company, Barer Institute Inc. ("Barer"), a wholly-owned preclinical cancer metabolism research operation, and a majority interest in Cornerstone Pharmaceuticals, Inc. ("Cornerstone"), formerly known as Rafael Pharmaceuticals Inc., a cancer metabolism-based therapeutics company, company. We also hold a majority equity interest in LipoMedix Pharmaceuticals Ltd. Rafael Medical Devices, LLC. ("LipoMedix" Rafael Medical Devices"), a clinical stage pharmaceutical company, the Barer Institute Inc. ("Barer"), a wholly-owned preclinical cancer metabolism research operation, an investment in Cyclo Therapeutics Inc. (Nasdaq: CYTH), ("Cyclo Therapeutics" or "Cyclo"), a clinical-stage biotechnology company dedicated to developing life-changing medicines for patients and families living with challenging diseases through its lead therapeutic asset, Trappsol® Cyclo™., an investment orthopedic-focused medical device company developing instruments to advance minimally invasive surgeries, and a majority interest in Day Three Labs, Inc. ("Day Three"), a company which reimagines empowers third-party manufacturers to reimagine their existing cannabis offerings with pharmaceutical-grade technology and innovation like Unlokt™ enabling them to bring to market better, cleaner, more precise and predictable products in the cannabis industry, versions by utilizing Day Three's pharmaceutical-grade technology and a majority interest in innovation like Unlokt™. Day Three and Rafael Medical Devices, LLC, an orthopedic-focused medical device company developing instruments to advance minimally invasive surgeries ("Rafael Medical Devices" and Day Three Labs together with the Pharmaceutical Companies, represent our "Investment "Portfolio Companies"). In November 2022, the Company resolved to curtail its early-stage development efforts, including pre-clinical research at Barer. The decision was taken to reduce spending as the Company focuses on exploring strategic opportunities. Since then, the Company has sought partners for programs at Farber and has entered into a license agreement for one of its technologies. The Company's primary focus is to expand our investment portfolio through opportunistic and strategic investments including therapeutics, which address high unmet medical needs. Upon closing of the planned merger with Cyclo, the Company intends to focus its efforts on making Trappsol® Cyclo™ its lead clinical program.

Historically, the Company owned multiple real estate assets. In 2020, the Company sold an office building located in Piscataway, New Jersey and, on August 22, 2022, the Company sold the building at 520 Broad Street in Newark, New Jersey that serves as headquarters for the Company and several tenants and an associated public garage (the "520 Property"). See Note 3 for further details on the sale transaction. Currently, As of July 31, 2024, the Company holds a portion of a commercial building in Jerusalem, Israel as its remaining owned real estate asset.

The Company holds debt and equity investments in Cornerstone Pharmaceuticals that includes preferred and common equity interests and a warrant to purchase additional equity. On June 17, 2021, the Company entered into a merger agreement to acquire full ownership of Cornerstone Pharmaceuticals in exchange for issuing Company Class B common stock to the other stockholders of Cornerstone Pharmaceuticals ("Merger Agreement" or "Merger"). On October 28, 2021, the Company announced that the AVENGER 500 Phase 3 clinical trial for CPI-613® (devimistat), Cornerstone Pharmaceuticals' lead product candidate, did not meet its primary endpoint of significant improvement in overall survival in patients with metastatic adenocarcinoma of the pancreas. In addition, following a pre-specified interim analysis, the independent data monitoring committee for the ARMADA 2000 Phase 3 study for devimistat recommended the trial to be stopped due to a determination that it was unlikely to achieve the primary endpoint (the "Data Events"). In connection with the preparation of the Company's financial statements for the first quarter ended October 31, 2021, accounting principles generally accepted in the United States of America ("U.S. GAAP") required that the Company assess the impact of the Data Events and determine whether the carrying values of the Company's assets were impaired based upon the Company's expectations to realize future value. In light of the Data Events, the Company concluded that the likelihood of further development of and prospects for CPI-613 is uncertain and fully impaired in the first quarter ended October 31, 2021 the value of its loans, receivables, and investment in Cornerstone Pharmaceuticals based upon its valuation of Cornerstone Pharmaceuticals. On February 2, 2022, the Company terminated the Merger Agreement with Cornerstone Pharmaceuticals, effective immediately, in accordance with its terms. Subsequently, on February 2, 2022, the Company withdrew its Registration Statement on Form S-4 related to the proposed Merger. On March 21, 2023, the Company loaned $2.0 million to Cornerstone which debt is represented by a Promissory Note made by Cornerstone (the "Promissory Note" or "Note").

Cornerstone is in the process of a comprehensive restructuring transaction including, the conversion of the debt under the Line of Credit Agreement and the Promissory Note held by the Company, the conversion and modification of other Cornerstone debt obligations, the extension of the Cornerstone debt held by RP Finance, a reverse stock split, the conversion of all outstanding preferred stock of Cornerstone into common stock and the adoption of certain governance measures. This transaction is subject to a number of conditions which are beyond the Company's control.

In May 2023, the Company first invested in Cyclo Therapeutics. Cyclo is a clinical stage clinical-stage biotechnology company that develops cyclodextrin-based products for the potential treatment of neurodegenerative diseases. Cyclo's lead drug candidate is Trappsol®Trappsol® Cyclo™ (hydroxypropyl beta cyclodextrin), a treatment for Niemann-Pick Type C disease ("NPC"). NPC Disease, type C1. NPC1 is a rare and fatal autosomal recessive genetic disease resulting in disrupted cholesterol metabolism that impacts the brain, lungs, liver, lifover, spleen, and other organs. In January 2017 the FDA granted Fast Track designation to Trappsol®Trappsol® Cyclo™ for the treatment of NPC. NPC1. Initial patient enrollment in the U.S. Phase I study commenced in September 2017, and in May 2020 Cyclo announced Top Line data showing a favorable safety and tolerability profile for Trappsol®demonstrating Trappsol® Cyclo™ was well tolerated in this study. Cyclo is currently conducting a Phase 3 III Clinical Trial Evaluating Trappsol®Cyclo™ in Pediatric and Adult Patients with Niemann-Pick Disease, Type C1. See Notes 11 and 12 for more information on the Company's investments in Cyclo.

As discussed in more detail below, on August 21, 2024, the Company entered into a merger agreement with Cyclo. In the event the merger is consummated, the Company intends to fund the TransportNPC phase III clinical trial, evaluating Trappsol® Cyclo™ in Niemann Pick C, to its interim analysis in the middle of 2025 and focus its efforts on Trappsol® Cyclo™ as its lead clinical program. At that point, the Company will make a determination as to whether or not to file an NDA for Trappsol® Cyclo™.

LipoMedix is a clinical stage Israeli company focused on the development of a product candidate that holds the potential to be an innovative, safe, and effective cancer therapy based on liposome delivery. As of July 31, 2024, the Company's ownership interest in LipoMedix was approximately 95%. LipoMedix has completed various clinical stages of Promitil® including Phase 1A (solid tumors) and 1B (as single agent and in combination with capecitabine and/or bevacizumab in colorectal cancer). Another phase 1B testing Promitil® as radiosensitizer is ongoing and near completion. A total of 149 patients have been treated with Promitil® as a single agent, or in combination with other anticancer drugs or radiotherapy, under the framework of a phase 1A and two 1B clinical studies and under named patient approval for compassionate use.

In 2019, the Company established Barer, a preclinical cancer metabolism research operation, to focus on developing a pipeline of novel therapeutic compounds, including compounds designed to regulate cancer metabolism with potentially broader application in other indications beyond cancer. Barer has been comprised of scientists and academic advisors that are experts in cancer metabolism, chemistry, and drug development. In addition to its own internal discovery efforts, Barer pursued collaborative research agreements and in-licensing opportunities with leading scientists from top academic institutions. Barer's majority owned subsidiary, Farber Partners, LLC ("Farber"), was formed around one such agreement with Princeton University's Office of Technology Licensing ("Princeton") for technology from the laboratory of Professor Joshua Rabinowitz, in the Department of Chemistry, Princeton University, for an exclusive worldwide license to its SHMT (serine hydroxymethyltransferase) inhibitor program. In November 2022, the Company resolved to curtail its early-stage development efforts, including pre-clinical research at the Barer Institute. Since then, the Company has sought partners for Farber programs and has entered into a license agreement for one of its technologies.

The Company owns a 37.5% equity interest in RP Finance LLC (“RP Finance”), which was, until March 13, 2024 (the date of the RP Finance Consolidation, as described in Note 3), accounted for under the equity method. RP Finance is an entity associated with members of the family of Howard Jonas (Executive Chairman, Chairman of the Board, and controlling stockholder of the Company) which holds 37.5% equity interest of RP Finance. RP Finance holds debt and equity investments in Cornerstone. In October 2021, Cornerstone received negative results of its Avenger 500 Phase 3 study for Devimistat in pancreatic cancer as well as a recommendation to stop its ARMADA 2000 Phase 3 study due to a determination that the trial would unlikely achieve its primary endpoint (the “Data Events”). Due to the Data Events, RP Finance fully impaired its then debt and equity investments in Cornerstone.

On March 13, 2024, Cornerstone consummated a restructuring of its outstanding debt and equity interests (the “Cornerstone Restructuring”). As a result of the Cornerstone Restructuring, Rafael became a 67% owner of the issued and outstanding common stock of Cornerstone (the “Cornerstone Acquisition”), and Cornerstone became a consolidated subsidiary of Rafael. The Cornerstone Acquisition is accounted for as an acquisition of a variable interest entity that is not a business in accordance with U.S. GAAP. The Company was determined to be the accounting acquirer for financial reporting purposes. See Note 3 to the Consolidated Financial Statements for additional information regarding the transaction. In 2016, conjunction with the Cornerstone Restructuring and Cornerstone Acquisition, the Company first invested in LipoMedix, reassessed its relationship with RP Finance, and as a clinical stage pharmaceutical company result determined that RP Finance is still a variable interest entity and that the Company became the primary beneficiary of RP Finance as the Company now holds a majority the ability to control repayment of the common stock.
In April 2023, RP Finance Line of Credit which directly impacts RP Finance’s economic performance. Therefore, following the Cornerstone Restructuring and Cornerstone Acquisition, the Company invested in Day Three Labs, consolidated RP Finance (the “RP Finance Consolidation”). See Note 3 for additional information on the majority-owner of Day three Labs Manufacturing, a company which reimagines existing cannabis offerings with pharmaceutical-grade technology and innovation like Unlokt™ to bring to market better, cleaner, more precise and predictable products in the cannabis industry. Consolidation.

In May 2021, the Company formed Rafael Medical Devices, an orthopedic-focused medical device company developing instruments to advance minimally invasive surgeries. In August 2023, the Company raised $925,000 from third parties in exchange for 31.62% 31.6% ownership of Rafael Medical Devices.

The In April 2023, the Company also holds first invested in Day Three, a 95% investment in LipoMedix, company which empowers third-party manufacturers to reimagine their existing cannabis offerings enabling them to bring to market better, cleaner, more precise and predictable versions by utilizing Day Three’s pharmaceutical-grade technology and innovation like Unlokt™. In January 2024, the Company entered into a development-stage, privately held Israeli company focused on the development series of an innovative, safe transactions with Day Three and effective cancer therapy based on liposome delivery. certain shareholders, acquiring a controlling interest of Day Three and subsequently consolidating Day Three’s results (the “Day Three Acquisition”).

The “Company” in these consolidated financial statements refers to Rafael Holdings and its subsidiaries on a consolidated basis.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

All majority-owned subsidiaries and RP Finance, LLC are consolidated with all intercompany transactions and balances eliminated in consolidation. In addition to Rafael Holdings, Inc., the subsidiaries entities included in these consolidated financial statements are as follows:

Company	Country of Incorporation	Percentage Owned
Broad Atlantic Associates, LLC	United States – Delaware	100 %
IDT R.E. Holdings Ltd.	Israel	100 %
Rafael Holdings Realty, Inc.	United States – Delaware	100 %
Barer Institute, Inc.	United States – Delaware	100 %*
The Barer Institute, LLC	United States – Delaware	100 %*
Hillview Avenue Realty, JV	United States – Delaware	100 %
Hillview Avenue Realty, LLC	United States – Delaware	100 %
Rafael Medical Devices, Inc. LLC	United States – Delaware	100 68 %
Levco Pharmaceuticals Ltd.	Israel	95 %***
Farber Partners, LLC	United States – Delaware	93 %
Pharma Holdings, LLC	United States – Delaware	90 %***
LipoMedix Pharmaceuticals Ltd. (Note 9)	Israel	95 %****
Altira Capital & Consulting, LLC	United States – Delaware	67 %
CS Pharma Holdings, LLC (Note 3)	United States – Delaware	45 %***
Day Three Labs, Inc. (Note 10)	United States – Delaware	84 %****
Cornerstone Pharmaceuticals, Inc. (Note 4)	United States – Delaware	67 %
RP Finance, LLC (Note 5)	United States – Delaware	38 %

* In November 2022, the Company resolved to curtail its early-stage development efforts, including pre-clinical research at Barer. The decision was taken to reduce spending as the Company focuses on exploring strategic opportunities.

** During Fiscal 2022, the Company discontinued further material investment in Levco. In August 2023, Levco was dissolved.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

*** 50% of CS Pharma Holdings, LLC is owned by Pharma Holdings, LLC. We have a 90% ownership in Pharma Holdings, LLC and, therefore, an effective 45% interest in CS Pharma Holdings, LLC. The Company, along with CS Pharma Holdings, LLC and Pharma Holdings LLC, collectively own securities representing 51% 67% of the outstanding capital stock of Cornerstone Pharmaceuticals and 42% of the capital stock on a fully diluted basis (excluding the remainder of the Warrant). Refer to Note 4 for further details.

*** During Fiscal 2022, the Company discontinued further material investment in Levco. Cornerstone.

**** On February 9, 2023, In May 2024, the Company increased its ownership interest in LipoMedix Pharmaceuticals Ltd. an additional 11% Day Three Labs, Inc. from 84% 79% to 95% 84%.

On March 15, 2022, the Company dissolved IDT 225 Old NB Road, LLC.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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 2023 2024 refers to the fiscal year ended July 31, 2023 July 31, 2024).

The accompanying consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with U.S. GAAP. The accompanying consolidated financial statements reflect the activity related to the 520 Property as discontinued operations.

Use of Estimates

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

Liquidity

As of July 31, 2023 July 31, 2024, the Company had cash and cash equivalents of approximately $21.5 million $2.7 million, and available-for-sale securities valued at approximately $57.7 million. On August 22, 2022, the Company received net proceeds of approximately $33 million in connection with the sale of the 520 Property (see Note 3 for further details) $63.3 million. The Company expects the balance of cash and cash equivalents, and available-for-sale securities to be sufficient to meet its obligations for at least the next 12 months from the issuance of these consolidated financial statements.

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.

As of July 31, 2024, there was one related party which represented 50% of the Company's accounts receivable balance. As of July 31, 2023, there was one customer which represented 27% of the Company's accounts receivable balance and one related party which represented 47% of the Company's accounts receivable balance.

For the year ended July 31, 2024, one customer represented 51% of total revenue, and one tenant and one related party tenant represented 27% and 17% of the Company's revenue, respectively. For the year ended July 31, 2023, including revenue from discontinued operations, a related parties party tenant represented 42% of the Company's revenue. As of July 31, 2023, there were two customers which represented 27% and 47% of the Company's accounts receivable balance. For the year ended July 31, 2022, including revenue from discontinued operations, related parties represented 58% of the Company's revenue, and as of July 31, 2022, two customers, one of which is a related party, represented 24% and 47% of the Company's accounts receivable balance, respectively.

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.

Reserve for Receivables

The Company evaluates accounts receivable, loans, interest and fees receivable for impairment under Accounting Standards Codification ("ASC") 310, *Receivables*. The Company also evaluates the reserve for losses and estimates collectability of accounts receivable, loans, interest and fees receivable based on historical bad debt experience, management's assessment of the financial condition of individual companies with which the Company conducts business, current market conditions, and reasonable and supportable forecasts of future economic conditions.

The allowance for doubtful accounts credit losses reflects the Company's best estimate of probable lifetime credit losses inherent in the accounts receivable balance. The allowance is determined based on known troubled accounts, historical experience and other currently available evidence. Doubtful accounts are written off upon final determination that the trade accounts will not be collected. The computation of this allowance is based on the tenants' or parking customers' payment histories, as well as certain industry or geographic specific credit considerations. If the Company's estimates of collectability differ from the cash received, then the timing and amount of the Company's reported revenue could be impacted. The credit risk Company recorded bad debt expense from continuing operations, which is mitigated by included in general and administrative expenses on the high quality Consolidated Statements of the Company's existing tenant base, inclusive Operations and Comprehensive Loss, of related parties, which represented 42% approximately $20 thousand and 58% of the Company's total revenue $0 for the years ended July 31, 2023 July 31, 2024 and 2022, 2023, respectively. The Company recorded bad debt expense from discontinued operations of approximately $110 thousand $0 and $4 $110 thousand for the years ended July 31, 2023 July 31, 2024 and 2022, 2023, respectively.

Convertible Note Receivable Related Party

The Convertible Note Receivable is Company holds convertible notes receivable that are classified as available-for-sale as defined under ASC Accounting Standards Codification ("ASC") 320, *Investments - Debt and Equity Securities*, and is are recorded at fair value. Subsequent changes in fair value are recorded in accumulated other comprehensive loss. income (loss).

The fair value of the Convertible Note Receivable is these convertible note receivables are estimated using a scenario-based analysis based on the probability-weighted present value of future investment returns, considering each of the possible outcomes available to the Company, including cash repayment, equity conversion, and collateral transfer scenarios. Estimating the fair value of the convertible note requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors.

Variable Interest Entities

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

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

Investments

The method of accounting applied to long-term investments in equity securities 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 include the identification of any variable interests in which the Company is the primary beneficiary. The consolidated financial statements include the Company's controlled affiliates. All significant intercompany accounts and transactions between the consolidated affiliates are eliminated.

Investments in equity securities may be accounted for using (i) the fair value option, if elected, (ii) fair value through earnings if fair value is readily determinable or (iii) for equity investments without readily determinable fair values, the measurement alternative to measure at cost adjusted for any impairment and observable price changes, as applicable. The election to use the measurement alternative is made for each eligible investment.

The Company has elected the fair value option to account for its investment in Cyclo Therapeutics, Inc. over which, as the Company has significant influence. influence over Cyclo's management. The fair value option is irrevocable once elected. The Company measured its initial investment in Cyclo at fair value and shall record all subsequent changes in fair value in earnings in the consolidated statement statements of operations. operations and comprehensive loss. The Company believes the fair value option best reflects the underlying economics of the investment. The Company has determined that Cyclo is a VIE; however, the Company has determined that it is not the primary beneficiary as the Company does not have the power to direct the activities of Cyclo that most significantly impact Cyclo's economic performance. See Note 9, "Investments. 11, "Investment in Cyclo Therapeutics, Inc."

Investments in which the Company does not have the ability to exercise significant influence over operating and financial matters are accounted for in accordance with ASC 321, *Investments - – Equity Securities*. Investments without readily determinable fair values are accounted for using the measurement alternative which is at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. The Company periodically evaluates its investments for impairment due to declines considered to be other than temporary. If the Company determines that a decline in fair value is other than temporary, then a charge to earnings is recorded in the accompanying consolidated statements of operations and comprehensive loss, and a new basis in the investment is established.

Investments - Hedge Funds

The Company accounts for its investments in hedge funds in accordance with ASC 321, *Investments – Equity Securities*. Unrealized gains and losses resulting from the change in fair value of these securities is included in unrealized (loss) gain on investments – investment - Hedge Funds in the consolidated statements of operations and comprehensive loss.

Corporate Bonds and US Treasury Bills

The Company's marketable securities are considered to be available-for-sale as defined under ASC 320, *Investments - Debt and Equity Securities*, and are recorded at fair value. Unrealized gains or losses are included in accumulated other comprehensive loss. Realized gains or losses are determined using the specific identification method and are released from accumulated other comprehensive loss and into earnings on the consolidated statements of operations and comprehensive loss.
Effective August 1, 2023, the Company uses a current expected credit losses ("CECL") model to estimate the allowance for credit losses on available-for-sale debt securities. For available-for-sale debt securities in an unrealized loss position, management first assesses whether it intends to sell, or it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through income. For available-for-sale debt securities that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, management considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors.
If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security are compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded for the credit loss, limited by the amount that the fair value is less than the amortized cost basis. Any decline in fair value that has not been recorded through an allowance for credit losses is recognized in other comprehensive income. No allowance for credit losses was recognized by the Company at July 31, 2024.

Cost Method Investment

The Prior to the Cornerstone Acquisition, the Company has had determined that Cornerstone Pharmaceuticals (see Note 4) is was a VIE; however, the Company has had determined that it is was not the primary beneficiary as the Company does did not have the power to direct the activities of Cornerstone Pharmaceuticals that most significantly impact Cornerstone Pharmaceuticals' Cornerstone's economic performance. See Note 3 for additional information.

Equity Method Investments

Investments classified as equity method consist of investments in companies in which the Company is able to exercise significant influence but not control. Under the equity method of accounting, the investment is initially recorded at cost, then the Company's proportional share of investee's underlying net income or loss is recorded as a component of income from continuing operations, with a corresponding increase or decrease to the carrying value of the investment. These investments are evaluated for impairment if events or circumstances arise that indicate that the carrying amount of such assets may not be recoverable.
The Company has determined that each of RP Finance, LLC ("RP Finance") and Day Three Labs, Inc. ("Day Three", RP Finance and Day Three collectively, are VIEs. Prior to the "Equity Method Investees" RP Finance Consolidation, which occurred as a result of the Cornerstone Acquisition, and the Company's investments in Day Three Acquisition, the Company accounted for RP Finance and Day Three collectively, the "Equity Method Investments"), (see Note 6 and Note 8), are each a VIE; however, the Company has determined that it is not the primary beneficiary as the Company does not have the power to direct the activities of the Equity Method Investees that most significantly impact the Equity Method Investees' economic performance and, therefore, is not required to consolidate the Equity Method Investees. The Company accounts for the Equity Method Investments using under the equity method of accounting. As of January 2, 2024, Day Three is consolidated as a majority-owned subsidiary. In conjunction with the Cornerstone Acquisition on March 13, 2024, the Company reassessed its relationship with RP Finance and, as a result, the Company has consolidated RP Finance.

Long-Lived Assets

Equipment, buildings, leasehold improvements, and furniture and fixtures are recorded at cost less accumulated depreciation and amortization. The related depreciation and amortization are depreciated on a computed using the straight-line basis method over their the estimated useful lives, which range as follows:

Classification	Years
Building and improvements	40
Tenant improvements	7-15
7-15Machinery and equipment	3-5
Other (primarily office equipment, and furniture and fixtures)	5

Properties

On August 22, 2022, Broad Atlantic Associates LLC, a wholly-owned subsidiary of the Company ("Broad Atlantic"), completed the sale of the 520 Property for a purchase price of $49.4 million. The 520 Property served serves as the Company's headquarters and had has several other tenants, and includes a related 800-car public parking garage. The Company determined that the 520 Property met the held-for-sale and discontinued operations criteria as of July 1, 2022. The 520 Property was disposed of on August 22, 2022.

The Company owns a portion of the 6th floor of a building located at 5 Shlomo Halevi Street, in Jerusalem, Israel.
Business Combinations
The purchase price for acquisitions are allocated to the assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. The fair value of identifiable intangible assets is based on detailed valuations that use information and assumptions provided by management, including expected future cash flows. We allocate any excess purchase price over the fair value of the identifiable net assets and liabilities acquired to goodwill. Identifiable intangible assets with finite lives are amortized over their useful lives. Acquisition-related costs, including advisory, legal, accounting, valuation, and other costs, are expensed in the periods in which the costs are incurred. The results of operations of acquired businesses are included in the consolidated financial statements from the acquisition date.

Impairment of Long-Lived Assets

The Company assesses the recoverability of long-lived assets, which include property and equipment, and intangible assets, in-process research and development and patents, whenever significant events or changes in circumstances indicate that its carrying amount may not be recoverable. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's carrying value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a change charge to operating results. For the years ended July 31, 2023 July 31, 2024 and 2022, 2023, the Company determined that there was no impairment of its long-lived assets.

Assets Held-for-Sale and Discontinued Operations

The Company classifies assets as held-for-sale if all held-for-sale criteria are met pursuant to ASC 360-10, *Property, Plant and Equipment*. Criteria include management commitment to sell the disposal group in its present condition and the sale being deemed probable of being completed within one year. Assets classified as held-for-sale are not depreciated and are measured at the lower of their carrying amount or fair value less cost to sell. The Company assesses the fair value of a disposal group, less any costs to sell, each reporting period it remains classified as held-for-sale and reports any subsequent changes as an adjustment to the carrying value of the disposal group, as long as the new carrying value does not exceed the initial carrying value of the disposal group.

Strategic changes in the Company's operations can be considered a discontinued operation if both the operations and cash flows of the discontinued component have been (or will be) eliminated from the ongoing operations of the Company and the Company will not have any significant continuing involvement in the operations of the discontinued component after the disposal transaction. The results of the discontinued operations shall be reflected as a discontinued operation on the consolidated statements of operations and comprehensive loss and prior periods shall be recast to reflect the earnings from discontinued operations. As a result of the agreement to sell the 520 Property, the accompanying consolidated financial statements reflect the activity related to the sale of the 520 Property as discontinued operations. The Company determined that the 520 Property met the held-for-sale and discontinued operations criteria as of July 1, 2022. The 520 Property was disposed of on August 22, 2022. See Note 3 14 for additional information regarding the results, major classes of assets and liabilities, significant non-cash operating items, and capital expenditures of discontinued operations.

Debt Issuance Costs *Goodwill*

The Company assesses goodwill for impairment on an annual basis or more frequently when events and circumstances occur indicating that the recorded goodwill may be impaired. The Company regularly monitors current business conditions and other factors including, but not limited to, adverse industry or economic trends and lower projections of profitability that may impact future operating results. The process of evaluating the potential impairment of goodwill requires significant judgment. In performing the Company's annual goodwill impairment test, the Company is permitted to first assess qualitative factors to determine whether it is more likely than not that the fair value of any of the Company's reporting units is less than its carrying amount, including goodwill. In performing the qualitative assessment, the Company considers certain events and circumstances specific to the reporting unit and the entity as a whole, such as macroeconomic conditions, industry and market considerations, overall financial performance and cost factors when evaluating whether it is more likely than not that the fair value of any of the reporting units is less than its carrying amount. The Company is also permitted to bypass the qualitative assessment and proceed directly to the quantitative test. If the Company chooses to undertake the qualitative assessment and concludes that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, the Company would then proceed to the quantitative impairment test. In the quantitative assessment, the Company compares the fair value of the reporting unit to its carrying amount, which includes goodwill. If the fair value exceeds the carrying value, no impairment loss exists. If the fair value is less than the carrying amount, a goodwill impairment loss is measured and recorded.

The Company assesses goodwill for impairment on an annual basis as of May 31 or more frequently when events and circumstances occur indicating that recorded goodwill may be impaired. The Company did not record an impairment charge during the year ended July 31, 2024.

In-Process Research and Development

Debt issuance costs The Company has acquired in-process research and development ("IPR&D") intangible assets pursuant to a business combination. These IPR&D assets are recorded net against the related debt and amortized to interest expense over the life considered indefinite-lived intangible assets until completion or abandonment of the related debt. During associated research and development efforts. These IPR&D assets are not amortized but reviewed for impairment at least annually, or when events or changes in the years ended July 31, 2023 and 2022, amortized debt issuance costs of $0 and $472 thousand, respectively, were recorded business environment indicate the carrying value may be impaired.

Acquired IPR&D pursuant to an asset acquisition that has no alternative future use is expensed immediately as a component of interest in-process research and development expense which is included in Discontinued Operations. the consolidated statements of operations and comprehensive loss.

Revenue Recognition

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

The Company disaggregates its revenue by source within its consolidated statements of operations and comprehensive loss.

The Company's infusion technology revenue is derived from Day Three's Unlokt technology which is recognized in accordance with ASC 606. Day Three provides manufacturing services where they use proprietary technology, equipment, and processes to manufacture water-soluble product for their customers at their customer facilities. Day Three is acting as a principal in the transaction, as it is primarily responsible for fulfillment and acceptability of the services. Infusion technology revenue is recognized over time as the Company's performance obligation is satisfied, which is generally within a 30-day period. The criterion in ASC 606-10-25-27, that the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced, is met given that the customer is controlling the product as Day Three is performing the service on the customer's premises. Revenue is recognized over the period of performance using an output method where the number of grams produced is the output, as such method best depicts the Company's efforts to satisfy the performance obligation. Customer billings in advance of revenue recognition result in contract liabilities. As of July 31, 2024, there were no contract liabilities recognized on the consolidated balance sheets related to infusion technology revenue.

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

The revenue derived from the 520 Property for the period prior to its sale, which included leasing office and parking space to the tenants, is presented within discontinued operations in the consolidated statements of operations and comprehensive loss.

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

The Company also earned revenue from parking which was derived primarily from monthly and transient daily parking. parking which is a component of income from discontinued operations. The monthly and transient daily parking revenue falls within the scope of ASC 606 and was 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.

Cost of Infusion Technology Revenue

The Company maintains an allowance for doubtful accounts for estimated losses resulting from the inability cost of tenants Infusion Technology revenue includes costs related to make required rent payments or parking customers to pay amounts due. supplies, materials, production labor, and travel costs.

Research and Development Costs

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

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

Repairs There were no such payment expenses during the years ended July 31, 2024 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. 2023.

Stock-Based Compensation

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

Income Taxes

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

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

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

Contingencies

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

Leases

The Company categorizes leases at their inception as either operating or finance leases. On certain lease agreements, the Company may receive rent holidays and other incentives. The Company recognizes lease costs on a straight-line basis without regard to deferred payment terms, such as rent holidays, that defer the commencement date of required payments. As of July 31, 2023 and 2022, the Company was not a lessee under any leasing arrangements.

Fair Value Measurements

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

- Level 1 - quoted prices in active markets for identical assets or liabilities;
- Level 2 - quoted prices in active markets for similar assets and liabilities and inputs that are observable for the asset or liability; or
- Level 3 - unobservable inputs for the asset or liability, such as discounted cash flow models or valuations.

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

Functional Currency

The U.S. Dollar is the functional currency of our entities operating in the United States. The functional currency for our subsidiaries operating outside of the United States is the New Israeli Shekel, the currency of the primary economic environment in which such subsidiaries primarily expend cash. The Company translates those subsidiaries' financial statements into U.S. Dollars. The Company translates assets and liabilities at the exchange rate in effect as of the consolidated financial statement date, and translates accounts from the consolidated statements of operations and comprehensive loss using the weighted average exchange rate for the period. The Company reports gains and losses from currency exchange rate changes related to intercompany receivables and payables, currently in non-operating expenses. which are not of a long-term investment nature, as part of other comprehensive loss.

Loss Per Share

Basic loss per share is computed by dividing net loss attributable to all classes of common stockholders of the Company by the weighted average number of shares of all classes of common stock outstanding during the applicable period. Diluted loss per share is determined in the same manner as basic loss per share, except that the number of shares is increased to include restricted stock still subject to risk of forfeiture and to assume exercise of potentially dilutive stock options using the treasury stock method, unless the effect of such increase would be anti-dilutive. The Company uses income loss from continuing operations as the "control number" or benchmark to determine whether potential common shares are dilutive or anti-dilutive for purposes of reporting earnings (loss) loss per share for discontinued operations.

Recently Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments*, which was codified in ASC 326, *Financial Instruments - Credit Losses* ("ASC 326"). The standard changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are recorded. Because the Company is a smaller reporting company, ASC 326 became effective for the Company for fiscal years beginning after December 15, 2022. As such, the Company adopted ASC 326 effective August 1, 2023, utilizing the modified retrospective transition method. Upon adoption, the Company updated its impairment model to utilize a forward-looking CECL model in place of the incurred loss methodology for financial instruments measured at amortized cost, primarily including its accounts receivable. In relation to available-for-sale ("AFS") debt securities, the guidance eliminates the concept of "other-than-temporary" impairment, and instead focuses on determining whether any impairment is a result of a credit loss or other factors. The adoption of ASC 326 did not have a material impact on our consolidated financial statements as of the adoption date.

Recently Issued Accounting Standards Not Yet Adopted

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") FASB or other standard setting bodies and are adopted by the Company as of the specified effective date. The Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In June 2016, the FASB issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which changes the impairment model for most financial assets and certain other instruments. For receivables, loans and other instruments, entities will be required to use a new forward-looking "expected loss" model that generally will result in the earlier recognition of allowance for losses. For available-for-sale debt securities with unrealized losses, entities will measure credit losses in a manner similar to current practice, except the losses will be recognized as allowances instead of reductions in the amortized cost of the securities. In addition, an entity will have to disclose significantly more information about allowances, credit quality indicators and past due securities. The new standard is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, and will be applied as a cumulative-effect adjustment to retained earnings. The Company intends to adopt the standard on August 1, 2023 and does not believe the adoption will have a material impact on its consolidated financial statements.

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

In June 2022, the FASB issued ASU 2022-03, *Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions* ("ASU 2022-03"), which clarifies the guidance in ASC Topic 820, *Fair Value Measurement* ("Topic 820"), when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security and introduces new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value in accordance with Topic 820. ASU 2022-03 is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years, and early adoption is permitted. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and intends to adopt the standard as of August 1, 2024.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). ASU 2023-07 updates reportable segment disclosure requirements primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for all entities for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The amendments should be applied retrospectively to all prior periods presented in the financial statements. The new guidance is effective for the Company in the annual period beginning August 1, 2024 and interim periods beginning February 1, 2025. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements.

NOTE 3 – DISCONTINUED OPERATIONS CORNERSTONE RESTRUCTURING, ACQUISITION, AND RP FINANCE CONSOLIDATION

Prior to the Cornerstone Restructuring, Rafael (directly via certain of its subsidiaries, and through an equity method investment in RP Finance) held certain debt and equity investments in Cornerstone, which are described in Note 4.

Restructuring of Cornerstone

On July 1, 2022 March 13, 2024, Rafael, Cornerstone, and other holders of debt and equity securities of Cornerstone agreed to various transactions which effected a recapitalization and restructuring of the outstanding debt and equity interests in Cornerstone. In the Cornerstone Restructuring, Rafael obtained shares of common stock of Cornerstone ("Cornerstone Common Stock") that gave the Company control over approximately 67% of the outstanding voting interests of Cornerstone (the "Cornerstone Acquisition"). For accounting purposes, Rafael was determined to be the acquirer, as the Company has been determined to be the primary beneficiary of Cornerstone, a VIE, in accordance with ASC 810. For Rafael, the Cornerstone Acquisition is the result of the Cornerstone Restructuring. As part of the Cornerstone Restructuring:

(i) all issued and outstanding shares of Cornerstone's preferred stock and non-voting common stock converted into shares of Cornerstone Common Stock (the "Mandatory Common Conversion") on a one-for-one basis, which shares of Cornerstone Common Stock were then subjected to the Reverse Stock Split (as defined below), including the conversion of Rafael's 60,673,087 shares of Cornerstone's Series D Preferred Stock into 6,067,306 shares of post-Reverse Stock Split Cornerstone Common Stock;

(ii) Cornerstone offered shares of Cornerstone's Common Stock to all holders of Cornerstone's promissory notes convertible into Cornerstone Series C preferred stock (the "Series C Convertible Notes") who were Accredited Investors with the purchase price to be paid through conversion of the outstanding principal amount and accrued interest on their Series C Convertible Notes held by each holder into Common Stock at the Cornerstone Restructuring Common Stock Price as described below (the "Series C Convertible Notes Exchange"). Approximately 94% of the outstanding Series C Convertible Notes participated in the Series C Convertible Notes Exchange, and $15.5 million of principal and accrued interest outstanding on the Series C Convertible Notes was converted into 15,739,661 shares of post-Reverse Stock Split Cornerstone Common Stock. Series C Convertible Notes with an aggregate principal and accrued interest amount of $0.9 million remaining outstanding, of which Series C Convertible Notes with an aggregate principal and accrued interest amount of $93 thousand were amended in the Cornerstone Restructuring to (A) extend the maturity date thereof to May 31, 2028 and (B) provide that, on conversion thereof, the 520 Property met converting holder will receive shares of Cornerstone Common Stock. The holders of these amended Series C Convertible Notes that remain outstanding waived such holders' rights in connection with the held-for-sale criteria Cornerstone Restructuring. Series C Convertible Notes with an aggregate principal and accrued interest amount of $0.8 million remained outstanding and were not amended in connection with the Cornerstone Restructuring. The principal and accrued interest are included in Convertible notes on the consolidated balance sheets;

(iii) Rafael converted the approximately $30.6 million of the outstanding principal and accrued interest under the RFL Line of Credit (as defined in Note 4) into 30,080,747 shares of post-Reverse Stock Split Cornerstone Common Stock. The conversion of the RFL Line of Credit, inclusive of accrued interest, into equity in Cornerstone represents a recovery of a previously written-off asset, and the Company therefore classified recorded the 520 Property as held-for-sale recovery in accordance with ASC 326, by recognizing a gain of $30.6 million in the consolidated balance sheets at July 31, 2022. The sale year ended July 31, 2024, in conjunction with and immediately prior to the Cornerstone Restructuring equal to the fair value of the 520 Property also represented a significant strategic shift that will have a major effect Cornerstone Common Stock, up to the amount of principal and accrued interest on the instrument, that was received in settlement of the RFL Line of Credit in connection with the Cornerstone Restructuring. Upon the consummation of the Cornerstone Acquisition, the investment was eliminated as Cornerstone became a majority-owned subsidiary of Rafael and the difference between the investment's carrying value and its fair value included in purchase consideration, which is based on the value of Cornerstone's Common Stock, resulted in a gain of $7.3 million that was recorded to the Company's operations additional paid-in capital given the related party nature of the transaction;

(iv) Rafael converted the approximately $2.1 million of the outstanding principal and financial results. Therefore, accrued interest pursuant to the 2023 Promissory Note (as defined in Note 4) into 2,116,932 shares of post-Reverse Stock Split Cornerstone Common Stock. Prior to the Cornerstone Restructuring, the Company has recorded the 2023 Promissory Note at its fair value as the security was classified the results of operations related to the 520 Property as discontinued operations available-for-sale. The 2023 Promissory Note is included in the consolidated statements consideration paid at its fair value (which was deemed to be the fair value of operations and comprehensive loss. Depreciation the Cornerstone Common Stock received) in the Cornerstone Acquisition in accordance with ASC 810-10-30-4. The Company recognized a gain of $0.6 million in the year ended July 31, 2024 for the realization of previously unrealized gains on the 520 Property ceased fair value of the 2023 Promissory Note in other comprehensive loss;

(v) Cornerstone and RP Finance amended the RPF Line of Credit (as defined in Note 5) to (i) extend the maturity date of the approximately $21.9 million in borrowings thereunder to May 31, 2028, (ii) limit the number of shares to be issued thereunder in respect of anti-dilution protection provided for therein in connection with the Cornerstone Restructuring and to provide RP Finance 3,658,368 shares of post-Reverse Stock Split Cornerstone Common Stock so that following the Cornerstone Restructuring, RP Finance holds six percent (6%) of the outstanding Common Stock of Cornerstone (the "RPF 6% Top Up Shares"), (iii) terminate any anti-dilution protection in respect of such ownership interest following consummation of the Cornerstone Restructuring, and (iv) terminate all future lending obligations of RP Finance under the RPF Line of Credit (as so amended, the "Amended RPF Line of Credit");

(vi) Rafael invested an additional $1.5 million in cash in exchange for 1,546,391 shares of post-Reverse Stock Split Cornerstone Common Stock;

(vii) Cornerstone amended and restated its certificate of incorporation, to, among other things, effect a reverse split of all of Cornerstone's capital stock on July 1, 2022 a one-for-ten basis (the "Reverse Stock Split"), set the number of authorized shares of Cornerstone Common Stock to be sufficient for issuance of the Common Stock in the Cornerstone Restructuring and eliminate the authorized preferred stock not required to be authorized as a result of the 520 Property being classified as held-for-sale. Mandatory Common Conversion;

On August 22, 2022, Broad Atlantic completed the sale (viii) Cornerstone amended prior agreements in place giving certain parties rights to designate members of the 520 Property Board and those rights have been eliminated. All directors are elected by the Cornerstone stockholders and as the majority stockholder, Rafael can control that vote. The Company has entered into a voting agreement (the "Voting Agreement") whereby Rafael has agreed to maintain three directors of Cornerstone that are independent of Rafael; and

(ix) Cornerstone increased the available reserve of Cornerstone Common Stock for an aggregate gross purchase price grant to employees, consultants and other service providers to approximately 10% of $49.4 million Cornerstone's fully diluted capital stock (the "Reserve Increase").

Acquisition of Cornerstone

As a result of the Cornerstone Restructuring, Rafael became a 67% owner of the issued and outstanding Common Stock of Cornerstone, which became a consolidated subsidiary of Rafael. The 520 Property Cornerstone Acquisition is accounted for as an acquisition of a VIE that is not a business in accordance with U.S. GAAP. The Company was encumbered by determined to be the accounting acquirer for financial reporting purposes. The guidance requires an initial screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a mortgage securing single asset or group of similar assets. If that screen test is met, the acquired entity is not a $15 million note payable which was business for financial reporting purposes. Accordingly, the Cornerstone Acquisition will be accounted for as an asset acquisition as substantially all of the fair value of Cornerstone's gross assets is concentrated within in-process research and development, an intangible asset.

Under ASC 810, the initial consolidation of a VIE shall not result in goodwill being recognized, and the acquirer shall recognize a gain or loss for the difference of (a) the sum of (i) the fair value of any consideration paid, off in this transaction. Refer to Note 15 for further information on (ii) the note payable. After repaying fair value of any noncontrolling interests, and (iii) the note payable, commissions, taxes, and other related costs, the Company received a net cash reported amount of approximately $33 million at closing.

The carrying value any previously held interests, and (b) the net amount of major classes of the VIE's identifiable assets and liabilities related to discontinued operations at July 31, 2022 recognized and measured in accordance with ASC 805, *Business Combinations* ("ASC 805"). In accordance with the calculation within ASC 810, no gain or loss was as follows: recognized on the Cornerstone Acquisition.

	As of July 31, 2022
	(in thousands)
Current assets held-for-sale	
Building and Improvements	$ 45,437
Land	10,412
Furniture and Fixtures	1,145
Other	205
Property and equipment	57,199
Less Accumulated Depreciation	(17,005)
Property and equipment, net	40,194
Total current assets held-for-sale	40,194
Total assets held-for-sale	$ 40,194
Current liabilities held-for-sale	
Total current liabilities	$ 15,000

The current portion net amount of deferred rental income included in Prepaid Expenses the VIE's identifiable assets and Other Current Assets was $0 and approximately $150 thousand as of July 31, 2023 and 2022, respectively. The noncurrent portion of deferred rental income included in Other Assets was $0 and approximately $1.3 million as of July 31, 2023 and 2022, respectively. The deferred rental income pertains liabilities recognized with respect to the 520 Property Cornerstone Acquisition is based upon management's preliminary estimates of and was settled at assumptions related to the date fair values of the sale of the 520 Property assets acquired and liabilities assumed, using currently available information. For this purpose, fair value shall be determined in accordance with the other working capital accounts of the 520 Property.
Discontinued operations include (i) rental fair value concepts defined in ASC 820, *Fair Value Measurements and parking revenues, (ii) payroll, benefits, facility costs, real estate taxes, consulting and professional fees dedicated to the 520 Property, (iii) depreciation and amortization expenses and (iv) interest (including amortization of debt issuance costs) on the note payable on the 520 Property. The operating results of these items are presented in our consolidated statements of operations and comprehensive loss as discontinued operations for all periods presented. Disclosures.*

The following table details presents, in accordance with ASC 810, the components comprising net loss from our discontinued operations: sum of (i) the fair value of consideration paid, (ii) the fair value of noncontrolling interests, and (iii) the reported amount of previously held interests (amounts in thousands):

	Year Ended July 31,	
	2023	2022
	(in thousands)	
Revenue from discontinued operations:		
Rental – Third Party	$ 68	$ 644
Rental – Related Party	115	2,161
Parking	66	694
Total revenue from discontinued operations	249	3,499
Costs and expenses from discontinued operations:		
General and administrative	468	2,683
Depreciation and amortization	—	1,317
Loss from discontinued operations	(219)	(501)
Other income	—	157
Interest expense	(87)	(1,486)
Loss from discontinued operations	(306)	(1,830)
Gain on disposal of discontinued operations	6,784	—
Gain (loss) from discontinued operations	$ 6,478	$ (1,830)

Fair value of consideration paid	
Fair value of RFL Line of Credit	$ 37,845
Fair value of 2023 Promissory Note	2,663
Cash consideration	1,500
(i) Total fair value of consideration paid	**42,008**
(ii) Fair value of noncontrolling interests	27,501
(iii) Reported value of previously held interests[(1)]	—
Sum of (i), (ii), and (iii)	**$ 69,509**

(1) Rafael's interest in the Series D Preferred Stock of Cornerstone, that was converted into Cornerstone Common Stock in the Cornerstone Restructuring, represents a previously held interest in Cornerstone that is included at its reported amount, or $0.

The gain on disposal of discontinued operations of approximately $6.8 million was derived from following table presents, in accordance with ASC 810, the gross proceeds of approximately $49.4 million from the sale net preliminary amount of the 520 Property, less VIE's identifiable assets and liabilities recognized and measured in accordance with ASC 805 (amounts in thousands):

Assets acquired and liabilities assumed	
Cash and cash equivalents	$ 2,756
Prepaid expenses and other current assets	121
Property and equipment	19
Other assets	48
Acquired IPR&D	89,861
Accounts payable	(2,006)
Accrued expenses	(1,188)
Series C Convertible Notes, short-term portion	(614)

Due to related parties	(1,289)
Other current liabilities	(28)
Series C Convertible Notes, long-term portion	(70)
Creditor payable, noncurrent	(2,745)
Amended RPF Line of Credit	(15,336)
Other liabilities	(20)
Total	**$ 69,509**

In accordance with the carrying value calculation within ASC 810, no gain or loss was recognized on the initial consolidation of Cornerstone. The Company incurred transaction costs of $716 thousand for the year ended July 31, 2024 for consulting, legal, accounting, and other professional fees that have been expensed as general and administrative expenses as part of the 520 Property of approximately $40.2 million, net of approximately $1.2 million in transaction costs Cornerstone Restructuring, Cornerstone Acquisition, and the write off of approximately $1.2 million of deferred rental income.

NOTE 4 – INVESTMENT IN CORNERSTONE PHARMACEUTICALS

Equity Investment in Cornerstone Pharmaceuticals and Impairment of Cost Method Investment

Cornerstone Pharmaceuticals is a clinical stage, cancer metabolism-based therapeutics company focused on the development and commercialization of therapies that exploit the metabolic differences between normal cells and cancer cells. RP Finance Consolidation.

The Company owns debt and equity interests and rights recognized a gain in the amount of $720 thousand on the reversal of a reserve on a receivable due from Cornerstone, Pharmaceuticals through a 90%-owned non-operating subsidiary, Pharma Holdings, LLC, or Pharma Holdings.

Pharma Holdings owns 50% of CS Pharma Holdings, LLC, or CS Pharma, a non-operating entity that owns equity interests in Cornerstone Pharmaceuticals. Accordingly, which was fully reserved for by the Company holds an effective 45% indirect interest due to the Data Events. This receivable balance is then eliminated in consolidation against the corresponding payable balance acquired from Cornerstone recorded in Cornerstone's Due to related parties balance in the assets held by CS Pharma.

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

Pharma Holdings holds 44.0 million shares To value the IPR&D, the Company utilized the Multi-Period Excess Earnings Method ("MPEEM"), under the Income Approach. The method reflects the present value of the projected operating cash flows generated by Cornerstone's assets after taking into account the cost to realize the revenue, and an appropriate discount rate to reflect the time value and risk associated with the invested capital. IPR&D acquired represents Cornerstone's research and development activities related to oncology-focused pharmaceuticals which seeks to exploit the metabolic differences between normal cells and cancer cells.

IPR&D represents the R&D asset of Cornerstone Pharmaceuticals' Series D Convertible Preferred Stock which is in-process, but not yet completed, and which has no alternative use. As the Cornerstone Acquisition has been accounted for as an acquisition of a warrant VIE that is not a business, it was determined that the fair value of IPR&D asset acquired with no alternative future use should be charged to increase IPR&D expense at the combined ownership acquisition date.

The Company assumed Cornerstone's liability to RP Finance under the Amended RPF Line of Pharma Holdings Credit at its fair value in the Cornerstone Acquisition and CS Pharma acquired RP Finance's receivable from Cornerstone under the Amended RPF Line of Credit at its fair value in the RP Finance Consolidation. These intercompany amounts are eliminated in consolidation. The Company will accrete the fair value of Cornerstone's liability and RP Finance's receivable under the Amended RPF Line of Credit to up to 56% the amount due on May 31, 2028 as interest expense and interest income, respectively, in the consolidated statements of operations and comprehensive loss over the estimated term of the fully diluted Amended RPF Line of Credit.

The creditors of Cornerstone do not have legal recourse to the Company's general credit.

The consolidated financial statements include the results of the Cornerstone Acquisition subsequent to the closing date. Cornerstone did not produce any revenue for the period from the closing date through July 31, 2024. Cornerstone incurred a net loss of $93.0 million, of which $30.7 million is attributable to non-controlling interests, for the period from the closing date through July 31, 2024, which is included in the Company's consolidated statements of operations and comprehensive loss for the year ended July 31, 2024. Cornerstone's results of operations included IPR&D expense of $89.9 million, related to the IPR&D asset acquired with no alternative future use, that was pushed down to the entity.

Consolidation of RP Finance

RP Finance, an entity in which the Company owns a 37.5% equity interests interest (previously accounted for as an equity method investment of Rafael), and in which an entity associated with members of the family of Howard Jonas holds an additional 37.5% equity interest, holds debt and equity investments in Cornerstone Pharmaceuticals (the "Warrant") (which is included in the Company's 67% equity ownership interest in Cornerstone). The exercise price In conjunction with the Cornerstone Acquisition, the Company reassessed its relationship with RP Finance and, as a result of the Warrant Cornerstone Restructuring and resulting Cornerstone Acquisition, determined that RP Finance is the lower of 70% of the price sold in an equity financing, or $1.25 per share, subject to certain adjustments.

On March 25, 2020, the Board of Directors of Cornerstone Pharmaceuticals extended the expiration date of the Warrant held by Pharma Holdings to purchase shares of the Warrant from December 31, 2020 to June 30, 2021, still a VIE and on August 31, 2020 the Board of Directors of Cornerstone Pharmaceuticals further extended the expiration date of the Warrant held by Pharma Holdings, LLC to purchase shares of the Warrant to August 15, 2021. In connection with the Merger Agreement, the Warrant expiration was extended to April 1, 2022. The Company has asserted that it may be entitled to a further extension of the Warrant. At this time, the Company does not intend to exercise the Warrant.

Pharma Holdings also holds certain governance rights in Cornerstone Pharmaceuticals including appointment of directors. Pharma Holdings is not now considered the primary beneficiary of RP Finance as the Company now holds the ability to control repayment of the RPF Line of Credit, which directly impacts RP Finance's economic performance. Therefore, the Company has consolidated RP Finance as a result of the Cornerstone Pharmaceuticals Acquisition (the "RP Finance Consolidation"). The RP Finance Consolidation is accounted for as it an acquisition of a VIE that is not a business in accordance with U.S. GAAP as RP Finance does not control or direct meet the activities definition of Cornerstone Pharmaceuticals that most significantly impact Cornerstone Pharmaceuticals' economic performance. a business under U.S. GAAP.

CS Pharma holds 16.7 million Under ASC 810, the initial consolidation of a VIE shall not result in goodwill being recognized, and the acquirer shall recognize a gain or loss for the difference of (a) the sum of (i) the fair value of any consideration paid, (ii) the fair value of any noncontrolling interests, and (iii) the reported amount of any previously held interests, and (b) the net amount of the VIE's identifiable assets and liabilities recognized and measured in accordance with ASC 805.

The following table presents, in accordance with ASC 810, the sum of (i) the fair value of consideration paid, (ii) the fair value of noncontrolling interests, and (iii) the reported amount of previously held interests (amounts in thousands):

(i) Fair value of consideration paid	$ —
(ii) Fair value of noncontrolling interests	12,667
(iii) Reported value of previously held interests[(1)]	—
Sum of (i), (ii), and (iii)	**$ 12,667**

(1) Rafael ownership of 37.5% of the equity interests in RP Finance, accounted for as an equity method investment prior to the RP Finance Consolidation, represents a previously held interest in Cornerstone that is included at its reported amount, or $0.

The following table presents, in accordance with ASC 810, the net amount of the VIE's identifiable assets and liabilities recognized and measured in accordance with ASC 805 (amounts in thousands):

Assets acquired and liabilities assumed	
Investments - Cornerstone common stock	$ 4,931
Due from Cornerstone - Amended RPF Line of Credit	15,336
Total	**$ 20,267**

In accordance with the calculation within ASC 810, a gain of $7.6 million was recognized as an adjustment to Rafael's additional paid-in capital, due to the related parties involved, upon the RP Finance Consolidation. The acquired RP Finance investment in Cornerstone of $4.9 million, consisting of the fair value of RP Finance's 3,919,598 shares of post-Reverse Stock Split Cornerstone Common Stock, is eliminated in consolidation, as Cornerstone is a consolidated subsidiary of Rafael with a corresponding decrease of $1.8 million to Rafael's additional paid-in capital and corresponding decrease of $3.1 million to noncontrolling interests, equivalent to their respective proportionate ownership interest in RP Finance's shares of Cornerstone Pharmaceuticals Series D Convertible Preferred Common Stock. CS Pharma owned

The Company assumed Cornerstone's liability to RP Finance under the Amended RPF Line of Credit at its fair value in the Cornerstone Acquisition and acquired RP Finance's receivable from Cornerstone under the Amended RPF Line of Credit at its fair value in the RP Finance Consolidation. These intercompany amounts are eliminated in consolidation.

The consolidated financial statements include the results of RP Finance subsequent to the closing date. The results of operations of RP Finance were insignificant.

Pro Forma Financial Information

The following table sets forth the pro forma consolidated results of operations of Rafael, Cornerstone, and RP Finance after giving effect to the Cornerstone Restructuring, the Cornerstone Acquisition, and the RP Finance Consolidation for the year ended July 31, 2024 and 2023, as if the Cornerstone Restructuring, the Cornerstone Acquisition, and the RP Finance Consolidation had collectively occurred on August 1, 2022. The pro forma results of operations are presented for informational purposes only and are not indicative of the results of operations that would have been achieved if the Cornerstone Restructuring, the Cornerstone Acquisition, and RP Finance Consolidation had taken place on the date noted above, or of results that may occur in the future.

(in thousands, except for share and per share amounts)	**Twelve Months ended July 31,**	
	2024	**2023**
Revenue	$ 637	$ 279
Loss from operations	(15,803)	(117,234)
Net loss from continuing operations attributable to common stockholders	(6,745)	(42,483)
Net loss per share from continuing operations attributable to common stockholders	(0.28)	(1.83)
Weighted average common shares outstanding	23,745,516	23,263,211

The pro forma loss from operations for the year ended July 31, 2023 includes the IPR&D expense of $89.9 million, related to the IPR&D asset acquired in the Cornerstone Acquisition with no alternative future use, which is reported in Rafael's historical financial statements for the year ended July 31, 2024.

The pro forma net loss from continuing operations attributable to common stockholders for the year ended July 31, 2023 includes a $10 million Series D Convertible gain of $31.3 million on the recovery of receivables from Cornerstone and the recognition of a net loss attributable to noncontrolling interests of Cornerstone of $31.5 million, which are reported in Rafael's historical financial statements for the year ended July 31, 2024.

NOTE 4 – INVESTMENT IN CORNERSTONE

Cornerstone is a clinical stage, cancer metabolism-based therapeutics company focused on the development and commercialization of therapies that seeks to exploit the metabolic differences between normal cells and cancer cells.

Prior to the Cornerstone Restructuring described in Note with 3.5% interest, 3, Rafael (directly via certain of its subsidiaries, and through an equity method investment in RP Finance) held certain debt and equity investments in Cornerstone Pharmaceuticals which was converted to included:

(a) 44.0 million shares of Series D Preferred Stock in January 2019.

The of Cornerstone held by Pharma Holdings LLC ("Pharma Holdings"), a 90% owned non-operating subsidiary of the Company, and its subsidiaries collectively own securities representing 51% 16.7 million shares of the outstanding capital stock of Cornerstone Pharmaceuticals and 42% 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 Cornerstone Pharmaceuticals, prior to any dividends to any other class held by CS Pharma Holdings LLC ("CS Pharma"), a non-operating subsidiary of capital stock the Company (the "Series D Preferred Stock"). Pharma Holdings owns 50% of Cornerstone Pharmaceuticals. In CS Pharma. Accordingly, the event of any liquidation, dissolution or winding up of Cornerstone Pharmaceuticals, or Company holds an effective 45% indirect interest in the event of any deemed liquidation, proceeds from such liquidation, dissolution or winding up shall be distributed first to the holders of Series D Stock. Except with respect to certain major decisions, or as required assets held 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.

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

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

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

The Instrument holds a contractual right to receive additional shares of Cornerstone Pharmaceuticals capital stock equal to 10% of the fully diluted capital stock of Cornerstone Pharmaceuticals (the "Bonus Shares") upon the achievement of certain milestones. The additional 10% is based on the fully diluted capital stock of Cornerstone Pharmaceuticals, excluding the remainder for the Warrant, at the time of issuance. If any of the milestones are met, the Bonus Shares are to be issued without any additional payment.

Pharma Holdings holds the Warrant as well as other equity and governance rights in Cornerstone Pharmaceuticals. The Company currently owns 51% of the issued and outstanding equity in Cornerstone Pharmaceuticals. Approximately 8% of the issued and outstanding equity is owned by the Company's subsidiary CS Pharma and 43% is held by the Company's subsidiary Pharma Holdings. The Company's subsidiary Pharma Holdings holds the Warrant. The Instrument holds 10% of the interest in Pharma Holdings and would need to contribute 10% of any cash necessary to exercise any portion of the Warrant. Following any exercise, a portion of the Company's interest in Cornerstone Pharmaceuticals would continue to be held for the benefit of the other equity holders in Pharma Holdings and CS Pharma. Cornerstone Pharmaceuticals may also issue additional equity interests, such as employee stock options, which will require the Company to pay additional cash to maintain the Company's ownership percentage or exercise the Warrant in full. The terms of the Warrant provide that it expired on April 1, 2022; however, the Company has asserted that it may be entitled to a further extension of the Warrant. At this time, the Company does not intend to exercise the Warrant.

Due to the Data Events, on October 28, 2021, the Company recorded an impairment charge of approximately $79.1 million related to the cost method investment in Cornerstone Pharmaceuticals representing the total amount of the Company's cost method investment. The impairment loss was included in "Impairment of cost method investment – Cornerstone Pharmaceuticals" in the consolidated statements of operations and comprehensive loss for the year ended July 31, 2022.

Approximately $17.3 million of the total impairment loss of $79.1 million was applicable to noncontrolling interests in certain of the Company's subsidiaries and was allocated to the holders of interests in CS Pharma and Pharma Holdings in the approximate amounts of $10.4 million and $6.9 million, respectively.

Line of Credit to Cornerstone Pharmaceuticals and Impairment of Related Receivable

On September 24, 2021, the Company entered into a Line of Credit Loan Agreement (the "Line of Credit Agreement") with Cornerstone Pharmaceuticals under which Cornerstone Pharmaceuticals borrowed $25 million from the Company. The first advance was in the amount of $1.9 million on September 24, 2021. On October 1, 2021, a second advance was made in the amount of $23.1 million. The Line of Credit Agreement accrues interest at 9% per annum. The maturity date of the Line of Credit Agreement was June 17, 2022, and the amounts due on that date were not paid. The Company is in discussions with Cornerstone Pharmaceuticals and is evaluating its rights and plan of action with respect to the Line of Credit Agreement (in the contexts of all of its interests in Cornerstone Pharmaceuticals).

Due to the Data Events, the Company previously recorded a full impairment of the value of the Series D Preferred Stock included in the Company's cost method investment in Cornerstone;

(b) a loan of $25 million by the Company to Cornerstone under a Line of Credit Agreement (the "RFL Line of Credit"). Due to the Data Events, the Company previously recorded a full reserve on the amounts $25 million in principal due to the Company, and on the accrued interest, from Cornerstone Pharmaceuticals related to the Line of Credit Agreement for $25 million during the year ended July 31, 2022. Cornerstone;

The Company also recorded (c) a loss on related party receivables of approximately $2.6 million related to other amounts owed by $2 million promissory note (the "2023 Promissory Note") from Cornerstone, Pharmaceuticals during the year ended July 31, 2022. The Company recorded a reserve on related party interest receivable of $1.9 million in Interest income, net, on the consolidated statements of operations and comprehensive loss during the year ended July 31, 2022. There were no amounts recorded during the year ended July 31, 2023.

Planned Restructuring

Cornerstone is in the process of a comprehensive restructuring transaction including, the conversion of the debt under the Line of Credit Agreement and the Promissory Note held by the Company, the conversion and modification of other Cornerstone debt obligations, the extension of the Cornerstone debt held by RP Finance, a reverse stock split, the conversion of all outstanding preferred stock of Cornerstone into common stock and the adoption of certain governance measures. This transaction is subject to a number of conditions which are beyond the Company's control.

NOTE 5 – CONVERTIBLE NOTE RECEIVABLE, RELATED PARTY

On March 21, 2023, the Company loaned $2.0 million to Cornerstone which is represented by a Promissory Note (the "Promissory Note" or "Note") made by Cornerstone. The Note, which bears bearing interest at a rate of seven and one-half percent (7.5%) per annum, was originally due and payable on May 22, 2023. On May 22, 2023, held by the Company. The 2023 Promissory Note was amended to extend the maturity date to November 30, 2023 and to waive any increase in the interest rate provided for in the Note, provided that the entire principal amount and all accrued interest thereon is repaid in cash or converted into equity securities of Cornerstone no later than November 30, 2023.

The Promissory Note is secured by a first priority security interest in all of Cornerstone's right, title and interest in and to all of the tangible and intangible assets purchased by Cornerstone pursuant to the Purchase Agreement purchase agreement between Cornerstone and Calithera Biosciences, Inc. ("Calithera"), which was a clinical-stage, precision oncology biopharmaceutical company that was developing targeted therapies to redefine treatment for biomarker-specific patient populations, and all proceeds therefrom and all rights to the data related to CB-839 (the "Collateral"). The Company recorded the 2023 Promissory Note at fair value and the security was classified as available-for-sale prior to the Cornerstone Restructuring;

(d) a $720 thousand receivable balance due from Cornerstone, which was fully reserved for by the Company due to the Data Events; and

(e) loans in the aggregate amount of $21.9 million by RP Finance to Cornerstone under a Line of Credit Agreement which provided for a revolving commitment of up to $50 million to fund clinical trials and other capital needs (the "RPF Line of Credit", see Note 5). The Company owns 37.5% of the equity interests in RP Finance and was required to fund 37.5% of funding requests from Cornerstone under the RPF Line of Credit. RP Finance also holds 261,230 post-Reverse Stock Split shares of Cornerstone Common Stock ("RPF Historical Cornerstone Shares"), issued to RP Finance in connection with entering into the RPF Line of Credit representing 12% of the issued and outstanding shares of Cornerstone Common Stock prior to the Cornerstone Restructuring, with such ownership interest subject to anti-dilution protection as set forth in the RPF Line of Credit agreement. The Company accounted for its investment in RP Finance under the equity method.

Due to the Data Events on October 28, 2021, the Company recorded a full impairment for the assets recorded related to Rafael's cost method investment in Cornerstone, the amounts due to Rafael under the RFL Line of Credit, and its investment in RP Finance.

A trust for the benefit of the children of Howard Jonas (Chairman of the Board and Executive Chairman and former Chief Executive Officer of the Company and Member of the Board of Cornerstone) holds a financial instrument (the "Instrument") that owns 10% of Pharma Holdings. The Instrument holds a contractual right to receive additional shares of Cornerstone capital stock equal to 10% of the fully diluted capital stock of Cornerstone (the "Bonus Shares") upon the achievement of certain milestones, each of which the Company has determined not to be probable. The additional 10% is based on the fully diluted capital stock of Cornerstone, at the time of issuance. If any of the milestones are met, the Bonus Shares are to be issued without any additional payment.

Prior to the Cornerstone Restructuring described in Note 3, the Company indirectly owned 51% of the issued and outstanding equity in Cornerstone and had certain governance rights, with approximately 8% of the issued and outstanding equity owned by the Company's subsidiary CS Pharma and 43% owned by the Company's subsidiary Pharma Holdings.

Prior to the Cornerstone Restructuring, the Company had determined that Cornerstone was a VIE; however, the Company had determined that it was not the primary beneficiary as it did not have the power to direct the activities of Cornerstone that most significantly impact Cornerstone's economic performance. In addition, the interests held in Cornerstone were Series D Convertible Preferred Stock and did not represent in-substance common stock.

The On March 13, 2024, Cornerstone consummated a restructuring of its outstanding debt and equity interests. See Note 3 for additional information regarding the Cornerstone Restructuring transaction.

NOTE 5 – INVESTMENT IN RP FINANCE, LLC

On February 3, 2020, Cornerstone entered into a Line of Credit with RP Finance ("RPF Line of Credit") which provided a revolving commitment of up to $50,000,000 to fund clinical trials and other capital needs. In connection with entering into the RPF Line of Credit, Cornerstone issued to RP Finance 261,230 shares (post-Reverse Stock Split) of Cornerstone Common Stock representing 12% of the issued and outstanding shares of Cornerstone Common Stock, with such interest on the Promissory Note accrues from the issuance date until the Note is paid in full or converted, which shall accrue on a quarterly basis. Subject subject to the amendment described above, anti-dilution protection as set forth in the event the total outstanding amount under the Promissory Note is not repaid by the amended maturity date, the rate RPF Line of interest shall be eleven percent (11%), retroactive from and after the maturity date. Subject to the amendment described above, following the occurrence of and during the continuation of an uncured Event of Default (as defined below), the outstanding principal amount shall bear interest at the rate of fourteen percent (14%) per annum (the "Default Interest Rate") until the earliest of (i) cure of such Event of Default, (ii) repayment of all outstanding amounts due under the Note, (iii) conversion of all then outstanding obligations under the Note, or (iv) transfer of all its rights related to the Collateral.

The entire (and not less than the entire) outstanding principal amount due under the Promissory Note together with all accrued unpaid interest thereon and other amounts owing thereunder (together, the "Owed Amount"), may, at Cornerstone's election at any time prior to the maturity date, be converted into a number of shares (the "Conversion Shares") calculated by dividing the entire Owed Amount by the conversion price used by Cornerstone in a Qualified Offering/Conversion (as defined in the Note), and if no such Qualified Offering/Conversion has been consummated, the fair market value for the Conversion as determined by an independent third party valuation firm (the "Conversion Price").

The Promissory Note contains certain trigger events (as defined in the Note) that generally, if uncured within five (5) trading days, may result in an event of default in accordance with the terms of the Notes (such event, an "Event of Default"). Upon an Event of a Default, the Company may consider the Promissory Note immediately due and payable. Upon an Event of Default, the interest rate may also be increased to the lesser of 18% per annum or the maximum rate permitted under applicable law. Credit.

The Company owns 37.5% of the equity interests in RP Finance, an entity associated with members of the family of Howard Jonas owns 37.5% of the equity interests in RP Finance, and the remaining 25% equity interests in RP Finance are owned by other stockholders of Cornerstone.

RP Finance had funded a cumulative total of $21.9 million to Cornerstone under the RPF Line of Credit, of which the Company had funded a cumulative total of $9.375 million in accordance with its 37.5% ownership interests in RP Finance. Due to the Data Events, the amounts funded had been fully reserved.

Prior to the Cornerstone Restructuring and resulting RP Finance Consolidation described in Note 3, the Company had determined that RP Finance was a VIE; however, the Company had determined that it was not the primary beneficiary as the Company did not have the power to direct the activities of RP Finance that most significantly impacted RP Finance's economic performance and, therefore, was not required to consolidate RP Finance. Therefore, the Company used the equity method of accounting to record its investment in RP Finance.

On March 13, 2024, Cornerstone consummated the Cornerstone Restructuring of its outstanding debt and equity interests. As part of the Cornerstone Restructuring, Cornerstone and RP Finance amended the RPF Line of Credit agreement. See Note 3 for additional information regarding the Cornerstone Restructuring transaction.

NOTE 6 – CONVERTIBLE NOTES PAYABLE

As of July 31, 2024, Cornerstone has $686 thousand in principal, and $236 thousand of accrued interest thereon, of Series C Convertible Notes outstanding (the "Series C Convertible Notes"). The Series C Convertible Notes accrue interest at a rate of 3.5% per annum and are due, together with accrued interest, one year (unless amended) from date of issuance and automatically accelerate upon the sale of Cornerstone in its entirety or the sale or license of substantially all of Cornerstone's assets or intellectual property. The Series C Convertible Notes (including all accrued and unpaid interest thereon) automatically convert into the same class of securities (including stock warrants) sold in Cornerstone's next equity financing (i) where Cornerstone receives gross proceeds of at least $10,000,000 from Institutional Investors (a "Qualified Financing"), or (ii) from an underwritten initial public offering ("IPO"). The conversion price of the Series C Convertible Notes upon a Qualified Financing shall be the lesser of (i) 90% of the price per share (or unit) at which the securities in the Qualified Financing are sold, or (ii) $1.25 price per share (or unit) (whichever is less) at the holder's selection of (i) or (ii), and 90% of the share price per share (or unit) at which securities in an IPO are first sold.

The outstanding Series C Convertible Notes are convertible, at the option of the holders, in certain equity financings consummated by Cornerstone or into equity securities and warrants to purchase equity securities of Cornerstone.

In the event of a liquidation event of Cornerstone prior to the repayment or conversion of the Series C Convertible Notes, the holders are entitled to receive either (a) an amount equal to the outstanding principal and interest due, or (b) the pro rata per share amount of the proceeds of such liquidation the holders would be entitled to had they exercised their conversion right.

Of the Series C Convertible Notes outstanding as of July 31, 2024:

(a) Series C Convertible Notes with an aggregate principal amount of $614 thousand remain outstanding and were not amended in connection with the Cornerstone Restructuring. The interest accrued on these Series C Convertible Notes is $213 thousand and is recorded in accrued expenses on the Promissory Note consolidated balance sheet as of July 31, 2024. In the Cornerstone Acquisition, Rafael recorded these Series C Convertible Notes as current liabilities at the value of their aggregate principal amount of $614 thousand, and $205 thousand of accrued interest thereon recorded in accrued expenses on the consolidated balance sheet as of the date of the Cornerstone Acquisition, as these values approximate their fair values. As of July 31, 2024, these Series C Convertible Notes are currently in default as they are beyond the maturity date; and

(b) Series C Convertible Notes with an aggregate principal amount of $72 thousand were amended in the Cornerstone Restructuring to (i) extend the maturity date thereof to May 31, 2028 and (ii) provide that, on conversion thereof, the converting holder will receive shares of Cornerstone Common Stock. The holders of these amended Series C Convertible Notes that remain outstanding waived such holders' rights in connection with the Cornerstone Restructuring. The interest accrued on these Series C Convertible Notes is $23 thousand as of July 31, 2024. In the Cornerstone Acquisition, Rafael recorded these Series C Convertible Notes as noncurrent liabilities at their fair value as of $70 thousand, which considers the security is classified as available-for-sale. Subsequent changes in aggregate principal plus accrued interest. The Company will accrete the fair value are recorded in unrealized gain or loss on available-for-sale securities of these Series C Convertible Notes to the value of the principal plus accrued interest thereon as a component of other comprehensive income (loss) the date of the Cornerstone Acquisition as interest expense in the consolidated statements of operations and comprehensive loss. loss over the estimated term of these amended Series C Convertible Notes.

For During the year ended July 31, 2023 July 31, 2024, the Company recorded a change $9 thousand of interest expense in fair value of approximately $79 thousand related relation to the decrease in fair value of the Promissory Note which was recognized in other comprehensive income (loss) Cornerstone Series C Convertible Notes to interest expense on the consolidated statements of operations and comprehensive loss.

NOTE 7 – ACCRUED EXPENSES

Interest income Accrued expenses consist of the following:

	July 31, 2024	July 31, 2023
	(in thousands)	
Accrued expenses, current		
Accrued bonuses	$ 654	$ 403
Accrued professional fees	437	276
Accrued payroll expenses	441	7
Accrued interest	213	—
Other accrued expenses	53	77
Total accrued expenses, current	1,798	763
Creditor payable, noncurrent	2,982	—
Total accrued expenses	$ 4,780	$ 763

In the Cornerstone Acquisition, Rafael assumed a forbearance agreement, signed by Cornerstone on June 2, 2023, with a major creditor (the "Creditor") of Cornerstone to which Cornerstone owed approximately $10.5 million arising from unpaid amounts in connection with work performed and costs incurred by the Promissory Note totaled Creditor under previous work orders. The outstanding balance does not bear interest. As part of Cornerstone's plan to seek new capitalization, it paid $2.0 million following the execution of a change order on July 21, 2023. Cornerstone also agreed to an additional payment of $2,000,000 upon the issuance of a FDA authorization to market any product of Cornerstone (the "FDA Approval Payment"). In the event Cornerstone completes a capital transaction which results in an aggregate of $100 million in additional capital received after January 1, 2023, Cornerstone agrees to pay an additional $4.0 million to the Creditor within 15 days of such capital transaction (the "Capital Raise Payment"). In exchange for Cornerstone's agreement to make timely payments of the above-mentioned sums due in the Agreement, and after the payment of the FDA Approval Payment and the Capital Raise Payment, the Creditor will waive approximately $54 $2.5 million of outstanding debt representing all remaining amounts due to the Creditor.

Following the payment of the initial $2.0 million, and pursuant to the terms of the agreement, the Creditor agreed to forbear from exercising any of its rights, remedies or claims in respect to the outstanding balance. The forbearance shall not be deemed to have otherwise waived, released, or adversely affected any of the Creditor's rights, remedies or claims in respect to the outstanding balance.

As part of the Cornerstone Acquisition, the creditor payable was recognized by the Company as an assumed liability and measured at its fair value of $2.7 million as of the date of the Cornerstone Acquisition. The Company will accrete the fair value of the creditor payable to the amount payable of $8.5 million owed to the Creditor as interest expense in the consolidated statements of operations and comprehensive loss over the estimated term of the forbearance agreement. The Company recorded $237 thousand of accretion in relation to the creditor payable recorded to interest expense in the consolidated statements of operations and comprehensive loss for the year ended July 31, 2023July 31, 2024.

The carrying value of the creditor payable was $3.0 million as of July 31, 2024 and is recorded included in interest receivable accrued expenses, noncurrent on the consolidated balance sheets.

NOTE 8 – CONVERTIBLE NOTE RECEIVABLE

On March 8, 2024, Day Three entered into a convertible note subscription agreement with a third-party company, Steady State LLC. Steady State LLC promises to pay to Day Three $1,000,000, together with interest, on October 16, 2026. The convertible note will accumulate simple interest at the annual rate being the lesser of: (i) the Bank of England base rate (updated on the first business day of each quarter) plus eight (8) percentage points, or (ii) 15% (computed on the basis of 365 days per year). Upon the closing and funding of a bona fide offering of equity securities by Steady State, LLC in an aggregate amount of at least $5,000,000, the convertible note will automatically convert into the number of membership interests equal to the outstanding principal plus accrued and unpaid interest divided by eighty percent (80%) of the price per membership unit in the offering. If a qualifying bona fide offering has not occurred on or before the maturity date, the principal and unpaid accrued interest of the convertible note may be converted, at the option of Day Three, into membership units. The convertible note receivable is classified as available-for-sale and recorded at fair value - see Note 15.

NOTE 6 – INVESTMENT IN RP FINANCE, LLC

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

The Company owns 37.5% of the equity interests in RP Finance and is required to fund 37.5% of funding requests from Cornerstone Pharmaceuticals under the RPF Line of Credit. The Instrument owns 37.5% of the equity interests in RP Finance, and is required to fund 37.5% of funding requests from Cornerstone Pharmaceuticals under the RPF Line of Credit. The remaining 25% equity interests in RP Finance are owned by other stockholders of Cornerstone Pharmaceuticals.

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

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

The Company has determined that RP Finance is a VIE; however, the Company has determined that it is not the primary beneficiary as the Company does not have the power to direct the activities of RP Finance that most significantly impact RP Finance’s economic performance and, therefore, is not required to consolidate RP Finance. Therefore, the Company will use the equity method of accounting to record its investment in RP Finance. The Company has recognized $0 in earnings from its ownership interests of 37.5% in RP Finance for the years ended July 31, 2023 and 2022, respectively, and a loss of $0 and $575 thousand from its ownership interests of 37.5% in RP Finance for the years ended July 31, 2023 and 2022, respectively. The assets and operations of RP Finance are not significant and the Company has identified the equity investment in RP Finance as a related party transaction (see Note 16).

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

As of July 31, 2023 and 2022, the Company has funded a cumulative total of $9.375 million in accordance with its 37.5% ownership interests in RP Finance. The Company recorded a reserve on related party interest receivable of $1.9 million in Interest income, net, on the consolidated statements of operations and comprehensive loss during the year ended July 31, 2022.

Impairment of Equity Method Investment

Due to the Data Events, during the three months ended October 31, 2021, the Company recorded equity in the loss of RP Finance of $575 thousand. As of July 31, 2023 and 2022, the equity method investment on the Company's balance sheet was $0, and no additional equity loss of RP Finance was recorded during the year ended July 31, 2023. The Company was not obligated to guarantee obligations of RP Finance and is not committed to provided further financial support for RP Finance. Additionally, during the year ended July 31, 2022, the Company recorded a loss on related party receivables of $9.375 million related to amounts owed by RP Finance.

NOTE 7 9 – INVESTMENT IN LIPOMEDIX PHARMACEUTICALS LTD.

LipoMedix is a development-stage, privately held Israeli company focused on the development of an innovative, safe and effective cancer therapy based on liposome delivery. As of July 31, 2023, the Company held 95% of the issued and outstanding ordinary shares of LipoMedix and has consolidated this investment from the second quarter of fiscal 2018.

In March 2021, the Company provided bridge financing in the principal amount of up to $400,000 to LipoMedix with a maturity date of September 1, 2021, and an interest rate of 8% per annum. As of September 1, 2021, LipoMedix was in default on the terms of the loan and as such, the interest rate has increased to 15% per annum.

On November 15, 2021, the Company entered into a share purchase agreement with LipoMedix to purchase up to 15,975,000 ordinary shares at $0.1878 per share for an aggregate purchase price of $3.0 million (the "LipoMedix SPA"). Additionally, LipoMedix issued the Company a warrant to purchase up to 15,975,000 ordinary shares at an exercise price of $0.1878 per share which expired on November 11, 2022.

As of the date of the LipoMedix SPA, there was an outstanding loan balance including principal of $400 thousand and accrued interest of $21.8 thousand owed by LipoMedix to the Company on a note made by LipoMedix in favor of the Company issued in March 2021. The amount due on the loan was netted against the approximately $3.0 million aggregate purchase price due to LipoMedix, resulting in a cash payment by the Company of approximately $2.6 million in exchange for the 15,975,000 shares purchased. As a result of the share purchase, the Company's ownership of LipoMedix increased to approximately 84% with a noncontrolling interest of approximately 16%. The Company recorded approximately $8 thousand to adjust the carrying amount of the noncontrolling interest to reflect the Company's increased ownership interest in LipoMedix's net assets.

On February 9, 2023, the Company entered into a Share Purchase Agreement with LipoMedix to purchase 70,000,000 ordinary shares at $0.03 per share for an aggregate purchase price of $2.1 million (the "2023 LipoMedix SPA"). As a result of the share purchase, the Company's ownership of LipoMedix increased to approximately 95% with a noncontrolling interest of approximately 5%. The Company recorded approximately $16 thousand to adjust the carrying amount of the noncontrolling interest to reflect the Company's increased ownership interest in LipoMedix's net assets.

As of July 31, 2024, the Company held 95% of the issued and outstanding ordinary shares of LipoMedix and has consolidated LipoMedix from the second quarter of fiscal 2018.

NOTE 10 – INVESTMENT IN DAY THREE LABS INC.

Initial investment in Day Three

On April 7, 2023, the Company entered into a Common Stock Purchase Agreement (the "Day Three Purchase Agreement") with Day Three. Day Three is a company which reimagines existing cannabis offerings with pharmaceutical-grade technology and innovation like Unlokt™ to bring to market better, cleaner, more precise and predictable products. Pursuant to the Day Three Purchase Agreement, the Company purchased 4,302 shares of common stock, post DTL Reverse Stock Split (as defined below), representing 38% of the outstanding shares of common stock of Day Three (33% on a fully diluted basis), for a purchase price of $3.0 million. The Company also received a warrant exercisable for 7,529 shares of common stock, post DTL Reverse Stock Split, which expires five years from the date of issuance or earlier based on the occurrence of certain events as defined in the Day Three Purchase Agreement (the "Day Three Warrant").

Prior to January 2024, the Company accounted for this investment as an equity method investment in accordance with the guidance in ASC 323, *Investments – Equity Method and Joint Ventures*. The Company determined that a 38% ownership interest in Day Three and its right to designate two members of the Board of Directors of Day Three (out of a current total of seven members) indicates that the Company is able to exercise significant influence.

The Company determined that Day Three is a VIE; however, the Company determined that, prior to January 2024, it was not the primary beneficiary as it did not have the power to direct the activities that most significantly impacted Day Three's economic performance. The Company has therefore concluded it was not required to consolidate Day Three. The Company used the equity method of accounting to record its investment in Day Three.

Day Three's fiscal year ends on December 31 and, as a result, the Company recognizes its share of Day Three's earnings/loss on a one-month lag. For the years ended July 31, 2024 and 2023, the Company recognized approximately $422 thousand and $203 thousand of equity in loss of Day Three, based on its proportionate share of Day Three's results through January 2, 2024, the effective date of the Day Three Acquisition, as discussed below. The assets and operations of Day Three are not significant to the Company's assets or operations.

Acquisition of Day Three

In January 2024, the Company entered into a series of transactions with Day Three and certain shareholders to purchase an aggregate of 13,771 shares of common stock, post DTL Reverse Stock Split, of Day Three, acquiring a controlling interest of Day Three (the "Day Three Acquisition"). As a result of the Day Three Acquisition, the Company holds an aggregate 79% of the issued and outstanding shares of common stock of Day Three. Day Three has options and warrants outstanding that, if and when exercised, could dilute the Company's ownership interest in Day Three. In connection with the Day Three Acquisition, the Day Three Warrant was terminated. The acquisition date was determined to be January 2, 2024, which is the date that Rafael obtained a controlling interest of the common stock of Day Three. The Day Three Acquisition is being accounted for as a business combination in accordance with ASC 805.

During the period of October 2023 through January 2024, the Company advanced $250,000 to Day Three pursuant to a promissory note (the "Day Three Note I"), $150,000 to Day Three pursuant to a promissory note (the "Day Three Note II"), $1,000,000 to Day Three pursuant to a third promissory note (the "Day Three Note III"), and $589,024 to Day Three pursuant to a fourth promissory note (the "Day Three Note IV") (collectively, the "Day Three Promissory Notes"). The Day Three Promissory Notes accrue interest at rate of between 5.01% and 5.19% per annum.

The aggregate consideration of the Day Three Acquisition was $3.1 million, which consisted of 1) cash consideration of $0.2 million, 2) accrued consideration of $0.2 million, 3) the exchange of principal and accrued interest amounts totaling to $2.0 million owed by Day Three to the Company pursuant to the Day Three Promissory Notes for common stock, and 4) the fair value of previously held interests in Day Three of $0.7 million.

The following table summarizes the purchase consideration transferred in the Day Three Acquisition as defined in ASC 805:

(in thousands)	Purchase Consideration
Cash consideration	$ 200
Accrued consideration	200
Exchange of Day Three Promissory Notes for Common Stock	2,000
Fair value of previously held interests[(1)]	742
Total purchase consideration	**$ 3,142**

(1) The Company remeasured its previously held equity interest in Day Three immediately before the Day Three Acquisition, previously accounted for under the equity method of accounting, to its fair value (determined using the implied enterprise value based on the purchase price multiplied by the ratio of the number of shares previously held to total shares, as of the acquisition date) and recognized a loss of $1.6 million recorded on the statements of operations and comprehensive loss as a Loss on initial investment in Day Three upon acquisition.

The following table summarizes the preliminary fair values of the assets acquired and liabilities assumed in the Day Three Acquisition as of the acquisition date:

(in thousands)	January 2, 2024
Cash and cash equivalents	$ 1,499
Accounts receivable	63
Prepaid expenses and other current assets	77
Property and equipment	408
Goodwill	3,050
Identifiable intangible assets	2,180
Accounts payable	(386)
Accrued expenses	(98)
Installment note payable	(2,500)
Total fair value of net assets acquired	**4,293**
Less: noncontrolling interest	(1,151)
Net assets acquired attributable to Rafael	**$ 3,142**

The preliminary fair values of the assets acquired and liabilities assumed in the Day Three Acquisition are subject to change as we perform additional reviews of our assumptions utilized. During the year ended July 31, 2024, the Company recognized an adjustment which changed the fair value of certain acquired liabilities and goodwill as a result of obtaining additional information about the estimated liabilities. Further adjustments may be necessary as additional information related to the fair values of assets acquired, liabilities assumed, and tax implications thereon is assessed during the measurement period (up to one year from the acquisition date).

The noncontrolling interest was recognized at fair value, which was determined using the implied enterprise value based on the purchase price multiplied by the ratio of the number of shares owned by minority holders to total shares, as of the acquisition date.

Included in the acquired liabilities assumed in the Day Three Acquisition is a non-interest bearing installment note payable of $2.5 million. The installment note was recognized by Day Three in relation to a 2021 asset purchase agreement for certain patents. The assumed installment note payable had a balance of $800 thousand due January 2024 (which was paid in January 2024) and the remaining $1.7 million due in November 2024. At July 31, 2024, the installment note payable has a remaining balance due of $1.7 million which is included in Installment note payable on the consolidated balance sheets.

Goodwill of $3.1 million arising from the Day Three Acquisition was included in the Infusion Technology segment as of July 31, 2024 and was attributable to potential synergies and an assembled workforce. The calculated goodwill is not deductible for tax purposes.

Intangible assets acquired primarily include patents, technology licenses and non-compete agreements. The weighted average amortization period for the acquired intangible assets is approximately 14.7 years.
The consolidated financial statements include the results of the Day Three Acquisition subsequent to the closing date. Pro forma information is not presented as the acquisition was not considered significant.
On January 23, 2024, Day Three entered into an asset purchase agreement for the sale of certain patents for $280 thousand.
On March 20, 2024, Day Three amended and restated its certificate of incorporation to, among other things, effect a reverse split of all of Day Three's common stock on a one-for-one-thousand basis (the "DTL Reverse Stock Split").
On May 1, 2024, Rafael entered into a stock purchase agreement with Day Three to purchase 7,194 shares of common stock at a purchase price of $173.75 per share for an aggregate purchase price of $1.25 million, $1 million of which was funded through the relief of an existing intercompany receivable. As a result of the transaction, Rafael has an 84% ownership interest in Day Three.
NOTE 8 – INVESTMENT IN DAY THREE LABS INC.
On April 7, 2023, the Company entered into a Common Stock Purchase Agreement (the "Day Three Purchase Agreement") with Day Three. Day Three is a cannabinoid ingredient manufacturer specializing in the development and commercialization of novel cannabis product solutions. Pursuant to the Day Three Purchase Agreement, the Company purchased 4,302,224 shares of common stock representing 38% of the outstanding shares of common stock of Day Three (33.333% on a fully diluted basis), for a purchase price of $3.0 million. The Company also received a warrant exercisable for 7,528,893 shares of common stock at an aggregate purchase price of $3.0 million, which expires five years from the date of issuance or earlier based on the occurrence of certain events as defined in the Day Three Purchase Agreement. As of the date of this report, the Company had not exercised the warrant.
The Company has accounted for this investment as an equity method investment in accordance with the guidance in ASC 323, Investments – *Equity Method and Joint Ventures*. The Company determined that a 38% ownership interest in Day Three and its right to designate two members of the Board of Directors of Day Three (out of a current total of seven members) indicates that the Company is able to exercise significant influence. Upon exercise of the warrant, the Company will have the right to appoint a third member of the Day Three Board of Directors.
The Company has determined that Day Three is a VIE; however, the Company is not the primary beneficiary as it does not have the power to direct the activities that most significantly impact Day Three's economic performance. The Company has therefore concluded it is not required to consolidate Day Three. The Company uses the equity method of accounting to record its investment in Day Three.
Day Three's fiscal year ends on December 31, and as a result, the Company will recognize its share of Day Three's earnings/loss on a one-month lag. For the year ended July 31, 2023, the Company recognized approximately $203 thousand of equity in loss of Day Three, based on its proportionate share of Day Three's results through June 30, 2023. The assets and operations of Day Three are not significant.
NOTE 9 11 – INVESTMENT IN CYCLO THERAPEUTICS, INC.

On May 2, 2023, the Company entered into a Securities Purchase Agreement (the "Cyclo SPA") with Cyclo. Cyclo is a clinical stage clinical-stage biotechnology company whose common stock is listed on the Nasdaq Capital Market under the symbol CYTH, that develops cyclodextrin-based products dedicated to developing life-changing medicines for the treatment of neurodegenerative diseases. patients and families living with challenging diseases through its lead therapeutic asset, Trappsol®. The Company purchased from Cyclo (i) 2,514,970 common shares (the "Purchased Shares") and (ii) a warrant to purchase 2,514,970 common shares with an exercise price of $0.71 per share (the "Cyclo "May Warrant"), at a combined purchase price equal to $0.835 per Purchased Share and Cyclo May Warrant to purchase one share, for an aggregate purchase price of $2.1 million. The May Warrant is exercisable until August 1, 2030.
Cyclo Warrant may be exercised for and the seven-year period following Company are party to a Registration Rights Agreement requiring Cyclo to file a registration statement with the date Cyclo obtains Securities and Exchange Commission to register the approval resale of the stockholders shares and shares of Cyclo to common stock underlying the exercise May Warrant, upon the request of the Cyclo Warrant. On July 31, 2023, the Cyclo stockholders approved the exercise in full of the warrant. Rafael.

On June 1, 2023 August 1, 2023, the Company entered into another pursuant to a Securities Purchase Agreement (the "Cyclo II SPA") with Cyclo. Pursuant to the Cyclo II SPA, dated June 1, 2023, the Company agreed to purchase purchased an additional 4,000,000 shares of common stock (the "Cyclo II Shares"), and received a warrant to purchase an additional 4,000,000 Shares (the "Cyclo II Warrant"), for an aggregate purchase price of $5,000,000. The Cyclo II Warrant has an exercise price of $1.25 per share and is exercisable for a period of seven years following the date of issuance. On July 31, 2023, Cyclo obtained the approval of its stockholders for the transactions contemplated by the Cyclo II SPA.
Subsequent to year end, on August 1, 2023, the Company completed the Cyclo II SPA with Cyclo, whereby the Company purchased 4,000,000 shares of common stock (the "Cyclo II Shares"), and a warrant to purchase an additional 4,000,000 Shares (the "Cyclo II Warrant"), for an aggregate purchase price of $5,000,000. until August 1, 2030. The August 1, 2023 investment increased the Company's percentage ownership of Cyclo common stock to approximately 34%. at the time of investment. As of the date of this report, filing, the Company had has not exercised the Cyclo II Warrant.

Pursuant to the Cyclo II SPA, the Registration Rights Agreement between the Company and Cyclo, dated May 2, 2023, has been amended to require Cyclo to file a registration statement with the Securities and Exchange Commission to register the resale of the Cyclo II Shares and shares of common stock underlying the Cyclo II Warrants, upon the request of the Company, and (ii) Cyclo agreed to appoint a designee of the Company (in addition to William Conkling, the Company's Chief Executive Officer) to Cyclo's Board of Directors, and to nominate such designee to serve as a director of Cyclo in connection with Cyclo's solicitation of proxies for Cyclo's next Annual Meeting of Stockholders. The Cyclo II SPA purchase price was paid on August 1, 2023, which is the effective date of the second Cyclo investment.
Subsequent to year end, on On October 20, 2023, the Company exercised the Cyclo May Warrant to purchase 2,514,970 common shares at an exercise price of $0.71 per share, pursuant to a Securities Purchase Agreement dated October 20, 2023, and in consideration received a new warrant (the "Replacement Warrant") to purchase an additional 2,766,467 common shares at an exercise price of $0.95 per share. The Replacement Warrant is exercisable until October 20, 2027. As of the date of this report, the Company had not exercised the Replacement Warrant. Both the Cyclo II Warrant and Replacement Warrant (collectively, the "Cyclo Warrants") are subject to the restriction that exercise(s) do not convey more than 49% ownership to the Company (the "Cyclo Blocker"). Upon exercise of the May Warrant, the Company recognized a realized gain of $424 thousand. The October 20, 2023 investment increased the Company's percentage ownership of Cyclo common stock to approximately 40% at the time of investment.
William Conkling, Rafael's CEO, serves on Cyclo's Board of Directors.
The Company has determined that Cyclo is a VIE; however, the Company has determined that it is not the primary beneficiary as the Company does not have the power to direct the activities of Cyclo that most significantly impact Cyclo's economic performance and, therefore, is not required to consolidate Cyclo. The Company has elected to account for its investment in Cyclo under the fair value option, with subsequent changes in fair value recognized as unrealized (gain) loss on investment - Cyclo in the consolidated statements of operations and comprehensive loss. During the years ended July 31, 2024 and 2023, the Company recognized an unrealized gain of $37 thousand and $2.7 million related to its investment in Cyclo common stock and warrants, respectively.
Summarized Fair Value Method Investment Details
The 31.5% ownership percentage as of July 31, 2024 is comprised of the shares of common stock owned by the Company and does not include the Cyclo Warrants. The total aggregate fair value of the Cyclo investment of $12,009,630 as of July 31, 2024 is comprised of common shares with an aggregate fair value of $10,745,629 and Cyclo

Warrants with an aggregate fair value of $1,264,001. The total aggregate fair value of the Cyclo investment of $4,763,102 as of July 31, 2023 is comprised of common shares with an aggregate fair value of $3,898,204 and the May Warrants with an aggregate fair value of $864,898, see Note 15.
Subsequent to year end, the Company entered into an Agreement and Plan of Merger with Cyclo. See Note 27 for further details.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 12 – CONVERTIBLE NOTE RECEIVABLES, DUE FROM CYCLO THERAPEUTICS, INC.

On June 11, 2024, the Company entered into a Note Purchase Agreement with Cyclo, pursuant to which Cyclo issued and sold a convertible promissory note in the principal amount of $2 million (the "Cyclo Convertible Note I") to the Company for $2 million in cash. The Cyclo Convertible Note I was issued with a maturity date of November 11, 2024 and bears interest at a rate of 5% per annum, payable upon maturity. The principal amount of the Cyclo Convertible Note I is convertible into shares of Cyclo's common stock at the option of the Company unless converted automatically upon certain events, as defined in the Cyclo Convertible Note I Note Purchase Agreement. On October 8, 2024, the maturity date of Convertible Note I was amended to be December 21, 2024, refer to Note 27.

On July 16, 2024, the Company entered into a First Amended and Restated Note Purchase Agreement with Cyclo, pursuant to which Cyclo issued and sold a convertible promissory note in the principal amount of $2 million (the "Cyclo Convertible Note II") to the Company for $2 million in cash. The Cyclo Convertible Note II was issued with a maturity date of November 11, 2024 and bears interest at a rate of 5% per annum, payable upon maturity. The principal amount of the Cyclo Convertible Note II is convertible into shares of Cyclo's common stock at the option of the Company unless converted automatically upon certain events, as defined in the Cyclo Convertible Note II Note Purchase Agreement. On October 8, 2024, the maturity date of Convertible Note II was amended to be December 21, 2024, refer to Note 27.

The Cyclo Convertible Note I and Cyclo Convertible Note II are together referred to as the "Cyclo Convertible Notes."

In the event that Cyclo consummates any public or private offering of its Equity Securities resulting in gross proceeds of at least $8,000,000 (excluding this Note) (a "Qualified Financing") at any time prior to the earlier of the Maturity Date and the repayment in full of this Note, then the outstanding principal balance of the Cyclo Convertible Notes, together with any accrued and unpaid interest thereon, will automatically convert into shares of Cyclo's common stock, par value $.0001 per share which are exercisable (the "Common Stock"), at a conversion price equal to the lesser of (i) $.95 (the "Base Price"), and (ii) eighty percent (80%) of the purchase price paid by the investors purchasing the Equity Securities in the Qualified Financing. For purposes of the Cyclo Convertible Notes, the term "Equity Securities" shall mean (1) any shares of Common Stock or preferred stock of Cyclo, (2) any security convertible or exchangeable for Common Stock or preferred stock of Cyclo, and (3) any other rights to purchase or otherwise acquire Common Stock or preferred stock of Cyclo, in each case issued in a period of four years Qualified Financing following the issuance date (the "Cyclo III Warrant" hereof.

In the event Cyclo consummates a Sale Transaction ("Sale Transaction" as defined in the Cyclo Convertible Notes' Agreements as a) the sale of all or substantially all of Cyclo's assets, b) the consolidation or merger of Cyclo or any of its subsidiaries with or into any other corporation or other entity or person or other similar transaction, or c) any other transaction or series of related transactions to which Cyclo is a party in which in excess of fifty percent (50%) of Cyclo's voting securities are transferred) with (i) Rafael or its affiliates, the Cyclo Convertible Notes shall be treated for as provided for in the terms of the definitive agreements relating to such Sale Transaction, or (ii) a third party other than Rafael or its affiliates, at the election of the Rafael, either (x) the outstanding principal balance of the Cyclo Convertible Notes, together with any accrued and unpaid interest thereon, shall convert into that number of shares of Common Stock at a conversion price equal to the lesser of (1) the base price of $0.95 and (ii) eighty percent (80%) of the implied value of Cyclo in the Sale Transaction, or (y) Cyclo will pay to Rafael an amount equal to the outstanding principal balance of the Cyclo Convertible Notes, together with any accrued and unpaid interest thereon, in full satisfaction of Cyclo's obligations under Cyclo Convertible Notes. Additionally, the Cyclo Convertible Notes shall be convertible, in whole or in part, and from time to time, at the discretion of Rafael, into validly issued, fully paid and non-assessable shares of Common Stock at a conversion price equal to the lowest of (i) the base price (Cyclo Convertible Note I and Cyclo Convertible Note II), for an aggregate (ii) the closing price of the Common Stock on NASDAQ on the trading date immediately preceding the date of conversion (Cyclo Convertible Note II, only) and (iii) 80% of the purchase price paid by the investors purchasing equity securities in any financing consummated within sixty (60) days preceding the date of $1,785,629. conversion (Cyclo Convertible Note II only).

The Cyclo Convertible Notes are required to be accounted for at fair value pursuant to ASC 825, *Financial Instruments* ("ASC 825"), at their respective dates of issuance and in subsequent reporting periods, as the Company elected to account for its prior investment in Cyclo common stock under the fair value option. The Company has elected to present interest income from the Cyclo Convertible Notes, together with the changes in fair value of the notes, along with the changes in fair value related to the investments in Cyclo, in unrealized gain on investments - Cyclo on the consolidated statements of operations and comprehensive loss. During the year ended July 31, 2024, the Company recognized an unrealized gain of $1.2 million, related to its investment in Cyclo Convertible Notes receivable. See Note 15 for further details.

The Company has elected Subsequent to account for its investment in Cyclo under the fair value option. The investment was measured at fair value and year end, the Company has recorded entered into an Agreement and Plan of Merger with Cyclo and entered into the subsequent changes in fair value as unrealized gain (loss) in the consolidated statements of operations Second and comprehensive loss.

The investment in the Third Amended and Restated Note Purchase Agreements with Cyclo, SPA resulted in an unrealized gain of approximately $2.1 million as the purchase price was lower than the fair value of the investment. The Company recognized total unrealized gains on its investment of $2.7 million in the accompanying consolidated statements of operations and comprehensive loss for the year ended July 31, 2023.

Summarized Fair Value (Level 1) Method Investment Details

	Ownership %	Aggregate Fair Value
	July 31, 2023	July 31, 2023
Cyclo	16%	$ 4,763,102

The 16% ownership percentage as of July 31, 2023 is comprised of the shares of common stock owned by whereby the Company and does not include the Cyclo Warrant. The total aggregate fair value of the Cyclo investment of $4,763,102 as of July 31, 2023 is comprised of common shares with an aggregate fair value of $3,898,204 and warrants with an aggregate fair value of $864,898. was issued $6.0 million in convertible notes receivable for $6 million in cash. See Note 27 for further details.

Summarized consolidated financial information of Cyclo, reported on a one month lag, is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue	$ 117,118	$ 541,886	$ 269,529	$ 736,790
Loss from operations	$ (4,632,942)	$ (3,456,024)	$ (9,640,074)	$ (6,390,481)
Net loss	$ (4,636,455)	$ (3,451,990)	$ (9,643,540)	$ (6,223,581)

NOTE 10 13 – INVESTMENTS IN MARKETABLE SECURITIES

The Company has classified its investments in corporate bonds, U.S. agency bonds, and U.S. treasury bills and convertible note receivable as available-for-sale securities. These securities are carried at estimated fair value with unrealized holding gains and losses included in accumulated other comprehensive loss income (loss) in stockholders' equity until realized. Investment transactions are recorded on their trade date. Gains and losses on marketable security transactions are reported on the specific-identification method. Interest income is accrued daily and adjusted for amortization of premiums and accretion of discounts on the corporate bonds, U.S. agency bonds, and U.S. treasury bills.

The amortized cost, gross unrealized holding gains, gross unrealized holding losses, and fair value for available-for-sale securities as of July 31, 2023 July 31, 2024 and 2022 July 31, 2023 are as follows:

July 31, 2023	*Amortized cost*	*Gross unrealized gains*	*Gross unrealized (losses)*	*Fair value*
	(in thousands)			
Available-for-sale securities:				
U.S. Treasury Bills	*$ 11,222*	*$ 53*	*$ —*	*$ 11,275*
Corporate bonds	*46,766*	*4,333*	*(4,660)*	*46,439*
Convertible note receivable, related party	*2,000*	*—*	*(79)*	*1,921*
Total available-for-sale securities	*$ 59,988*	*$ 4,386*	*$ (4,739)*	*$ 59,635*

July 31, 2024	*Amortized cost*	*Gross unrealized gains*	*Gross unrealized (losses)*	*Fair value*
	(in thousands)			
U.S. Agency bonds	*4,079*	*—*	*(3)*	*4,076*
Corporate bonds	*55,252*	*2*	*(32)*	*55,222*
Total available-for-sale securities	*$ 63,300*	*$ 2*	*$ (37)*	*$ 63,265*

July 31, 2022	*Amortized cost*	*Gross unrealized gains*	*Gross unrealized (losses)*	*Fair value*
	(in thousands)			
Available-for-sale securities:				
U.S. Treasury Bills	$ 11,222	$ 53	$ —	$ 11,275
Corporate bonds	$ 36,761	$ 81	$ (144)	$ 36,698
Total available-for-sale securities	$ 36,761	$ 81	$ (144)	$ 36,698

July 31, 2023	*Amortized cost*	*Gross unrealized gains*	*Gross unrealized (losses)*	*Fair value*
	(in thousands)			
Available-for-sale securities:				
U.S. Treasury Bills	$ 11,222	$ 53	$ —	$ 11,275
Corporate bonds	$ 46,766	$ 4,333	$ (4,660)	$ 46,439
Total available-for-sale securities	$ 57,988	$ 4,386	$ (4,660)	$ 57,714

During the year ended July 31, 2024, the Company reclassified approximately $1.8 million of unrealized gains out of accumulated other comprehensive income (loss) related to the sale of available-for-sale securities into realized gain on available-for-sale securities. During the year ended July 31, 2023, the Company reclassified approximately $154 thousand of unrealized gains out of accumulated other comprehensive loss income (loss) related to the sale of available-for-sale securities into consolidated net loss in the consolidated statements of operations and comprehensive loss in realized gain on available-for-sale securities.

Maturities of corporate Corporate bonds, U.S. agency bonds, and U.S. Treasury Bills held as of July 31, 2023 July 31, 2024 were all due within one year.

Marketable securities in an unrealized loss position as of July 31, 2023 July 31, 2024 and 2023 were not deemed impaired at acquisition and acquisition. Effective August 1, 2023, the Company evaluates subsequent declines unrealized losses to determine whether the decline in fair value are not deemed attributed to declines in has resulted from credit quality. The Company believes that it is more likely than not that it will receive a full recovery of par value on losses or other factors. No such credit losses have been identified during the securities, although there can be no assurance that such recovery will occur. year ended July 31, 2024.

NOTE 14 – DISCONTINUED OPERATIONS

On July 1, 2022, the Company determined that the 520 Property met the held-for-sale criteria and the Company therefore classified the 520 Property as held-for-sale in the consolidated balance sheets at July 31, 2022. The sale of the 520 Property also represented a significant strategic shift that will have a major effect on the Company's operations and financial results. Therefore, the Company has classified the results of operations related to the 520 Property as discontinued operations in the consolidated statements of operations and comprehensive loss. Depreciation on the 520 Property ceased on July 1, 2022, as a result of the 520 Property being classified as held-for-sale.

On August 22, 2022, Broad Atlantic completed the sale of the 520 Property for an aggregate gross purchase price of $49.4 million.

The 520 Property was encumbered by a mortgage securing a $15 million note payable which was paid off in this transaction. See Note 20 for further information on the note payable. After repaying the note payable, commissions, taxes, and other related costs, the Company received a net cash amount of approximately $33 million at closing.

Discontinued operations include (i) rental and parking revenues, (ii) payroll, benefits, facility costs, real estate taxes, consulting and professional fees dedicated to the 520 Property, (iii) depreciation and amortization expenses and (iv) interest (including amortization of debt issuance costs) on the note payable on the 520 Property. The operating results of these items are presented in our consolidated statements of operations and comprehensive loss as discontinued operations for all periods presented.

	Year Ended July 31, 2023
Revenue from discontinued operations:	
Rental – third party	$ 68
Rental – related party	115
Parking	66
Total revenue from discontinued operations	249
Costs and expenses from discontinued operations:	
General and administrative	468
Depreciation and amortization	—
Loss from discontinued operations	(219)
Interest expense	(87)
Loss from discontinued operations	(306)
Gain on disposal of discontinued operations	6,784
Income from discontinued operations	$ 6,478

The gain on disposal of discontinued operations of approximately $6.8 million was derived from the gross proceeds of approximately $49.4 million from the sale of the 520 Property, less the carrying value of the 520 Property of approximately $40.2 million, net of approximately $1.2 million in transaction costs and the write off of approximately $1.2 million of deferred rental income.

NOTE 11 15 – FAIR VALUE MEASUREMENTS

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

- **Level 1** - quoted prices in active markets for identical assets or liabilities;
- **Level 2** - quoted prices in active markets for similar assets and liabilities and inputs that are observable for the asset or liability; or
- **Level 3** - unobservable inputs for the asset or liability, such as discounted cash flow models or valuations.

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

The following is a listing of the Company's assets required to be measured at fair value on a recurring basis and where they are classified within the fair value hierarchy as of July 31, 2024 and July 31, 2023 and 2022: are as follows:

	July 31, 2023			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Available-for-sale securities - Corporate Bonds	$ —	$ 46,439	$ —	$ 46,439
Available-for-sale securities - U.S. Treasury Bills	11,275	—	—	11,275
Investment in equity securities	294	—	—	294
Investment in Cyclo Therapeutics Inc. - Common stock	3,898	—	—	3,898
Investment in Cyclo Therapeutics Inc. - Warrants	865	—	—	865
Hedge funds	—	—	4,984	4,984
Convertible note receivable, related party	—	—	1,921	1,921
Total	$ 16,332	$ 46,439	$ 6,905	$ 69,676

	July 31, 2024			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Available-for-sale securities - Corporate and U.S. Agency Bonds	$ —	$ 59,298	$ —	$ 59,298
Available-for-sale securities - U.S. Treasury Bills	3,967	—	—	3,967
Investment in Cyclo - Common Stock	10,746	—	—	10,746
Convertible note receivables, due from Cyclo	—	—	5,191	5,191
Investment in Cyclo - Warrants	—	—	1,264	1,264
Hedge funds	—	—	2,547	2,547
Convertible note receivable	—	—	1,146	1,146
Total	$ 14,713	$ 59,298	$ 10,148	$ 84,159

	July 31, 2023			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Available-for-sale securities - Corporate Bonds	$ —	$ 46,439	$ —	$ 46,439
Available-for-sale securities - U.S. Treasury Bills	11,275	—	—	11,275
Investment in equity securities	294	—	—	294
Investment in Cyclo Therapeutics Inc. - Common Stock	3,898	—	—	3,898
Investment in Cyclo Therapeutics Inc. - Warrants	865	—	—	865
Hedge funds	—	—	4,984	4,984
Convertible note receivable, related party	—	—	1,921	1,921
Total	$ 16,332	$ 46,439	$ 6,905	$ 69,676

As of July 31, 2024 and July 31, 2023, the Company did not have any liabilities measured at fair value on a recurring basis.

	July 31, 2022			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Available-for-sale securities - Corporate Bonds	$ —	$ 36,698	$ —	$ 36,698
Hedge funds	—	—	4,764	4,764
Total	$ —	$ 36,698	$ 4,764	$ 41,462

As of July 31, 2023 and 2022, the Company did not have any liabilities measured at fair value on a recurring basis.

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

	Year Ended July 31,		Year Ended July 31,	
	2023	2022	2024	2023
	(in thousands)		(in thousands)	
Balance, beginning of period	$ 4,764	$ 5,268	$ 6,905	$ 4,764
Total gain (loss) included in earnings	220	(504)		
Convertible note receivable, related party	2,000	—		
Withdrawal from Hedge Fund Investments			(2,500)	—
Unrealized gain on Hedge Fund			63	220
Investment in Cyclo Warrants			1,338	—
Unrealized loss on Cyclo Warrants			(74)	—
Funding of Convertible note receivable, related party			—	2,000
Unrealized gain on Convertible note receivable, related party			742	—
Realized loss on Convertible note receivable, related party released from AOCI			(663)	—
Conversion of convertible note receivable, related party			(2,000)	—
Funding of Convertible note receivable			1,000	—
Change in fair value of Convertible note receivable			146	—
Funding of Cyclo Convertible Note I			2,000	—
Funding of Cyclo Convertible Note II			2,000	—
Unrealized gain on issuance of Cyclo Convertible Note I			665	—
Unrealized gain on issuance of Cyclo Convertible Note II			648	—
Change in fair value of Cyclo Convertible Notes			(122)	—
Total loss included in other comprehensive loss	(79)	—	—	(79)
Balance, end of period	$ 6,905	$ 4,764	$ 10,148	$ 6,905

Hedge funds classified as Level 3 include investments and securities which may not be based on readily observable data inputs. The availability of observable inputs can vary from security to security and is affected by a wide variety of factors, including, for example, the type of security, whether the security is new and not yet established in the marketplace, the liquidity of markets, and other characteristics particular to the security. The fair value of these assets is estimated based on information provided by the fund managers or the general partners. Therefore, these assets are classified as Level 3. During the year ended July 31, 2024, the Company requested a withdrawal from Hedge Fund Investments of $2.5 million. The withdrawal was funded during the three months ended January 31, 2024.

Available-for-sale securities classified as Level 3 include a convertible note receivable, related party (see Note 5)8) which may not be based on readily observable data inputs. The availability of observable inputs can vary and is affected by a wide variety of factors, including, for example, the type of security, whether the security is new and not yet established in the marketplace, the liquidity of markets, and other characteristics particular to the security. The fair value of this asset is estimated using a scenario-based analysis based on the probability-weighted present value of future investments investment returns, considering each of the possible outcomes available to us, including cash repayment, equity conversion, and collateral transfer scenarios. Estimating the fair value of the convertible note requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. Therefore, this asset is classified as Level 3.

The Company holds $0.1 recognizes the fair value of the Cyclo Warrants utilizing a Black-Scholes option pricing valuation model (“Black-Scholes model”) at acquisition and $0.5 million each reporting date. The application of the Black-Scholes model utilizes significant assumptions, including expected volatility, expected life, marketability discount and risk-free interest rate. In order to determine the volatility, we measured expected volatility based on several inputs, including considering a peer group of publicly traded companies and the implied volatility of Cyclo’s publicly-traded warrants. As a result of the unobservable inputs that were used to determine the expected volatility of the Cyclo Warrants, the fair value measurement of these warrants reflected a Level 3 measurement within the fair value measurement hierarchy. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The expected volatility is a key assumption or input to the valuation of the Cyclo Warrants; however, changes in the expected

volatility assumption will have less of an effect on the Black-Scholes model valuation as the Cyclo Warrants approach their expiration. The Cyclo Warrants are subject to limits on exercise and any sales of the underlying shares of common stock would be subject to volume restrictions for which a discount to the stock price of Cyclo was applied. The Black-Scholes model further incorporated a discount for the overall lack of marketability for the Cyclo Warrants.

Below are the unobservable inputs to the Cyclo Warrants which reflect a Level 3 measurement within the fair value measurement hierarchy as of July 31, 2023 July 31, 2024:

Unobservable Input	Range	Weighted Average
Price Per Share [1]	$ 0.7-$0.74	$ 0.72
Exercise Price	$ 0.95 - $1.25	$ 1.13
Expected Volatility	85% - 104%	96.2%
Risk - Free Rate [2]	4.0%-4.1%	4.04%
Marketability Discount	38%-41%	55.0%
Remaining Term (Years)	3.2 - 6.0	4.9
Fair Value per Warrant [3]	$ 0.19	$ 0.19

[1] Closing price of Cyclo's common shares adjusted to reflect regulatory resale restrictions which ranged from 40.0% to 50.0%.

[2] US Treasury rate for a period commensurate with the Remaining Term.

[3] Concluded fair value per warrant as of July 31, 2024.

The Company used a scenario-based analysis to estimate the fair value of the Cyclo Convertible Notes based on the probability-weighted present value of future investment returns, considering each of the possible outcomes available to the Company, including cash repayment and 2022, equity conversion. Estimating the fair values of the Cyclo Convertible Notes requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. The four scenarios included maturity, a subsequent financing, a change in control, and an event of default, whereby total probability of one-hundred percent (100%) is allocated across the four scenarios, at issuance and each subsequent reporting period. With respect to the scenario reflecting maturity of the Cyclo Convertible Notes, the associated volatility assumption reflects voluntary conversion of the Cyclo Convertible Notes prior to their respective maturities. The Company used scenario-based analyses at June 11, 2024, July 16, 2024, and July 31, 2024 to determine the issuance date and period-end fair values of the Cyclo Convertible Note I and Cyclo Convertible Note II, respectively, with the following inputs:

	Convertible Note I		Convertible Note II	
Input	Issuance at June 11, 2024	Remeasured at July 31, 2024	Issuance at July 16, 2024	Remeasured at July 31, 2024
Discount factor	0.927 - 0.932	0.95 - 0.955	0.942	0.955
Conversion price	$ 0.95	$ 0.95	$ 0.95	$ 0.95
Dividend	0 %	0 %	0 %	0 %
Risk free rate	5.29% - 5.30 %	5.24% - 5.26 %	5.25 %	5.26 %
Stock price	$ 1.24	$ 1.19	$ 1.22	$ 1.19
Term	0.39 - 0.42 years	0.28 - 0.25 years	0.30 years	0.25 years
Equity volatility	61.0% - 73.0 %	59.0% - 67.0 %	65.0 %	59.0 %
Black-Scholes Merton Call Value	$ 0.22 - $0.39	$ 0.15 - $0.31	$ 0.19- $0.33	$ 0.15 - $0.29

The Company holds $0 and $65 thousand as of July 31, 2024 and July 31, 2023, respectively, 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 investment is was liquidated during the year ended July 31, 2024. The investment was accounted for under ASC 321, *Investments - Equity Securities*, using the measurement alternative as defined within the guidance, and the Company recorded an impairment loss of $334 thousand and $0 for the years ended July 31, 2023 and 2022, respectively. guidance.

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.

The Company’s financial instruments include trade accounts receivable, trade accounts payable, and due from related parties. The recorded carrying amounts of accounts receivable, accounts payable and due to related parties approximate their fair value due to their short-term nature.

NOTE 12 16 – ACCOUNTS RECEIVABLE

Accounts receivable consisted of the following:

	July 31, 2023	July 31, 2022
	(in thousands)	
Accounts Receivable - Third Party	$ 247	$ 196
Accounts Receivable - Related Party	211	158
Less Allowance for Doubtful Accounts	(245)	(197)
Accounts Receivable, net	$ 213	$ 157

	July 31, 2024	July 31, 2023
	(in thousands)	
Accounts receivable - third party	$ 338	$ 247
Accounts receivable - related party	333	211
Less allowance for credit losses	(245)	(245)
Accounts receivable, net	$ 426	$ 213

NOTE 13 17 – PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	July 31, 2023	*July 31, 2022*	*July 31, 2024*	*July 31, 2023*
	(in thousands)		*(in thousands)*	
Building and Improvements	*$ 2,505*	*$ 2,505*		
Building and improvements			*$ 2,505*	*$ 2,505*
Machinery and equipment			*552*	*—*
Other	*68*	*68*	*81*	*68*
	2,573	*2,573*	*3,138*	*2,573*
Less Accumulated Depreciation	*(878)*	*(803)*		
Less accumulated depreciation and amortization			*(1,018)*	*(878)*
Total	*$ 1,695*	*$ 1,770*	*$ 2,120*	*$ 1,695*

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

Depreciation expense and amortization pertaining to property and equipment was approximately $78 $137 thousand and $72 $78 thousand for the years ended July 31, 2023 July 31, 2024 and 2022, 2023, respectively.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 18 - GOODWILL AND INTANGIBLE ASSETS

Goodwill

The Company's headquarters are located following is a summary of goodwill by reportable segment for the year ended July 31, 2024:

	Healthcare	Real Estate	Infusion Technology	Consolidated
			(in thousands)	
Balance as of July 31, 2023	$ —	$ —	$ —	$ —
Day Three Acquisition	—	—	3,050	3,050
Balance as of July 31, 2024	$ —	$ —	$ 3,050	$ 3,050

Intangible assets

The following is a summary of intangible assets at 520 Broad Street July 31, 2024:

	Weighted average remaining useful life (years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
			(in thousands)	
Intellectual Property	15	$ 1,885	(73)	$ 1,812
Non-compete Agreements	2	50	(15)	35
Total Intangible Assets		$ 1,935	(88)	$ 1,847

Amortization expense for the next five years and thereafter for intangible assets is estimated to be as follows for years ending:

Year Ending July 31,	*(in thousands)*
2025	$ 148
2026	132
2027	123
2028	123
2029	123
Thereafter	1,198
Total	$ 1,847

Amortization of intangible assets totaled $88 thousand for the year ended July 31, 2024, and is included in Newark, New Jersey, where it occupies office space depreciation and which was previously owned by amortization expense within the Company. The table above excludes the assets consolidated statements of the 520 Property which were classified as held-for-sale as of July 31, 2022 operations and subsequently sold on August 22, 2022. Refer to Note 3 for further information on the 520 Property. comprehensive loss.

NOTE 14 19 – LOSS PER SHARE

Basic loss per share is computed by dividing net loss attributable to all classes of common stockholders of the Company by the weighted average number of shares of all classes of common stock outstanding during the applicable period. Diluted loss per share includes potentially dilutive securities such as stock options, unvested restricted stock, warrants to purchase common stock, and other convertible instruments unless the result of inclusion would be anti-dilutive.

The securities set forth in the table below have been excluded from the calculation of diluted net loss per share for the years ended July 31, 2023 and 2022 because inclusion of all such securities would have been anti-dilutive for all periods presented.

The following table summarizes the Company's potentially dilutive securities which have been excluded from the calculation of dilutive loss per share as their effect would be anti-dilutive:

	Year Ended July 31,	
	2023	2022
Shares issuable upon exercise of stock options	388,409	1,021,277
Shares issuable upon vesting of restricted stock	684,766	1,507,373
	1,073,175	2,528,650

	Year Ended July 31,	
	2024	2023
Shares issuable upon exercise of stock options	638,409	388,409
Shares issuable upon vesting of restricted stock	608,540	684,766
	1,246,949	1,073,175

The diluted loss per share computation equals basic loss per share for the years ended July 31, 2023 July 31, 2024 and 2022 2023 because the Company had a net loss from continuing operations in all such periods and the impact of the assumed vesting of restricted shares and exercise of stock options and warrants would have been anti-dilutive.

The following table summarizes the basic and diluted loss per share calculations (in thousands, except for share and per share amounts):

	Year Ended July 31,		*Year Ended July 31,*	
	2023	*2022*	*2024*	*2023*
Numerator:				
Net loss from continuing operations	*$ (8,693)*	*$ (140,547)*	*$ (65,003)*	*$ (8,693)*
Net loss attributable to noncontrolling interests	*(339)*	*(17,719)*	*(30,593)*	*(339)*
Numerator for net loss from continuing operations	*(8,354)*	*(122,828)*	*(34,410)*	*(8,354)*
Numerator for discontinued operations	*6,478*	*(1,830)*	*—*	*6,478*
Net loss attributable to Rafael Holdings, Inc.	*$ (1,876)*	*$ (124,658)*	*$ (34,410)*	*$ (1,876)*
Denominator:				
Weighted average basic and diluted shares outstanding	*23,263,211*	*19,767,342*	*23,745,516*	*23,263,211*
Loss per share attributable to common stockholders				
Basic and diluted:				
Continuing operations	*$ (0.36)*	*$ (6.22)*	*$ (1.45)*	*$ (0.36)*
Discontinued operations	*0.28*	*(0.09)*	*—*	*0.28*
Total basic and diluted loss per share	*$ (0.08)*	*$ (6.31)*	*$ (1.45)*	*$ (0.08)*

NOTE 15 20 – NOTE PAYABLE, HELD-FOR-SALE

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

The Note Payable bore interest at a rate per annum equal to seven and one-quarter percent (7.25%) from July 9, 2021 through July 31, 2021 and thereafter at an interest rate per annum equal to the 30-day LIBOR Rate, as published in *The Wall Street Journal*, plus 6.90% per annum, but in no event less than seven and one-quarter percent (7.25%) per annum. The Note Payable was due on August 1, 2022, subject to the Company's option to extend the maturity date until August 1, 2023 for a fee equal to three-quarters of one percent (0.75%) of the Note Payable.

The Loan Agreement contained customary affirmative covenants, negative covenants and events of default, as defined in the Loan Agreement, including covenants and restrictions that, among other things, restricted the Borrower's ability to incur liens, or transfer, lease or sell the collateral as defined in the Loan Agreement. A failure to comply with these covenants would have permitted the Lender to declare the Borrower's obligations under the Loan Agreement, together with accrued interest and fees, to be immediately due and payable. The Company was in compliance compliance with the covenants in the Loan Agreement as of July 31, 2022. The Company extended the maturity date to November 1, 2022 and paid an extension fee of $37,500 on July 29, 2022.

In connection with the sale of the 520 Property, on August 22, 2022, the Company paid off the outstanding principal balance of $15 million and accrued interest of approximately $87,000 on the Note Payable. Refer to See Note 3 14 for further details on the subsequent sale of the 520 Property.

Interest expense under the Note Payable, which is recognized in loss on discontinued operations, amounted to $87 thousand for the year ended July 31, 2023, and $1.2 million for the year ended July 31, 2022.
Unamortized debt issuance costs on the Note Payable totaled approximately $0 as of July 31, 2023 and 2022. Amortization of the debt discount on the Note Payable totaled approximately $0 and $472 $87 thousand for the years ended July 31, 2023 July 31, 2024 and 2022, 2023, respectively.

NOTE 16 21 – RELATED PARTY TRANSACTIONS

IDT Corporation

The Company IDT Corporation ("IDT"), a related party through common ownership and some common members of management, has historically maintained an intercompany balance a due to/from related parties balance 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 as the relevant persons were also providing services to IDT. IDT billed the Company approximately $313 $296 thousand and $343 $313 thousand for services during the years ended July 31, 2023 July 31, 2024 and 2022, 2023, respectively, of which $70 thousand and $69 thousand is included in due to related parties at July 31, 2023 July 31, 2024 and 2022, respectively. 2023.

IDT leased, prior to the Company's sale of the property, 520 Property, approximately 80,000 square feet of office space plus parking at the 520 Property and currently leases approximately 3,600 square feet of office space in Jerusalem, Israel. The Company invoiced IDT approximately $108 thousand and $211 thousand of which approximately $102 thousand is included in discontinued operations during for the year years ended July 31, 2023. The Company invoiced IDT approximately $2.1 million, of which approximately $2.0 million is included in discontinued operations for office rent July 31, 2024 and parking during the year ended July 31, 2022. 2023, respectively. As of July 31, 2023 July 31, 2024 and 2022, 2023, IDT owed the Company approximately $210 $332 thousand and $157 $210 thousand, respectively, for office rent and parking.
Cornerstone Pharmaceuticals
Until October 31, 2021, the Company had provided Cornerstone Pharmaceuticals with administrative, finance, accounting, tax and legal services. Howard S. Jonas and William Conkling currently serve on the Board of Directors of Cornerstone Pharmaceuticals. The Company billed Cornerstone Pharmaceuticals $120 thousand for the year ended July 31, 2022. As of July 31, 2023 and July 31, 2022, Cornerstone Pharmaceuticals owed the Company $720 thousand, for which a full allowance for uncollectibility has been recorded.
Due to the Data Events, in the year ended July 31, 2022, the balance owed to the Company by Cornerstone Pharmaceuticals was fully reserved, resulting in a loss on related party receivable of $720 thousand (see Note 4).
On March 21, 2023, the Company entered into a Promissory Note with Cornerstone Pharmaceuticals, wherein, Cornerstone Pharmaceuticals promises to pay the Company $2 million together with all interest accrued on May 22, 2023, or such earlier date as the Promissory Note is required or permitted to be repaid (see Note 5). On May 22, 2023, the Promissory Note was amended to extend the maturity date to November 30, 2023 and to waive the interest increase (see Note 5). parking plus Israeli value added tax.

Genie Energy Ltd.

The Company Genie Energy Ltd. ("Genie"), a related party through common ownership and some common members of management, leased office space at 520 Broad Street prior to Genie. the Company's sale of the 520 Property. The Company invoiced Genie approximately $19 thousand which is included in discontinued operations during the year ended July 31, 2023. Genie pays the Company for payroll costs for certain personnel which totaled approximately $10 thousand during the year ended July 31, 2023.

Related Party Rental Income

The Company leased space to related parties (including IDT Corporation -– see above) which represented approximately 42% 17% and 58% 42% of the Company's total revenue for the years ended July 31, 2023 July 31, 2024 and 2022, 2023, respectively. The portion of related party rental income pertaining to the 520 Property has been classified in discontinued operations on the consolidated statements of operations and comprehensive loss for the years ended July 31, 2023 and 2022.

RP Finance

For the year ended July 31, 2023, the Company recognized $0 from its ownership interests of 37.5% in RP Finance. For the year ended July 31, 2022, the Company recognized a loss of $575 thousand in income from its ownership interests of 37.5% in RP Finance. .

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

In December 2020, IDT Corporation and Genie Energy Ltd, on whose Boards of Directors Howard Jonas, the Company's Chairman of the Board and Executive Chairman and former Chief Executive Officer serves, each purchased 218,245 shares of Class B common stock for consideration of $5 million each. In connection with the purchases, each purchaser was granted warrants (the "Issued Warrants") to purchase twenty percent (20%) of the shares of Class B common stock purchased by such purchaser. The Issued Warrants have an exercise price of $22.91 per share and expired on June 6, 2022. The Issued Warrants were not exercised. The shares and Issued Warrants were issued in reliance on the exemption from registration provided for under Section 4(a)(2) of the Securities Act of 1933, as amended.

On June 22, 2022, the Company entered into a Stock Purchase Agreement (the "I9 SPA") with I9 Plus, LLC, an entity affiliated with members of the family of Howard Jonas. On July 6, 2022, pursuant to the I9 SPA, the Company sold 3,225,806 shares of the Company's Class B common stock to I9 Plus, LLC at a price per share of $1.86 and an aggregate sale price of $6 million.

On July 31, 2023, eight trusts, each for the benefit of a child of Howard S. Jonas, the Company's Executive Chairman and Chairman of the Board, with independent trustees, transferred an aggregate of 787,163 shares of Class A common stock of the Company (representing all of the issued and outstanding shares of the Class A common stock of the Company, and 51.3% of the aggregate voting power of all issued and outstanding shares of capital stock of the Company) to a limited partnership. Howard Jonas is the sole manager of the sole general partner of the limited partnership and, therefore, has sole voting and dispositive power over the shares of Class A common stock held by the limited partnership. Following the transfer, Mr. Jonas will be is the controlling stockholder of the Company and the Company is a controlled company as defined in Section 303A of the New York Stock Exchange Listed Company Manual.

LipoMedix Pharmaceuticals, Ltd.

As of During the date of the LipoMedix SPA, on November 15, 2021, there was an outstanding loan balance including principal of $400 thousand and accrued interest of $21.8 thousand owed by LipoMedix to the Company on the note from March 2021. The amount due on the loan was netted against the $3.0 million aggregate purchase price due LipoMedix, resulting in a cash payment by the Company of approximately $2.6 million in exchange for the 15,975,000 shares purchased. As a result of the share purchase, the Company's ownership of LipoMedix increased to approximately 84% with a noncontrolling interest of approximately 16%.

On February 9, 2023 year ended July 31, 2024, the Company entered into paid Sam Beyda, who serves as Chief Executive Officer and a share purchase agreement with LipoMedix to purchase 70,000,000 ordinary shares at $0.03 per share for an aggregate purchase price Director of $2.1 million. As Day Three and is Howard Jonas' son-in-law, a result of salary in the share purchase, the Company's ownership of LipoMedix increased to approximately 95% with a noncontrolling interest of approximately 5%. The Company recorded approximately $16 thousand to adjust the carrying amount of the noncontrolling interest to reflect the Company's increased ownership interest in LipoMedix's net assets.

Investment in Equity Securities

The Company entered into a Cooperation Agreement with Genie, IDT and trusts for the benefit of certain family members of Howard Jonas related to an investment in a third-party publicly traded company. Subsequently, the Company and Genie agreed to share the expenses related to the investment equally and each would retain any return from its own investments. The Company invested $1.6 million in the third-party company and after selling a portion of its interest made a profit of $309 $160 thousand.

NOTE 17 22 – INCOME TAXES

At July 31, 2023, the Company had federal net operating loss ("NOL") carryforwards from domestic operations of approximately $63.2 million, to offset future taxable income, state NOLs of $40.4 million, and NOLs from foreign operations of $7.6 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 components of loss from continuing operations before income taxes, including equity in loss of Day Three, are as follows:

	For the Years Ended July 31,		*For the Years Ended July 31,*	
	2023	***2022***	***2024***	***2023***
	(in thousands)		***(in thousands)***	
Domestic	*$ (6,056)*	*$ (137,978)*	*$ (67,653)*	*$ (6,259)*
Foreign	*(2,689)*	*(1,994)*	*(30)*	*(2,689)*
Loss before income taxes	*$ (8,745)*	*$ (139,972)*	*$ (67,683)*	*$ (8,948)*

Benefit from income taxes as presented in the consolidated statements of operations and comprehensive loss consisted of the following:

	For the Year Ended July 31,		*For the Years Ended July 31,*	
	2023	***2022***	***2024***	***2023***
	(in thousands)		***(in thousands)***	
Current:				
Foreign	*$ 19*	*$ —*	*$ 19*	*$ 19*
Federal	*—*	*—*	*—*	*—*
State	*(274)*	*—*	*(2,602)*	*(274)*
Total current expense (benefit)	*(255)*	*—*		
Total current benefit			*(2,583)*	*(255)*
Deferred:				
Foreign	*—*	*—*	*(73)*	*—*
Federal	*—*	*—*	*(17)*	*—*
State	*—*	*—*	*(7)*	*—*
Total deferred expense	*—*	*—*		
Total deferred benefit			*(97)*	*—*
Benefit from income taxes	*$ (255)*	*$ —*	*$ (2,680)*	*$ (255)*

The differences reconciliation between income taxes expected at the U.S. federal statutory income Company's effective tax rate attributable to on pretax loss from continuing operations and income taxes attributable to pretax loss from continuing operations are reported the statutory tax rate for the years ended July 31, 2024 and July 31, 2023 is as follows:

	At July 31,	
	2023	**2022**
	(in thousands)	
U.S. federal income tax at statutory rate	$ (1,877)	$ (29,514)
State income tax	(479)	(8,752)
Valuation allowance	2,958	35,001
Foreign tax rate differential	(583)	(459)
Tax law change	—	—
Permanent differences	—	3,632
Rate change	—	—
Sale of state NOLs	(274)	-
Other	-	92
Benefit from income taxes	$ (255)	$ —

	For the Years Ended July 31,	
	2024	2023
	(in thousands)	
U.S. federal income tax at statutory rate	$ (14,213)	$ (1,877)
Permanent items - Cornerstone Acquisition	18,871	—
Nondeductible items	672	—
State income tax	1,807	(479)
Foreign operations	(1)	(583)
Other	627	—
Cornerstone Acquisition impact to deferred tax assets	(51,546)	—
Derecognition of Cornerstone investment due to Cornerstone Acquisition	23,312	—
Sales of state NOLs	(2,613)	(274)
Change in valuation allowance	20,404	2,958
Benefit from income taxes	$ (2,680)	$ (255)

During the year ended July 31, 2024, the Company received proceeds of approximately $2.6 million from the sale of the Company's 2020-2022 New Jersey NOLs totaling $31.6 million through the New Jersey Technology Business Tax Certificate Transfer Program. During the year ended July 31, 2023, the Company received proceeds of approximately $274 thousand for from the sale of the Company's 2018 and Company's 2019 New Jersey tax credits NOLs totaling $3.3 million through the New Jersey Technology Business Tax Certificate Transfer Program. The Company has not recorded U.S.

Deferred income taxes reflect the net tax effects of temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax expense for foreign purposes. Realization of net deferred tax assets is dependent upon future earnings, because it has not generated if any, foreign earnings. the timing and amount of which are uncertain.

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

	At July 31,		At July 31,	
	2023	2022	2024	2023
	(in thousands)		(in thousands)	
Deferred tax assets:				
Net operating loss carryforwards	$ 17,852	$ 15,170	$ 61,204	$ 17,852
Unrealized gain/loss	30,236	31,850		
Unrealized loss			—	30,236
R&D credits, net of uncertain tax position			6,145	—
Capitalized Sec. 174 research and experimental expenditures			3,121	689
Stock-based compensation			2,486	1,858
Depreciation	(1)	1	286	(1)
R&D amortization	689	-		
Reserves and accruals	237	236	249	237
Stock-based compensation	1,858	1,839		
Charitable contributions			141	—
Gross deferred tax assets	50,871	49,096	71,362	50,871
Less valuation allowance	(50,871)	(49,096)	(71,275)	(50,871)
Total deferred tax assets	—	—		
Total deferred tax liabilities	—	—		
Deferred tax assets, net	$ —	$ —		
Total deferred tax assets, net of valuation allowance			2,357	—
Deferred tax liabilities:				
Unrealized gain			(2,327)	—
Amortization			(30)	—
Total deferred tax liabilities:			(2,357)	—
Deferred tax liability, net			$ —	$ —

The Company continually evaluates the likelihood of the realization of deferred tax assets and adjusts the carrying amount of the deferred tax assets by the valuation allowance to the extent the future realization of the deferred tax assets is more likely than not. The Company considers many factors when assessing the likelihood of future realization of its deferred tax assets, including its recent cumulative earnings experience by taxing jurisdiction, expectation of future taxable income or loss, the carryforward periods available to the Company for tax reporting purposes, and other relevant factors.

Deferred tax assets established for the excess outside tax basis of an investee are derecognized upon the event that the investee becomes a domestic subsidiary as a result of a business combination or consolidation, as it is likely that the deferred tax asset will no longer qualify for recognition. During the year ended July 31, 2024, the Company derecognized unrealized loss deferred tax assets related to prior investments in Cornerstone and Day Three as a result of the Cornerstone Acquisition and Day Three Acquisition, respectively.

As of July 31, 2024, based on the Company's history of losses and its assessment of future losses, management believes that it is more likely than not that future taxable income will not be sufficient to realize the deferred tax assets. Therefore, a valuation allowance has been applied to deferred tax assets.

Effective for tax years beginning after December 31, 2021, taxpayers are required to capitalize any expenses incurred that are considered incidental to research and experimentation ("R&E") activities under IRC Section 174. While taxpayers historically had the option of deducting these expenses under IRC Section 174, the December 2017 Tax Cuts and Jobs Act mandates capitalization and amortization of R&E expenses for tax years beginning after December 31, 2021. Expenses incurred in connection with R&E activities in the US must be amortized over a 5-year period and R&E expenses incurred outside the US must be amortized over a 15-year period. R&E activities are broader in scope than qualified research activities that are considered under IRC Section 41 (relating to the research tax credit).

As of July 31, 2024, the Company has federal, state, and foreign net operating loss carryforwards of approximately $270.0 million, $17.5 million and $11.6 million, respectively. Federal net operating loss carryforwards in the amount of $83.1 million begin expiring in 2025 and approximately $186.9 million have an indefinite life. Federal NOL carryforwards generated after tax year 2021 are subject to an 80% limitation on taxable income, do not expire and will carryforward indefinitely. State net operating loss carryforwards in the amount of $17.5 million begin expiring in 2042. Foreign net operating loss carryforwards in the amount of $11.6 million have an indefinite life.

The utilization of the Company's net operating losses may be subject to a U.S. federal limitation due to the "change in ownership provisions" under Section 382 and 383 of the Internal Revenue Code and other similar limitations in various state jurisdictions. Such limitations may result in a reduction of the amount of net operating loss carryforwards and research and development tax credits in future years and possibly the expiration of certain net operating loss and research and development tax credits carryforwards before their utilization.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examinations by federal, foreign, and state and local jurisdictions, where applicable. There are currently no pending tax examinations. The Company's tax years are still open under statute from 2021 to the present in the U.S. and from 2020 to present in the Company's foreign operations. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service and state and local tax authorities to the extent utilized in a future period.

The Company is also subject to certain non-income taxes such as value added taxes, sales taxes, and property taxes. The Company has taken certain positions that management feels, although not free from doubt, should not result in a successful challenge by certain tax authorities.

As required by the uncertain tax position guidance in ASC No. 740, *Income Taxes*, ("ASC 740") the Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant tax authority. The Company applied the uncertain tax position guidance in ASC 740 to all tax positions for which the statute of limitations remained open. Any estimates of tax contingencies contain assumptions and judgments about potential actions by taxing jurisdictions. Any interest and penalties related to uncertain tax positions would be included as part of the income tax provision.

The Company's conclusions regarding uncertain tax positions may be subject to review and adjustment at a later date based upon ongoing analysis of or changes in tax laws, regulations and interpretations thereof as well as other factors.

A reconciliation of the beginning and ending amount of unrecognized tax benefits associated with uncertain tax positions is as follows:

	At July 31,	
	2024	**2023**
	(in thousands)	
Balance, beginning of the year	$ —	$ —
Additions of tax positions related to the prior year	6,218	—
Balance, end of year	$ 6,218	$ —

NOTE 18 23 – BUSINESS SEGMENT INFORMATION

The Company conducts business as two three operating segments, Healthcare, Infusion Technology and Real Estate. The Company's reportable segments are distinguished by types of service, customers and methods used to provide their services. The operating results of these business segments are regularly reviewed by the Company's Chief Executive Officer who is the chief operating decision-maker. Following the Day Three Acquisition, the chief operating decision-maker began reviewing the operating results of Day Three and in accordance with the Company's accounting policy, the Company concluded this resulted in a new operating segment, which the Company refers to as Infusion Technology.

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 Healthcare segment based primarily on research and development efforts and results of clinical trials and the Infusion Technology and Real Estate segment segments based primarily on results of operations.

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

The Real Estate segment consists of the Company's real estate holdings, which is currently comprised of a portion of a commercial building in Israel. The revenue, revenues, and (loss) income from operations and (loss) income before taxes of the 520 Property have been excluded from the Real Estate segment in the figures below due to its classification of held-for-sale and discontinued operations, and operations.

The Infusion Technology segment is comprised of a majority equity interest in Day Three. Revenues associated with the sale of the 520 Property on August 22, 2022. Infusion Technology segment include infusion technology revenue derived from Day Three's Unlokt technology.

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

(in thousands)	***Healthcare***	***Real Estate***	***Total***	***Healthcare***	***Infusion Technology***	***Real Estate***	***Total***
Year Ended July 31, 2023							
Year Ended July 31, 2024							
Revenues	*$ —*	*$ 279*	*$ 279*	*$ —*	*$ 355*	*$ 282*	*$ 637*
(Loss) income from operations	*(15,121)*	*78*	*(15,043)*	*(102,032)*	*(675)*	*80*	*(102,627)*
Year Ended July 31, 2022							
Revenues	*$ —*	*$ 410*	*$ 410*				
(Loss) income from operations	*(60,658)*	*181*	*(60,477)*				

(in thousands)	**Healthcare**	**Infusion Technology**	**Real Estate**	**Total**
Year Ended July 31, 2023				
Revenues	$ —	$ —	$ 279	$ 279
(Loss) income from operations	(15,121)	—	78	(15,043)

Total assets by segment are not provided to or reviewed by the CODM.

Geographic Information

Infusion Technology Segment

Revenue from the Infusion Technology segment is entirely from customers located in the United States.

Real Estate Segment

Revenues from tenants located outside of the United States were generated entirely from related parties located in Israel. Revenues from these non-U.S. customers as a percentage of total revenues, which are inclusive of revenue from discontinued operations, were as follows (revenues by country are determined based on the location of the related facility):

Year Ended July 31,	***2023***	***2022***	***2024***	***2023***
Revenue from tenants located in Israel	*53%*	*7%*	*100%*	*53%*

Assets

Net property, plant, and equipment and total assets held outside of the United States, which summarized by geographic area are located in Israel, were as follows:

(in thousands)	***United States***	***Israel***	***Total***	***United States***	***Israel***	***Total***
July 31, 2024						
Property, plant, and equipment, net				*$ 783*	*$ 1,337*	*$ 2,120*
Total assets				*93,434*	*3,398*	*96,832*
July 31, 2023						
Property, plant, and equipment, net	*$ 293*	*$ 1,402*	*$ 1,695*	*$ 293*	*$ 1,402*	*$ 1,695*
Total assets	*95,244*	*3,585*	*98,829*	*95,244*	*3,585*	*98,829*
July 31, 2022						
Property, plant, and equipment, net	*$ 305*	*$ 1,465*	*$ 1,770*			
Total assets	*114,053*	*4,267*	*118,320*			

NOTE 19 24 – COMMITMENTS AND CONTINGENCIES

Legal Proceedings

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.

License Agreements

Cornerstone is a party to two license agreements in connection with certain technology being used for products under development and is required to make certain annual maintenance payments. In December 2022, Broad Atlantic entered into addition, royalty payments, calculated on a settlement agreement with low single digit percentage of net sales, as defined in the respective agreements, will be required upon the commercialization of licensed technology. Sublicensing fees are calculated and due based upon a vendor providing for the payment by the Company percentage of $113 thousand representing payment in full for repair work done on the premises prior gross sublicense fees. Cornerstone expenses license obligation payments to our sale of the 520 Property. This amount is included in discontinued operations research and development on the consolidated statements of operations and comprehensive loss.

One worldwide license agreement requires Cornerstone to reimburse the other party for costs associated with filing and defending various patents worldwide. Payment obligations under this license agreement remain in effect until the last underlying patents granted under the license agreement expire in their respective countries. The last patent expired in 2019. License maintenance fees are currently $20,000 per year and continue for the term of the agreement, which expires in 2026. The license maintenance fees are replaced by minimum royalties of $10,000 during the first year following governmental approval to market products and escalates to $1,000,000 during the term of the agreement. Cornerstone is also responsible to pay fees on any sub-licensing of the licensed patents. Cornerstone may credit each annual license maintenance fee in full against all royalties and sublicensing fees due during the same calendar year. Cornerstone may terminate the license agreement upon 90 days' notice. Either party may terminate the license agreement if the other party commits any material breach of any covenant or promise and does not cure such breach within 30 days of the receipt of written notice of such material breach. In May 2017, Cornerstone renegotiated the agreement referred to as the "second license." In exchange for a waiver of certain product development milestones, Cornerstone modified the agreement to pay a low single digit percentage royalty for a duration of five years on Net Sales of product sold after the expiration of the licensed patent and potentially up to eight years. As of July 31, 2024, there are no products being marketed which are covered by the patents under the license agreement.

The remaining minimum payments required under the license agreement, assuming the agreement is not terminated by Cornerstone, excluding any escalation for receiving government marketing approval subsequent to July 31, 2018, are $20,000 per year. The agreement may continue until January 1, 2029 (if not earlier terminated).

Cornerstone's second license continues until the termination of the later of the last to expire patent or royalty obligation under the agreement on a country-by-country basis (currently, or as otherwise provided in the license agreement). Fifty percent of the maintenance fee payments, up to $1.1 million, may be credited against the potential future royalty payments, calculated on a single digit percentage of net sales, as defined, that Cornerstone would have to make to the license holder should royalties be paid. The agreement may be terminated on 15 days' written notice after default by the other party if said default is not cured within 30 days of receipt of notice by the defaulting party. In addition, Cornerstone may terminate the agreement on 15 days' written notice to the license holder. Royalties are due based on Gross Sales, as defined, for products sold relating to patented and unpatented technology, and shall terminate on the 15th anniversary of the first commercial sale of the product in the corresponding country or territory. Sublicense payments are due in connection with any sublicense fees received relating to patented and non-patented products related to the patented technology and proprietary know-how, as provided in the agreement. As of July 31, 2024, there were no products being marketed which are covered by the patents under the license agreement. There were no additional annual license maintenance fees required beyond 2010.

As part of a royalty agreement, Cornerstone is obligated to pay royalties, based upon percentage (low single digit) of net sales, to Altira Capital and Consulting LLC ("Altira"), a consolidated subsidiary of the Company. The royalty obligations remain in effect, on a country-by-country basis, until the last to expire patent claims associated with such products and services expire or are no longer in force. No payments have been made in connection with a royalty pool. As of July 31, 2024, the last to expire patent claim is to remain in force until fiscal 2034.

NOTE 20 25 – EQUITY

Share Repurchase Program

In April 2023, Effective April 14, 2023, the Company's Board of Directors approved a share repurchase program (the "2023 Share Repurchase Program") authorizing the repurchase of up to $5 million of the Company's Class B common stock. Under the 2023 Share Repurchase Program, which took effect on April 14, 2023, the Company may was authorized to purchase, at purchase prices up to $1.75 per share, shares of its shares Class B common stock from time to time until the earlier of June 16, 2023 (the "Plan Termination Date") or when $5 million worth of shares at $1.75 per share or below have been purchased. . In July 2023, the 2023 Share Repurchase Program was amended to extend the Plan Termination Date to July 1, 2024. On December 22, 2023, the earlier of July 1, 2024, or when $5 million worth of shares at $1.75 per Company suspended the share or below have been purchased. repurchase program through the Plan Termination Date.

The timing and amount of any share repurchases under the 2023 Share Repurchase Program will be determined at the Company's discretion and based on market conditions and other considerations. Share repurchases under the authorizations may be made through open market purchases or pursuant to pre-set trading plans meeting the requirements of Rule 10b5-1 under the Securities Exchange Act of 1934. The program does not obligate the Company to acquire any particular amount of its Class B common stock, and the repurchase program may be suspended or discontinued at any time at the Company's discretion.

During the year ended July 31, 2023 July 31, 2024, the Company did not repurchase any repurchased 101,487 of its Class B common stock. stock for a total cost of $168 thousand under the 2023 Share Repurchase Program.

Class A Common Stock and Class B Common Stock

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

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

On June 1, 2021, the Company filed a Registration Statement on Form S-3 to issue 48,859 shares of Class B common stock for payment due on the purchase of Altira, an investment which has been subsequently fully impaired.

On August 19, 2021, the Company entered into a Securities Purchase Agreement (the "Institutional Purchase Agreement") with Institutional Investors certain third-party institutional investors (the "Institutional Investors") and a Securities Purchase Agreement with I9Plus, LLC, (the "Jonas Purchase Agreement"), an entity affiliated with Howard S. Jonas, the Chairman of the Board of Directors of the Company. On August 24, 2021, the Company issued 2,833,425 shares of Class B common stock (the "Institutional Shares"), par value $0.01 per share, to the Institutional Investors, at a purchase price equal to $35.00 per share, for aggregate gross proceeds of approximately $99.2 million, before deducting placement agent fees and other offering expenses. Additionally, pursuant to the Jonas Purchase Agreement, the Company issued 112,501 shares of Class B common stock to I9Plus, LLC, at a purchase price equal to $44.42 per share, which was equal to the closing price of a share of the Class B common stock on the New York Stock Exchange on August 19, 2021 (the "Jonas Offering"). The Jonas Offering resulted in additional aggregate gross proceeds of approximately $5.0 million. The total net proceeds from the issuance of shares was were $98.0 million after deducting transaction costs of $6.2 million.

On August 19, 2021, in connection with the Institutional Purchase Agreement, the Company entered into a Registration Rights Agreement with the Institutional Investors whereby the Company agreed to prepare and file a registration statement with the SEC within 30 days after the earlier of (i) the date of the closing of the Merger Agreement, and (ii) the date the Merger Agreement is terminated in accordance with its terms, for purposes of registering the resale of the Institutional Shares and any shares of Class B common stock issued as a dividend or other distribution with respect to the Institutional Shares.

On February 15, 2022, the Company filed a Registration Statement on Form S-3 (as amended on March 2, 2022) registering the resale by the Institutional Investors of the shares purchased by them. The Registration Statement was declared effective on March 7, 2022.

In March 2018, the Company established its 2018 Equity Incentive Plan was created and adopted by the Company in March 2018. Plan. On January 19, 2022, the Company's stockholders approved the 2021 Equity Incentive Plan (the "2021 Plan"). The 2018 Equity Incentive Plan was suspended and replaced by the 2021 Plan and, following January 19, 2022, no new grants are to be awarded under the 2018 Equity Incentive Plan. Existing grants under the 2018 Equity Incentive Plan will not be impacted by the adoption of the 2021 Plan. Any of the Company's employees, directors, consultants, and other service providers, and those of the Company's affiliates, are eligible to participate in the 2021 Plan. In accordance with applicable tax rules, only employees (and the employees of parent or subsidiary corporations) are eligible to be granted incentive stock options. The 2021 Plan authorizes stock options (both incentive stock options or non-qualified stock options), stock appreciation rights, restricted stock, restricted stock units, and cash or other stock-based awards. On January 19, 2022, the Company filed a Registration Statement on Form S-8 registering 1,919,025 shares of Class B Common Stock common stock reserved for issuance under the 2021 Plan. On November 28, 2022, the Company's Board of Directors approved an amendment to the 2021 Plan that, among other things, increases the number of shares of the Company's Class B Common Stock common stock available for the grant of awards thereunder by an additional 696,770, which the stockholders approved on January 23, 2023. The maximum number of shares of Class B common stock that may be issued under the 2021 Plan is 2,615,795 shares. As of July 31, 2023 July 31, 2024, there were 953,516 171,986 shares still available for issuance under the 2021 Plan.

On February 15, 2022, the Company filed a Registration Statement on Form S-3 (as amended on March 2, 2022) registering the resale by institutional investors (the "Institutional Investors") of the shares purchased by them. The Registration Statement was declared effective on March 7, 2022.

On June 22, 2022, the Company entered into a Stock Purchase Agreement (the "I9 SPA") with I9 Plus. On July 6, 2022, pursuant to the I9 SPA, the Company sold 3,225,806 shares of the Company's Class B common stock to I9 Plus at a price per share of $1.86 and an aggregate sale price of $6 million, presented in common stock sold to related party within the statement of stockholders' equity. The price per share was calculated to be the greater of (1) the volume weighted average price for the Class B common stock on the New York Stock Exchange for the five trading days ending on June 21, 2022 (which were the five trading days beginning with the first full trading day following the date that the transaction was approved by the Board of Directors of the Company, and its Corporate Governance Committee which consists solely of independent members of the Board) and (2) the closing price of the Class B common stock on June 21, 2022 (the trading day immediately preceding the date of the I9 SPA to ensure that the sale price was not below the Minimum Price under NYSE Rule 312.03(b)). The shares were issued in reliance on the exemption from registration provided for under Section 4(a)(2) of the Securities Act of 1933, as amended.

On July 6, 2022, pursuant to the I9 SPA dated June 22, 2022 with I9 Plus, LLC, an entity affiliated with members of the family of Howard Jonas, the Company sold 3,225,806 shares of the Company's Class B common stock to I9 Plus, LLC at a price per share of $1.86 and an aggregate sale price of $6 million.

Employment Agreement

On June 13, 2022, the Company entered into an employment agreement with Howard S. Jonas (who serves as the Chairman of the Board and Executive Chairman of the Company) (the "Employment Agreement"), which provides, among other things: (i) a term of five years (subject to extension unless either party elects not to renew); (ii) an annual base salary of $260,000, of which $250,000 is payable through the issuance of restricted shares of the Company's Class B common stock ("Class B Stock") with the value of the shares based upon the volume weighted closing price of the Class B Stock on the NYSE on the thirty days ending with the NYSE trading day immediately preceding the issuance to be issued within thirty days of the date of the Employment Agreement (the "Start Date") and each annual anniversary, and such shares vesting, contingent on Mr. Jonas' remaining in continuous service to the Company, in substantially equal amounts on the three, six, nine and twelve month anniversaries of the Start Date or annual anniversary; and (iii) a grant of restricted shares of Class B common stock with a value of $600,000, issuable within 30 days with the value of the shares based upon the volume weighted closing price of the Class B Stock common stock on the NYSE on the thirty 30 days ending with the NYSE trading day immediately preceding the issuance and such shares, and vesting, contingent on Mr. Jonas' Jonas remaining in continuous service to the Company, in substantially equal amounts on the first and second annual anniversaries of the Start Date. On June 19, 2024, the Employment Agreement was amended to provide an annual base salary of $294,000, of which $250,000 is payable through the issuance of Class B common stock in accordance with the terms defined above.

Stock Options

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)	Number of **Options**	Weighted Average Exercise **Price**	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value **(in thousands)**
Outstanding at July 31, 2021	*683,414*	*$ 11.13*	*3.05*	*$ 26,982*				
Granted	*518,304*	*20.54*	*9.25*	*—*				
Cancelled / Forfeited	*(180,441)*	*—*	*—*	*—*				
Outstanding at July 31, 2022	*1,021,277*	*12.11*	*4.47*	*—*	*1,021,277*	*$ 12.11*	*4.47*	*$ —*
Granted	*175,000*	*2.08*	*9.51*	*—*	*175,000*	*2.08*	*9.51*	*—*
Expired	*(589,205)*	*—*	*—*	*—*	*(589,205)*	*—*	*—*	*—*
Cancelled / Forfeited	*(218,663)*	*—*	*—*	*—*	*(218,663)*	*—*	*—*	*—*
Outstanding at July 31, 2023	***388,409***	***$ 14.51***	***8.71***	***$ —***	*388,409*	*$ 14.51*	*8.71*	*$ —*
Exercisable at July 31, 2023	***65,456***	***$ 20.98***	***8.13***	***$ —***				
Granted					*250,000*	*1.84*	*9.50*	*—*
Outstanding at July 31, 2024					***638,409***	***$ 9.55***	***8.39***	***$ —***
Exercisable at July 31, 2024					***114,602***	***$ 13.13***	***7.61***	***$ —***

The weighted average grant date fair value per unit for the options granted during the years ended July 31, 2024 and 2023, was $1.34 and $1.58, respectively. At July 31, 2023 July 31, 2024, there is were unrecognized compensation costs related to non-vested stock options of $1.3 million, which are expected to be recognized over the next 3.2 years. 2.2 years from July 31, 2024.

The value of option grants is calculated using the Black-Scholes option pricing model with the following assumptions for options granted during the years ended July 31, 2023 July 31, 2024 and 2022: 2023, respectively:

	For the Year Ended July 31,		For the Year Ended July 31,	
	2023	2022	2024	2023
Risk-free interest rate	*3.60% - 3.66%*	*0.67% - 1.7%*	*3.98%*	*3.66%*
Expected term (in years)	*6.11*	*6.04 - 6.11*	*6.25*	*6.11*
Expected volatility	*95.00%*	*75% - 93%*	*88%*	*95%*
Expected dividend yield	*—%*	*—%*	*—%*	*—%*

The options granted had a $1.58 and $3.29 weighted average grant date fair value during the years ended July 31, 2023 and 2022, respectively.

Rafael Medical Devices Inc. Stock Options

The Rafael Medical Devices Inc. 2022 Equity Incentive Plan (the "RMD 2022 Plan") was created and adopted by the Company in May 2022. The RMD 2022 Plan allows for the issuance of up to 10,000 shares of Class B common stock which may be awarded in the form of incentive stock options or restricted shares.
In connection with the conversion of Rafael Medical Devices from a Delaware corporation to a Delaware limited liability company, Rafael Medical Devices adopted the Rafael Medical Devices, LLC 2023 Equity Incentive Plan (the "RMD 2023 Plan") in August 2023. The RMD 2023 Plan allows for issuance of up to 46,125 Class A Units (the "Units"). There are 4,734 shares were 2,247 Units available for issuance under the RMD 2022 2023 Plan as of July 31, 2023 July 31, 2024.

The fair value of Rafael Medical Devices, LLC common stock records compensation expense for stock-based awards based upon an assessment of the grant date fair value for options using the Black-Scholes model. The expected term was estimated for financial reporting purposes determined according to the simplified method, which is the average of the vesting tranche dates and the contractual term. Due to the lack of company specific historical and implied volatility data, the estimate of expected volatility is primarily based on the historical volatility of a valuation group of $4.02 per similar companies that are publicly traded. For these analyses, characteristics from comparable companies are selected, including enterprise value and position within the industry, and with historical share price information sufficient to meet the expected life of the share-based awards. The risk-free interest rate is determined by reference to the U.S. Treasury Constant Maturity Treasury rates with remaining maturities similar to the expected term of the options. Expected dividend yield is zero as of January 31, 2022. To determine Rafael Medical Devices, LLC has never paid cash dividends and does not expect to pay cash dividends in the foreseeable future.
The following table summarizes assumptions used to compute the fair value of Units granted under the common stock, RMD 2023 Plan during the Company first determined an enterprise value using accepted valuation approaches; adjusted these valuation approaches with relevant discounts and then allocated the equity value to the common stock and common stock equivalents on a fully diluted basis. The enterprise value was estimated using the generally accepted income approach. The income approach estimates enterprise value based on the estimated present value of future cash flows the business is expected to generate over its remaining life. The estimated present value is calculated using a discount rate reflective of the risks associated with an investment in a similar company in a similar industry or having a similar history of revenue growth. The Company then subtracted the net non-operating assets and applied a discount for lack of marketability to determine equity fair value. year ended July 31, 2024:

Risk-free interest rate	4.24-4.54%
Expected term (in years)	5-6.25
Expected volatility	113%
Expected dividend yield	—%

A summary of stock option activity for Rafael Medical Devices, Inc. LLC is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual **Term (in years)**	Aggregate Intrinsic Value (in thousands)	Number of **Options**	Weighted Average Exercise **Price**	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value **(in thousands)**
Outstanding at July 31, 2021	—	$ —	—	$ —				
Granted	*5,266*	*3.82*	*9.76*	—				
Outstanding at July 31, 2022	*5,266*	$ *3.82*	*9.76*	$ —	*5,266*	$ *3.82*	*9.76*	$ —
Granted	—	—	—	—	—	—	—	—
Outstanding at July 31, 2023	***5,266***	***$ 3.82***	***8.76***	**—**	*5,266*	$ *3.82*	*8.76*	$ —
Exercisable at July 31, 2023	***2,633***	***$ 3.82***	***8.76***	***$ —***				
Granted					*43,878*	*10.00*	*9.01*	—
Cancelled / Forfeited					*(5,266)*	*3.82*	—	—
Outstanding at July 31, 2024					***43,878***	***$ 10.00***	***9.01***	***$ —***
Exercisable at July 31, 2024					***11,886***	***$ 10.00***	***9.01***	***$ —***

The weighted average grant date fair value per unit for the RMD option grants during the year ended July 31, 2024 was $8.50. At July 31, 2024, the total unrecognized compensation related to stock option awards granted was $193 thousand, which the Company expects to recognize over a weighted average period of approximately 3.0 years.

Cornerstone Stock Options

Cornerstone has outstanding stock options and non-qualified options to purchase Cornerstone's common stock which were granted under Cornerstone's 2009 and 2018 Stock Incentive Plans (the "Plans"), as well as additional options issued during a prior capital raise.

At July 31, 2023 July 31, 2024, there were 1,004,341 options outstanding granted under the Plans that are unrecognized compensation costs related to non-vested stock vested with a weighted average exercise price of $24.17 per share and a weighted average remaining contractual term of 4.4 years. The fair value of outstanding options of $5 thousand, which are expected granted under the Plans assumed during the Cornerstone Acquisition were determined to be recognized over de minimis.

In connection with Cornerstone's 2003 common stock offerings, Cornerstone entered into an option agreement with an individual in connection with identifying investors. The option agreement grants the next 1.44 years. right to purchase an option (a "Purchase Option") to purchase 472,000 Class A Options ("Class A Options"), which allows the purchase of 0.25 shares of common stock for each Class A Option at $11.00 per share. In order to secure this Class A Option, a Purchase Option must initially be purchased for $.005 per potential share of Class A options. Upon exercise of each Class A Option, a right is granted to one Class B Option ("Class B Options"), which allow the purchase of 0.25 shares of common stock for each Class B Option at $12.50 per share. The expiration date of the Class A Options is the later of October 29, 2005 or six months from the date the Company's shares become publicly traded. The Class B Options expire 180 days from the exercise of the Class A Options. In 2003, 625,000 options (the "Cornerstone Common Options") were granted with an exercise price of $11.00 per share to a 2003 investor. These Cornerstone Common Options are set to expire 180 days following the closing of an IPO, or from the date Cornerstone's shares become publicly traded. The fair value of the Class A Options, Class B Options, and Cornerstone Common Options assumed during the Cornerstone Acquisition were determined to be de minimis.

As part of the Cornerstone Restructuring, as detailed in Note 3, Cornerstone increased the available reserve of Cornerstone Common Stock for grant to employees, consultants and other service providers to approximately 10% of Cornerstone's capital stock following the Cornerstone Restructuring, the Mandatory Common Conversion and the Reverse Stock Split (the "Reserve Increase") but prior to the issuance of the RPF 6% Top Up Shares or any shares to the holders of the Remaining Series C Convertible Notes after the Closing.

Restricted Stock

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.

In January 2022, the Company granted 33,360 restricted shares of Class B common stock to non-employee directors, 18,336 of which were granted under the 2018 Equity Incentive Plan, and 15,024 of which were granted under the 2021 Plan. The restricted shares vested immediately on the grant date. The share based share-based compensation cost was approximately $151 thousand, which was included in general and administrative expense in the consolidated statement statements of operations and comprehensive loss.

On February 1, 2022, the Company issued 986,835 shares of Class B restricted stock to two members of the executive team. officers. Approximately 24% of the restricted shares vest vested in December 2022, with the remaining shares vesting ratably each quarter through December 2025.

On June 14, 2022, the Company issued 452,130 shares of Class B restricted stock to Howard S. Jonas.

In January 2023, the Company issued 120,019 shares of Class B restricted stock to certain members of its Board of Directors, and 100,000 shares of Class B restricted stock to its new Chief Financial Officer.

During January 2023, 296,759 shares of Class B restricted stock were cancelled or forfeited due to (i) the cancellation of 285,036 shares of restricted stock in connection with the departure of the Company's former Chief Financial Officer and (ii) the remaining shares forfeited upon the termination of certain employees of the Company.

In connection with Patrick Fabbio's January 27, 2023 departure as the Company's Chief Financial Officer, the Company and Mr. Fabbio entered into a Separation and General Release Agreement (the "Separation Agreement"), which provides, among other things, that the Company shall pay Mr. Fabbio severance in the amount of $307,913, which is included in selling, general and administrative expense on the consolidated statement of operations and comprehensive loss for the year ended July 31, 2023.

In connection with the termination of Mr. Fabbio's position as Chief Financial Officer of the Company, there was a material forfeiture of his Class B restricted shares and stock options resulting in a reversal of approximately $915 thousand in stock-based compensation expense for the year ended July 31, 2023 that was previously recorded to selling, general and administrative expense.

On August 28, 2023, the Company issued 111,408 shares of Class B restricted stock to Howard S. Jonas.
On October 25, 2023, the Company issued 135,000 shares of Class B restricted stock to employees of the Company.
On January 5, 2024, the Company issued 101,402 shares of Class B restricted stock to certain members of its Board of Directors.
On June 13, 2024, the Company issued 159,016 shares of Class B restricted stock to Howard S. Jonas.
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	Number of Non-vested **Shares**	Weighted Average Grant Date Fair Value
Outstanding at July 31, 2021	*1,007,975*	*$ 46.77*		
Granted	*1,533,311*	*4.24*		
Vested	*(90,608)*	*16.86*		
Cancelled / Forfeited	*(943,305)*	*(48.50)*		
Outstanding at July 31, 2022	*1,507,373*	*$ 4.22*	*1,507,373*	*$ 4.22*
Granted	*220,019*	*1.99*	*220,019*	*1.99*
Vested	*(745,867)*	*3.37*	*(745,867)*	*3.37*
Cancelled / Forfeited	*(296,759)*	*(5.10)*	*(296,759)*	*(5.10)*
Non-vested shares at July 31, 2023	*684,766*	*$ 4.04*		
Outstanding at July 31, 2023			*684,766*	*$ 4.04*
Granted			*506,826*	*1.75*
Vested			*(583,052)*	*3.15*
Non-vested shares at July 31, 2024			*608,540*	*$ 2.99*

At July 31, 2023 July 31, 2024, there was $1.8 million $0.8 million of total unrecognized compensation cost related to non-vested stock-based compensation arrangements, which is expected to be recognized over the next four years.

On November 21, 2021, Ameet Mallik resigned as Chief Executive Officer of the Company, effective January 31, 2022. In connection with his resignation, there was a material forfeiture of the former CEO's Class B restricted shares, resulting in a reversal of approximately $19.0 million in stock-based compensation expense that was previously recorded to selling, general and administrative expense. Additionally, pursuant to the terms of his employment agreement, the Company paid $5.0 million relating to his severance payout, which is included in selling, general and administrative expense on the consolidated statement of operations and comprehensive loss for the year ended July 31, 2022.
A summary of the stock-based compensation expense for the Company's equity incentive plans is presented below (in thousands):

	For the Year Ended July 31,		***For the Year Ended July 31,***	
	2023	***2022***	***2024***	***2023***
General and administrative	*$ 3,044*	*$ 17,270*	*$ 2,000*	*$ 3,044*
Research and development	*194*	*791*	*296*	*194*
Forfeiture of RSUs within general and administrative	*(931)*	*(18,978)*	*—*	*(931)*
Forfeiture of RSUs within research and development	*(119)*	*—*	*—*	*(119)*
Net stock-based compensation expense	*$ 2,188*	*$ (917)*	*$ 2,296*	*$ 2,188*

Securities Purchase Agreement

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

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

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

During fiscal 2021, IDT and Genie each exercised 43,649 warrants, resulting in a total of 87,298 shares of Class B common stock issued for proceeds of approximately $2 million.
On June 6, 2022, the Company's outstanding warrants to purchase 26,189 shares of common stock at an exercise price of $22.91 per share expired. There were no exercises As of warrants during the year ended July 31, 2022. At July 31, 2022 July 31, 2024, the Company had no outstanding warrants.

NOTE 21 26 – LEASES

The Company is the lessor of the Israeli property which is leased to tenants under net operating leases with a term expiration date within 2025. Lease income included on the consolidated statements of operations and comprehensive loss was $0.3 million $282 thousand and $0.3 million $279 thousand for the years ended July 31, 2023 July 31, 2024 and 2022, 2023, respectively. During the years ended July 31, 2023 July 31, 2024 and 2022, 2023, no real estate property taxes were included in rental income.

The future contractual minimum lease payments to be received (excluding operating expense reimbursements) by the Company as of July 31, 2023 July 31, 2024, under a non-cancellable operating leases which expire on various dates through 2025 lease are as follows:

Year ending July 31,	***Related Parties***	***Other***	***Total***	***Related Parties***	***Other***	***Total***
		(in thousands)			***(in thousands)***	
2024	*$ 77*	*$ —*	*$ 77*			
2025	*78*	*—*	*78*	*$ 78*	*$ —*	*$ 78*
Total Minimum Future Rental Income	*$ 155*	*$ —*	*$ 155*	*$ 78*	*$ —*	*$ 78*

A related party has the right to terminate the Israeli lease upon four months' notice.

NOTE 22 27 – SUBSEQUENT EVENTS

Issuance Agreement and Plan of Merger with Cyclo
On August 21, 2024, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement"), by and among: the Company; Tandem Therapeutics, Inc., a Nevada corporation and a wholly-owned subsidiary of the Company ("First Merger Sub"); Tandem Therapeutics, LLC, a Nevada limited liability company and a wholly-owned subsidiary of the Company ("Second Merger Sub" and together with First Merger Sub, the "Merger Subs"); and Cyclo. The Merger Agreement and the transactions contemplated thereby were unanimously approved by the Company and Cyclo's boards of directors (the "Boards"). The Merger Agreement also requires approval of Cyclo's stockholders (the "Cyclo Shareholder Vote") and the issuance of the Company's Class B Common Stock,
On August 28, 2023, $0.01 par value per share ("Rafael Class B Common Stock") in the Company granted 111,408 restricted Business Combination (as defined below) requires approval by the Company's stockholders (the "Rafael Shareholder Vote"). Upon such approvals and satisfaction or waiver of all other conditions set forth in the Merger Agreement and the effectiveness of a registration statement on Form S-4 to register the shares of Rafael Class B common stock of the Company to Howard Jonas, the Chairman of the Board and Executive Chairman and former Chief Executive Officer of the Company and Member of the Board of Cornerstone Pharmaceuticals, pursuant to his employment agreement.
Rafael Medical Devices, LLC outside party investment
During the fourth quarter of the year ended July 31, 2023, the Company received $825 thousand as a deposit from outside third party investors for the purchase of membership units Common Stock of Rafael Medical Devices, LLC. On August 1, 2023, to be issued in the Company received an additional $100 thousand and closed on Business Combination, as defined below, the sale of units in exchange of $925 thousand, whereby Business Combination will be consummated (the date upon which is referred to as the Company will now hold 53.4% (on a fully diluted basis) ownership interests in Rafael Medical Devices, LLC. As of July 31, 2023, the Company recorded the funds received within prepaid expenses and other current assets and other current liabilities within the consolidated balance sheets. "Closing Date").

The Business Combination

The Merger Agreement provides for, among other things, that at the First Effective Time (the "First Effective Time"), First Merger Sub will merge with and into Cyclo (the "First Merger"), First Merger Sub will cease to exist, and Cyclo will become a wholly-owned subsidiary of the Company. Immediately following the First Merger, Cyclo will merge with and into Second Merger Sub, with Second Merger Sub being the Surviving Entity of the subsequent merger (the "Second Merger" and together with the First Merger, the "Business Combination").

If the Business Combination is consummated, Rafael would become the primary beneficiary of Cyclo, a VIE that constitutes a business. In accordance with ASC 810, the initial consolidation of a VIE that is a business shall be accounted for as a business combination in accordance with the provisions in Topic 805.

Consideration to Cyclo Equity Holders in the Business Combination

At the First Effective Time: (i) any shares of Cyclo Capital Stock then held by Cyclo or in Cyclo's treasury immediately prior to the First Effective Time shall be canceled and retired and shall cease to exist, and no consideration shall be delivered in exchange therefor; (ii) any shares of Cyclo Capital Stock then held by Rafael immediately prior to the First Effective Time shall be canceled and retired and shall cease to exist, and no consideration shall be delivered in exchange therefor; (iii) except as provided in (i) and (ii) above, each share of Cyclo Common Stock issued and outstanding immediately prior to the First Effective Time shall cease to be an existing and issued share of Cyclo Common Stock, and shall be converted, by virtue of the First Merger and without any action on the part of the holders thereof, into the right to receive a number of validly issued, fully paid and nonassessable shares of Rafael Common Stock equal to the Exchange Ratio (as defined below). The shares of Rafael Common Stock to be issued upon conversion of the Cyclo Common Stock are referred to as the "Merger Consideration".

The "Exchange Ratio" means the quotient (rounded down to four decimal places) obtained by dividing (x) $0.95 by (y) the sum of the (A) Total Net Cash Amount, plus (B) Total Loan Amount, divided by the total number of shares of Rafael Capital Stock outstanding at the First Effective Time, including any shares of Rafael Capital Stock issuable upon exercise or conversion of outstanding securities of Rafael with exercise or conversion prices that are no greater than 150% of the then market price for the Rafael Class B common stock.

The "Total Net Cash Amount" is defined in the Merger Agreement as (a) the sum of the total of (i) cash, cash equivalents and marketable securities of Rafael as of the Closing Date; and (ii) Included Assets (as defined below), minus (b) the amount of Rafael's current liabilities (on an unconsolidated basis), including, without limitation, accounts payable and accrued expenses, as of the end of the last month immediately prior to the Closing Date, updated for material changes to such amounts following such date until the Closing Date, and determined in a manner consistent with the manner such liabilities were historically reflected in Rafael's financial statements.

The "Included Assets" is defined in the Merger Agreement as the appraised value of the real estate located at 5 Shlomo Levy Street, Har Hotzvim Jerusalem and the value of the Globis Capital Partners, L.P. holdings as of the latest calendar quarter ending prior to the First Effective Time. Total Loan Amount shall mean the outstanding principal amount of all amounts loaned by Rafael to Cyclo between June 11, 2024 and the Closing, including, without limitation, the Cyclo Convertible Notes, Cyclo Convertible Note III (as defined below) and Cyclo Convertible Note IV (as defined below), plus the accrued and unpaid interest thereon as of the date of the Closing.

The "Parent Capital Stock" (also referred to as "Rafael Capital Stock") is defined in the Merger Agreement as the Rafael Class B common stock, $0.01 par value per share, the Rafael Class A common stock, par value $0.01 per share, of Rafael and the Rafael preferred stock, $0.01 par value per share.

All compensatory options to purchase Cyclo common stock shall automatically convert into options to acquire, on substantially similar terms and conditions, an adjusted number of shares of Rafael Class B Common Stock, based upon the Exchange Ratio (rounded down to the nearest whole share), at an adjusted exercise price per share, based upon the Exchange Ratio (rounded up to the nearest whole cent).

Unless otherwise provided for in outstanding warrant agreements, all outstanding warrants to purchase Cyclo common stock (other than those held by Rafael which will be cancelled) will automatically be converted into warrants to purchase an adjusted number of shares of Rafael Class B Common Stock, based upon the Exchange Ratio, at an adjusted exercise price per share, based upon the Exchange Ratio. Certain Cyclo warrants have the right to elect to receive cash payment in lieu of receiving warrants to purchase Rafael Class B Common Stock.

For U.S. federal income tax purposes, the Business Combination is intended to qualify as a "reorganization" within the meaning of Section 368(a)(1) of the Internal Revenue Code of 1986, as amended.

No fractional shares of Rafael Class B Common Stock will be issued in connection with the Business Combination, and holders of Cyclo common stock who would otherwise be entitled to receive a fraction of a share of Rafael Class B Common Stock, shall, in lieu of any such fractional shares to which they would otherwise be entitled, receive the number of shares of Rafael Class B Common Stock to which such holder of Cyclo common stock would be entitled to receive aggregated and rounded up to the nearest whole share.

Cyclo Securities held by the Company

Cyclo's common stock and warrants held by the Company will be cancelled and retired and shall cease to exist upon consummation of the Business Combination.

The Cyclo Convertible Notes, Cyclo Convertible Note III (as defined below), Cyclo Convertible Note IV (as defined below) and Cyclo Convertible Note V (as defined below) will be forgiven at the closing of the Business Combination.

Representations and Warranties; Covenants

The Merger Agreement contains representations, warranties and covenants of each of the parties thereto that are customary for transactions of this type.

Under the Merger Agreement, (a) Cyclo has agreed, among other things, (i) to conduct its business in the ordinary course, and not to take certain actions without the consent of the Company, (ii) not to solicit or engage in discussions regarding any alternative acquisition proposal or other transaction similar to the Business Combination, (iii) seek approval of its stockholders to the Business Combination, and (iv) use reasonable best efforts to cause all conditions to the Business Combination to be satisfied and to consummate the Business Combination, and (b) the Company has agreed (i) not to take certain actions without the consent of Cyclo, (ii) use reasonable efforts to cause the shares of Rafael Class B Common Stock to be issued in the Business Combination to be listed on the New York Stock Exchange, (iii) create, register with the Securities and Exchange Commission ("SEC") and list on the New York Stock Exchange a class of warrants to be issued to certain holders of publicly-traded warrants to purchase Cyclo common stock, (iv) increase the number of shares available for grant under its equity plan to cover options to be issued to holders of Cyclo Options, (v) seek approval of its stockholders to the issuance of the shares of the Rafael Class B Common Stock in the Business Combination, and (vi) use reasonable best efforts to cause all conditions to the Business Combination to be satisfied and to consummate the Business Combination.

The Company has also agreed, so long as Cyclo is not in active discussions regarding an acquisition proposal, to fund Cyclo through the earlier of the consummation of the Business Combination or termination of the Merger Agreement in such amounts as may be necessary for Cyclo to operate its business and pay its debts and obligations as they become due, provided that Cyclo is being operated in a manner consistent with the terms of the Merger Agreement and the financial forecast previously shared with the Company (the "Pre-Closing Funding"). Following the closing, the Company will fund Cyclo's TransportNPC™ clinical trial to its 48-week interim analysis up to a maximum amount, when added to the Pre-Closing Funding, of $25 million.

The Merger Agreement places certain restrictions on the operation of Rafael's business prior to the closing of the Business Combination, and such restrictions, the waiver of which is subject to the consent of Cyclo, may prevent Rafael from making certain acquisitions, taking certain other specified actions or otherwise pursuing business opportunities during the pendency of the Business Combination that Rafael would have made, taken or pursued if these restrictions were not in place.

In addition, in connection with the closing of the Business Combination, the Company has agreed to appoint Markus W. Sieger, a current independent member of Cyclo's board of directors, to the Company's Board.

Lock-Up Agreements

The Merger Agreement provides that Cyclo's directors and their affiliates that will receive shares of Rafael Class B Common Stock pursuant to the Merger Agreement or upon exercise of Rafael options received upon conversion of Cyclo options in the Business Combination have each agreed to enter into a lock-up agreement which contains certain restrictions on transfer of such shares of Rafael Class B Common Stock for a period of the earlier of (a) six (6) months following closing of the Business Combination or (b) the date on which Rafael completes a liquidation, merger, share exchange, reorganization or other similar transaction that results in all of Rafael's stockholders having the right to exchange their Rafael Class B Common Stock for cash, securities or other property.

Voting Agreement

In connection with the entry into the Merger Agreement, Rafael and certain other holders of Cyclo common stock entered into voting agreements pursuant to which those holders have agreed to vote in favor of the Merger Agreement and the consummation of the Business Combination at any meeting of Cyclo's stockholders and take other actions in furtherance of the consummation of the Business Combination until the earlier of (i) the First Effective Time and (ii) the termination of the Merger Agreement (the "Voting Agreement").

Support Agreement

In connection with the entry into the Merger Agreement, Howard Jonas entered into a support agreement (the "Support Agreement") with Rafael and Cyclo, under which Mr. Jonas has agreed to vote all shares of Rafael capital stock over which he exercises voting control to approve the issuance of the Rafael Class B Common Stock to the stockholders of Cyclo as contemplated by the Merger Agreement.

Termination

The Merger Agreement may be terminated under certain customary and limited circumstances prior to closing of the Business Combination, including, but not limited to, (i) by the mutual written consent of the Company and Cyclo, (ii) by the Company, subject to certain exceptions, if any of the representations or warranties of Cyclo are not true and correct or if Cyclo fails to perform any of its covenants or agreements under the Merger Agreement (iii) by Cyclo, subject to certain exceptions, if any of the representations or warranties made by the Company are not true and correct or if the Company fails to perform any of its covenants or agreements under the Merger Agreement; (iv) by either the Company or Cyclo, if the Business Combination has not been consummated on or prior to November 30, 2024; provided, however, that, in the event that the SEC has not declared effective under the Securities Act of 1933, as amended (the "Securities Act") the Form S-4 by the date which is 45 calendar days prior to the End Date of November 30, 2024 pursuant to the Merger Agreement, then the End Date shall automatically be extended to December 31, 2024 (the "End Date"), unless the breach of any covenants or obligations under the Merger Agreement by the party seeking to terminate was the principal cause of the failure to consummate the transactions contemplated by the Merger Agreement; (v) by either the Company or Cyclo, if any governmental entity has issued an order or taken any other action permanently enjoining, restraining or otherwise prohibiting the transactions contemplated by the Merger Agreement and such order or other action has become final and non-appealable; (vi) by either the Company or Cyclo, if the required approvals by the stockholders of the Company and Cyclo have not been obtained; and (vii) by the Company, if Cyclo's Board (or a committee thereof) makes a Cyclo Adverse Change Recommendation, as defined in the Merger Agreement. A "Cyclo Adverse Change Recommendation" means during the pre-closing Period, neither Cyclo's board nor any committee thereof shall (i)(A) withdraw, withhold, amend or qualify or modify, in each case, in a manner adverse to Rafael, or publicly propose to withdraw, withhold, amend or qualify or modify, in each case, in a manner adverse to Rafael, Cyclo's board recommendation, (B) fail to include Cyclo's board recommendation in the joint proxy statement/prospectus, (C) fail to publicly reaffirm Cyclo's board recommendation within ten (10) business days after Rafael so requests in writing (it being understood that the Rafael shall only be entitled to make up to two (2) such reaffirmation requests), (D) approve, recommend or declare advisable, or publicly propose to approve, recommend or declare advisable, any acquisition proposal other than from Rafael and Rafael's affiliates or (E) if any tender offer or exchange offer is commenced for equity securities of Cyclo, fail to recommend against such tender offer or exchange offer by the earlier of (1) the tenth (10th) business day after the commencement of such tender offer or exchange offer and (2) the third (3rd) business day prior to Cyclo's stockholders meeting other than a "stop, look and listen" communication pursuant to Rule 14d-9(f) under the Exchange Act.

If the Business Combination is validly terminated in accordance with the Merger Agreement, then either of Rafael or Cyclo shall reimburse the terminating party for their reasonable documented out-of-pocket expenses, including all fees and expenses of counsel, financial advisors and accountants, actually incurred in connection with the Merger Agreement, in an amount not to exceed $250,000 in cash, or if Rafael terminates the Business Combination in the event of a Cyclo Adverse Change Recommendation, Cyclo will promptly pay to Rafael an amount equal to $400,000 in cash (the "Company Termination Fee").

The Business Combination is expected to close in the fourth calendar quarter of 2024, following the receipt of the required approvals by Rafael and Cyclo stockholders and the fulfillment of other customary closing conditions.

RAFAEL HOLDINGS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Second Amended and Restated Note Purchase Agreement

On August 21, 2024, Rafael entered into a Second Amended and Restated Note Purchase Agreement with Cyclo, pursuant to which Cyclo issued and sold a convertible promissory note in the principal amount of $3 million to Rafael for $3 million (the "Cyclo Convertible Note III") in cash. The Cyclo Convertible Note III matures on December 21, 2024 and bears interest at a rate of 5% per annum, payable upon maturity. The principal amount of the Cyclo Convertible Note III is convertible into shares of Cyclo's common stock at the option of Rafael (provided, however, that Rafael may not elect to convert the convertible note (or prior convertible notes) issued by Cyclo to Rafael in connection with previous loans if, following such conversion, Rafael will beneficially own more than 49.9% of Cyclo's common stock); and automatically on certain other events.

Third Amended and Restated Note Purchase Agreement

On September 9, 2024, Rafael entered into a Third Amended and Restated Note Purchase Agreement with Cyclo, pursuant to which Cyclo issued and sold a convertible promissory note in the principal amount of $3 million (the "Cyclo Convertible Note IV") to Rafael for $3 million in cash. The Cyclo Convertible Note IV matures on December 21, 2024 and bears interest at a rate of 5% per annum, payable upon maturity. The principal amount of the Cyclo Convertible Note IV is convertible into shares of Cyclo's common stock at the option of Rafael (provided, however, that Rafael may not elect to convert the convertible note (or prior convertible notes) issued by Cyclo to Rafael in connection with previous loans if, following such conversion, Rafael will beneficially own more than 49.9% of Cyclo's common stock); and automatically on certain other events.

Fourth Amended and Restated Note Purchase Agreement

On October 8, 2024, Rafael entered into a Fourth Amended and Restated Note Purchase Agreement with Cyclo, pursuant to which Cyclo issued and sold a convertible promissory note in the principal amount of $3 million (the "Cyclo Convertible Note V") to Rafael for $3 million in cash. The Cyclo Convertible Note V matures on December 21, 2024 and bears interest at a rate of 5% per annum, payable upon maturity. The principal amount of the Cyclo Convertible Note V is convertible into shares of Cyclo Common Stock at the option of Rafael (provided, however, that Rafael may not elect to convert the convertible note (or prior convertible notes issued by Cyclo to Rafael in connection with previous loans if, following such conversion, Rafael will beneficially own more than 49.9% of Cyclo Common Stock); and automatically on certain other events.

Also on October 8, 2024, the maturity dates of the Cyclo Convertible Note I and the Cyclo Convertible Note II were amended to be December 21, 2024.

Exhibit 4.2

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934

Our authorized capital stock consists of (i) 35 million shares of Class A common stock, (ii) 200 million shares of Class B common stock, and (iii) 10 million shares of Preferred Stock.

The following description of our classes of authorized stock does not purport to be complete and is subject to and qualified in its entirety by reference to our charter and bylaws, copies of which are filed as exhibits to the Annual Report on Form 10-K to which this Exhibit 4.2 is a part.

Class A Common Stock

Holders of shares of our Class A common stock are entitled to three votes for each share on all matters to be voted on by the stockholders. Holders of our Class A common stock are entitled to share ratably in dividends, if any, as may be declared from time to time by the Board of Directors in its discretion from funds legally available therefor. Each share of our Class A common stock may be converted, at any time and at the option of the holder, and automatically converts upon transfers to unaffiliated parties, into one fully paid and non-assessable share of our Class B common stock.

As of October 27, 2023 November 5, 2024, there were 787,163 of our shares of Class A common stock outstanding.

Class B Common Stock

Holders of shares of our Class B common stock are entitled to one tenth of one vote for each share on all matters to be voted on by the stockholders. Holders of our Class B common stock are entitled to share ratably in dividends, if any, as may be declared from time to time by the Board of Directors in its discretion from funds legally available therefor.

As of October 27, 2023 November 5, 2024, there were 23,719,472 23,886,987 shares of Class B common stock outstanding.

Preferred Stock

The Board of Directors has the authority to fix the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by the stockholders.

As of October 27, 2023 November 5, 2024, there were no shares of our preferred stock were outstanding.

Anti-Takeover Effects of Our Charter and By-Laws

Some provisions of Delaware law and our Certificate of Incorporation and By-Laws could make the following more difficult:

- acquisition of us by means of a tender offer;
- acquisition of us by means of a proxy contest or otherwise; or
- removal of our incumbent officers and directors.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions also are designed to encourage persons seeking to acquire control of us to first negotiate with our Board of Directors. We believe that the benefits of increased protection give us the potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us and outweigh the disadvantages of discouraging those proposals because negotiation of them could result in an improvement of their terms.

Certificate of Incorporation; By-Laws

Our Certificate of Incorporation and By-Laws contain provisions that could make more difficult the acquisition of us by means of a tender offer, a proxy contest or otherwise. These provisions are summarized below.

Undesignated Preferred Stock. The authorization of our undesignated preferred stock makes it possible for our Board of Directors to issue our preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes of control of our management.

Size of Board and Vacancies.Our Certificate of Incorporation provides that the number of directors on our Board of Directors will be between three and seventeen. Newly created directorships resulting from any increase in our authorized number of directors or any vacancies in our Board of Directors resulting from death, resignation, retirement, disqualification, removal from office or other cause will be filled solely by the vote of our remaining directors in office.

Stockholder Meetings. Under our By-Laws, only our (i) Chairman of the Board, (ii) Executive Chairman, (iii) Chief Executive Officer, (iv) President, (v) Corporate Secretary, or (vi) any Assistant Secretary may call special meetings of our stockholders and shall be called by any such officer at the request in writing of a majority of our Board of Directors or at the request in writing of stockholders owning our issued and outstanding capital stock representing not less than a majority of the voting power of all our issued and outstanding capital stock.

Exhibit 10.4

November 16, 2023
Dear Dr. Goldberg;
It is our pleasure to offer you a position at Rafael Holdings, Inc. and or its subsidiaries ("Rafael" or the "Company"). This letter agreement (the "Letter Agreement") outlines the terms of your employment at the Company as follows:

1. Position and Duties:

You will serve as Chief Medical Officer (the "Position"), reporting to the CEO or to such other person as designated by the Company from time to time (in either case, as relevant, your "Supervisor"). In this Position you will oversee all aspects of the medical facets of the Company's operations and its subsidiaries, affiliates and entities in which the Company holds a significant stake. This is a full-time position for which you agree to devote one hundred percent of your working hours. You may work at the Company's Newark, NJ headquarters or work from home on a regular basis but in no event less than three days in the office every other week. You will travel for purposes of Company business, in accordance with the Company's needs, as such needs are determined by Supervisor.

2. Term:

Your employment at the Company will commence on November 20, 2023 (the "Start Date"). Please note that your employment shall be at-will and shall not be for any set or fixed period of time, and shall continue until terminated by either you or the Company.

3. Compensation:

During the Term, you will be compensated at an annual base salary rate of $425,000 (the "Base Salary"), which will be paid to you on a prorated basis less payroll deductions and required withholdings, in accordance with the Company's standard payroll procedures. Your position is classified as exempt for purposes of relevant wage-hour law and therefore you will not be entitled to overtime pay.
In addition to the Base Salary, you will also be eligible for an annual discretionary bonus in an amount up to 40% of your Base Salary (prorated for your initial year of employment), your entitlement to which and any amount thereof to be determined in the sole and absolute discretion of the Company paid out based upon the achievement of personal and corporate objectives attainment.

4. Equity:

Subject to the approval of the Compensation Committee of the Board of Directors of the Company you will be entitled to an initial grant of employee stock options to purchase 250,000 shares of Class B common stock (the "Options"). The Options shall be submitted for approval at the Company's next regularly scheduled quarterly Compensation Committee Meeting of the Board of Directors of the Company held post your Start Date, and if approved, granted within thirty (30) days thereafter. The vesting schedule shall be as follows: Options with respect to twenty-five percent (25%) of the underlying shares shall vest on the first anniversary of the grant date and additional Options with respect to twenty-five (25%) (in each case, rounded to a whole number of shares) of the underlying shares shall vest on each twelve-month anniversary of the first anniversary, so that all Options shall vest by the fourth anniversary of the grant date. The terms and conditions of the grant of the Options shall be as set forth in the Company's 2018 Stock Option and Incentive Plan, as amended from time to time (the "Plan") and the related grant agreement and related terms as required by the Company.

All unvested Options shall terminate if your full-time employment with the Company shall cease for any reason.
You will be eligible to receive additional equity grants at the sole discretion of the Compensation Committee of the Board.

5. Paid Time Off and Benefits:

In addition to Company-designated paid holidays, each calendar year you shall be entitled to take paid time off in accordance with the Company's applicable policies, as may be updated from time to time, and applicable law.
As a full-time employee of the Company, you will be eligible for health insurance coverage and other employee benefits, in each case as available to similarly situated employees, in accordance with the relevant plans, as such plans are adopted by the Company.
You shall also be entitled to reimbursement for pre-approved business expenses incurred by you in the course of your performance of your duties, as per Company policy, provided that you submit to the Company applicable invoices and other documentation, in form and in substance in accordance with Company policy.

6. Company Property:

During the Term, the Company may provide you with the benefit of using Company property, such as, but not limited to, a Company-provided laptop. You are obligated to use such Company property in accordance with Company guidelines, and to return any such property to the Company upon the Company's request, but in any case, upon the termination of your employment, regardless of the reason for such termination.

7. Restrictive Covenants:

As a condition of your employment at the Company, you are obligated to sign and comply with the terms set forth in the Non-Disclosure and Non-Competition Agreement attached to this Letter Agreement as Schedule A (the "NDNC").

8. Governing Law and Agreements:

During the period of your employment at the Company, you will be expected to abide by all policies of the Company, as established from time to time. The terms of your employment, as well as your post-employment obligations, will be governed by the terms of this Letter Agreement, the NDNC, and applicable law. It is agreed that the terms of this Letter Agreement (including any attachments hereto) constitute the entire understanding between you and the Company regarding the subject matter hereof and supersede any previous understanding or agreement (whether oral or written) between you and the Company, and/or the Company's management.

The Company shall have the right to assign its rights and obligations under this Letter Agreement to any individual, entity, corporation, or partnership that succeeds to all or a portion of the relevant business or assets of the Company. This Letter Agreement is personal to you, and you may not assign your rights and obligations under this Letter Agreement to any third party.

By your signature below, you represent that you are not bound by any agreement, whether oral or written, with a third party, where such agreement would in any way limit your ability to perform your obligations under this Letter Agreement, and you agree that at no time during your employment with the Company will you undertake responsibilities or obligations that will present a conflict of interest with, or limit your ability to fulfil the duties of, your position at the Company.

9. Notices:

All notices and other communications under this Letter Agreement shall be in writing and shall be given by hand, by email, or by first class mail, certified or registered with return receipt requested, and shall be deemed to have been duly given three (3) days after mailing, twenty-four (24) hours after transmission of an email, or immediately upon hand delivery or explicit acknowledgement of receipt.

10. Section 409A of the Internal Revenue Code of 1986 as amended:

You and the Company hereby affirm that with respect to any and all payments and benefits under this Letter Agreement, the intent is that such payments and benefits either: (i) do not constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Internal Revenue Code ("Section 409A"), and therefore are exempt from Section 409A, (ii) are subject to a "substantial risk of forfeiture" and are exempt from Section 409A under the "short−term deferral rule" set forth in Treasury Regulation §1.409A−1(b)(4), or (iii) are in compliance with the terms of 409A. In any event, you and the Company further confirm that they intend to have all provisions of this Letter Agreement construed, interpreted and administered in a manner consistent with the requirements for avoiding taxes or penalties under Section 409A. By way of example, and not limitation, solely for purposes of determining the time and form of payments, which are subject to Section 409A, due you under this Letter Agreement in connection with your termination of employment with the Company, you shall not be deemed to have incurred a termination of employment unless and until you shall incur a "separation from service" within the meaning of Section 409A. Each amount or installment to be paid or benefit to be provided under this Letter Agreement shall be construed as a separate and distinct payment for purposes of Section 409A. Without limiting the foregoing and notwithstanding anything contained herein to the contrary, to the extent required to avoid accelerated taxation and/or tax penalties under Section 409A, amounts that would otherwise be payable and benefits that would otherwise be provided pursuant to this Letter Agreement or any other arrangement between you and the Company during the six (6) month period immediately following your separation from service shall instead be paid on the first business day after the date that is six (6) months following your separation from service (or, if earlier, your date of death). To the extent required to avoid accelerated taxation and/or tax penalties under Section 409A, amounts reimbursable to you under this Letter Agreement shall be paid to you on or before the last day of the year following the year in which the expense was incurred and the amount of expenses eligible for reimbursement (and in-kind benefits provided to you) during one year may not affect amounts reimbursable or provided in any subsequent year. The Company makes no representation that any or all of the payments described in this Letter Agreement will be exempt from or comply with Section 409A and makes no undertaking to preclude Section 409A from applying to any such payment. You understand and agree that you shall be solely responsible for the payment of any taxes, penalties, interest or other expenses incurred by you on account of non- compliance with Section 409A.

11. Dispute Resolution:

In the event of a dispute between you and the Company arising out of or related to your employment with the Company (with the exception of disputes arising under the NDNC set forth in Schedule A and claims that pursuant to applicable law a party is prohibited from requiring another party to agree to submit to arbitration), you and the Company agree to exclusively settle such dispute by means of arbitration pursuant to the Federal Arbitration Act, administered by the American Arbitration Association ("AAA"), with such arbitration to take place in New Jersey or another mutually agreed upon location and to be conducted in accordance with the AAA's Employment Arbitration Rules. In such arbitration, a single arbitrator, appointed by the mutual agreement of you and the Company: (i) shall not amend or modify the terms of this Letter Agreement or of any Company policy, and (ii) shall render a decision within ten (10) business days from the later of closing statements or submission of post-hearing briefs by the parties. The arbitration award shall be final and binding, and any state or federal court shall have jurisdiction to enter a judgment on such award. It is understood that this requirement to arbitrate disputes means that by signing below, you and the Company specifically waive any right either party may have to a trial by jury in a court of law with respect to all claims and demands arising out of or related to your employment with the Company, including, without limitation, any rights you may assert under any federal, state, or local laws or regulations applicable to your employment with the Company (with the exception of disputes arising under the NDNC set forth in Schedule A and claims that pursuant to applicable law a party is prohibited from requiring another party to agree to submit to arbitration). For the avoidance of doubt, the parties acknowledge and agree that the existence of a claim by a party that is not subject to arbitration pursuant to this paragraph shall not impair the enforceability of this paragraph with respect to any other claim brought by that party. Notwithstanding the foregoing, nothing in this paragraph shall be interpreted to mean that you cannot file a charge with the Equal Employment Opportunity Commission and/or the National Labor Relations Board or any comparable federal, state, or local governmental agency.

The terms of this Letter Agreement are conditional upon your providing to the Company, within your first three (3) days of employment, a completed I-9 form accompanied by documentation that you are authorized to work in the United States, in accordance with applicable law. In addition, the Company reserves the right to conduct a background check, and your employment at the Company shall be conditional upon the results of such background check, in each case accordance with applicable law. If the Company determines not to have you commence employment based on the results of a background check (in accordance with all requirements of applicable law), your employment relationship with the Company shall be null and void, and the Company shall have no further obligations to you whatsoever.

We are excited to have you join us as a member of the Rafael team.

To accept this offer of employment and the terms and conditions hereof, please sign this Letter Agreement below and the attached Schedule A (and Exhibit A thereto) in the spaces provided and return all signed documents to David Polinsky at david.polinsky@rafaelholdings.com.

Very truly yours,

/s/ David Polinsky,

David Polinsky,
Chief Financial Officer

AGREED TO AND ACCEPTED BY:

/s/ John Goldberg, MD

John Goldberg, MD

DATE: 11/17/2023

Exhibit 21.01

DOMESTIC SUBSIDIARIES

Name
Altira Capital & Consulting, LLC (DE)
Barer Institute, Inc. (DE)
Broad-Atlantic Associates, LLC (DE)
CS Pharma Holdings, LLC (f/k/a Mort2Chai Partners, LLC) (DE)
Day Three Labs, Inc. (DE)
Farber Partners, LLC (DE)
Pharma Holdings, LLC (f/k/a IDT-Rafael Holdings, LLC(DE)
Rafael Holdings Realty, Inc. (f/k/a IDT Capital, Inc.) (DE)
Rafael Medical Devices, LLC (DE)
RP Finance LLC (DE)
Tandem Therapeutics, Inc. (NV)
Tandem Therapeutics, LLC (NV)
The Barer Institute, LLC (f/k/a Rafael Realty, LLC) (NJ)

FOREIGN SUBSIDIARIES

IDT R.E. Holdings Ltd. (Israel)
LipoMedix Pharmaceuticals Ltd. (Israel)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in registration statement No. 333-282558 on Form S-4, registration statement No. 333-274254 on Form S-8, registration statement No. 333-262754 on Form S-3/A, registration statement No. 333-256865 on Form S-3, registration statement No. 333-256565 on Form S-3 and registration statement No. 333-253455 on Form S-3 of Rafael Holdings, Inc. of our report dated October 30, 2023 November 6, 2024 related to our audits of the consolidated financial statements of Rafael Holdings, Inc. as of July 31, 2023 July 31, 2024 and 2022 2023 and for the years then ended, included in the Annual Report on Form 10-K of Rafael Holdings, Inc. for the year ended July 31, 2023 July 31, 2024.

/s/ CohnReznick LLP

New York, New York

October 30, 2023 November 6, 2024

Exhibit 31.01

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a)
AS ADOPTED PURSUANT TO SECTION ***Certification of Chief Executive Officer***
pursuant to Section 302 OF THE SARBANES-OXLEY ACT OF of the Sarbanes-Oxley Act of 2002

I, William Conkling, certify that:

I, William Conkling, certify that:

1. I have reviewed this Annual Report on Form 10-K of Rafael Holdings, Inc.;

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

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

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

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: October 30, 2023 November 6, 2024

/s/ William Conkling

William Conkling
Chief Executive Officer
William Conkling
Chief Executive Officer

Exhibit 31.02

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a)
AS ADOPTED PURSUANT TO SECTION ***Certification of Principal Financial Officer***
pursuant to Section 302 OF THE SARBANES-OXLEY ACT OF of the Sarbanes-Oxley Act of 2002

I, David Polinsky, certify that:

1. I have reviewed this Annual Report on Form 10-K of Rafael Holdings, Inc.;

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

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

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

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: October 30, 2023 November 6, 2024

/s/ David Polinsky

David Polinsky
Chief Financial Officer
David Polinsky
Chief Financial Officer

Exhibit 32.01

CERTIFICATION PURSUANT TO RAFAEL HOLDINGS, INC.
Certification Pursuant to
18 U.S.C. SECTION Section 1350

(AS ADOPTED PURSUANT TO SECTION as Adopted Pursuant to Section 906 OF THE SARBANES-OXLEY ACT OF of the Sarbanes-Oxley Act Of 2002)

In connection with the Annual Report of Rafael Holdings, Inc. (the "Company") on Form 10-K for the annual period ended July 31, 2023 July 31, 2024 as filed with the Securities and Exchange Commission (the "Report"), I, William Conkling, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 30, 2023 November 6, 2024

/s/ William Conkling

William Conkling
Chief Executive Officer
William Conkling
Chief Executive Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Rafael Holdings, Inc. and will be retained by Rafael Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.02

CERTIFICATION PURSUANT TO RAFAEL HOLDINGS, INC.
Certification Pursuant to
18 U.S.C. SECTION Section 1350

(AS ADOPTED PURSUANT TO SECTION as Adopted Pursuant to Section 906 OF THE SARBANES-OXLEY ACT OF of the Sarbanes-Oxley Act Of 2002)

In connection with the Annual Report of Rafael Holdings, Inc. (the "Company") on Form 10-K for the annual period ended July 31, 2023 July 31, 2024 as filed with the Securities and Exchange Commission (the "Report"), I, David Polinsky, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 30, 2023 November 6, 2024

/s/ DavidDavd Polinsky

Davd Polinsky
Chief Financial Officer
David Polinsky
Chief Financial Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Rafael Holdings, Inc. and will be retained by Rafael Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

DISCLAIMER

THE INFORMATION CONTAINED IN THE REFINITIV CORPORATE DISCLOSURES DELTA REPORT™ IS A COMPARISON OF TWO FINANCIALS PERIODIC REPORTS. THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORT INCLUDING THE TEXT AND THE COMPARISON DATA AND TABLES. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED IN THIS REPORT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S ACTUAL SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

REFINITIV