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

FORM 20-F

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2024

OR

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

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report _____
For the transition period from _____ to_____

Commission file number 001-35773

RedHill Biopharma Ltd.
(Exact name of Registrant as specified in its charter)

N/A
(Translation of Registrant's name into English)

Israel
(Jurisdiction of incorporation or organization)

21 Ha'arba'a Street, Tel Aviv 6473921, Israel
(Address of principal executive offices)

Razi Ingber, Chief Financial Officer
21 Ha'arba'a Street, Tel Aviv 6473921, Israel
Tel: 972-3-541-3131; Fax: 972-3-541-3144
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing ten thousand (10,000) Ordinary Shares [1]	RDHL	NASDAQ Capital Market
Ordinary Shares, par value NIS 0.01 per share [2]		

(1) Evidenced by American Depositary Receipts.
(2) Not traded on the Nasdaq Capital Market, but listed above in connection with the listing of the American Depositary Shares.

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 12,899,831,000 Ordinary Shares

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

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, or an emerging growth company. See definition of "large accelerated filer ," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated filer ☐ **Accelerated filer ☐** **Non-accelerated filer ☒**
Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, 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. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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 which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐

International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

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Unless the context otherwise requires, all references to "RedHill," "we," "us," "our," the "Company" and similar designations refer to RedHill Biopharma Ltd. and its wholly owned subsidiary, RedHill Biopharma Inc. ("RedHill U.S."). The term "including" means "including but not limited to", whether or not explicitly so stated. The term "NIS" refers to New Israeli Shekels, the lawful currency of the State of Israel, the terms "dollar", "US$", "$" or "U.S." refer to U.S. dollars, the lawful currency of the United States of America. Our functional and presentation currency is the U.S. dollar. Unless otherwise indicated, U.S. dollar amounts herein (other than amounts originally receivable or payable in dollars) have been translated for the convenience of the reader from the original NIS amounts at the representative rate of exchange as of April 8, 2025 ($1 = NIS 3.766). The dollar amounts presented should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated. Foreign currency transactions in currencies other than U.S. dollars are translated in this Annual Report (as defined below) into U.S. dollars using exchange rates in effect at the date of the transactions.

Unless otherwise indicated or the context requires, the term "therapeutic candidates" refers to investigational drug products that are still in development and have not been approved by the United States Food and Drug Administration ("FDA") or other relevant regulatory authority and the term "commercial products" means products approved by the FDA that we commercialize or promote from time to time.

Effective August 20, 2024, we effected a ratio change of the American Depositary Shares (ADSs) to our ordinary shares from the previous ratio of one (1) ADS representing four hundred (400) ordinary shares to a new ratio of one (1) ADS representing ten thousand (10,000) ordinary shares. The ratio change had the same effect as a one-for-twenty-five reverse ADS split. Unless otherwise indicated, ADSs and per ADS amounts in this Annual Report have been retroactively adjusted to reflect the changes in ratio for all periods presented.

FORWARD-LOOKING STATEMENTS

Some of the statements under the sections entitled "Item 3. Key Information – Risk Factors," "Item 4. Information on the Company," "Item 5. Operating and Financial Review and Prospects" and elsewhere in this Annual Report on Form 20-F (the "Annual Report") may include forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms, including "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, many of which are beyond the Company's control and cannot be predicted or quantified. In addition, the section of this Annual Report entitled, "Item 4. Information on the Company", contains information obtained from independent industry and other sources that we may not have independently validated. You should not put undue reliance on any forward-looking statements. Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements.

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

- the going concern reference in our financial statements and our ability to obtain additional financing or successfully conclude a strategic business transaction;
- our ability to regain and maintain compliance with the listing standards of the Nasdaq Capital Market ("Nasdaq");
- Our ability to close strategic business transactions;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;

- our ability to obtain additional financing;
- the commercialization and market acceptance of Talicia® and any future commercial products;
- our ability to generate sufficient revenues from Talicia® and any future commercial products, including obtaining commercial insurance and government reimbursement;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials, and to complete the development of such therapeutic candidates and obtain approval for marketing by the FDA or other regulatory authorities;
- our reliance on third parties to satisfactorily conduct key portions of our commercial operations, including manufacturing and other supply chain functions, market analysis services, safety monitoring, regulatory reporting and sales data analysis and the risk that those third parties may not perform such functions satisfactorily;
- our ability to maintain an appropriate sales and marketing infrastructure;
- our ability to establish and maintain corporate collaborations;
- that Talicia® or commercial products that we may commercialize or promote in the future may be withdrawn from the market by regulatory authorities and our need to comply with continuing laws, regulations and guidelines to maintain clearances and approvals for those products;
- our exposure to significant drug product liability claims;
- the initiation and completion of any postmarketing studies or trials;
- our ability to acquire products approved for marketing in the U.S. that achieve commercial success and to maintain our own marketing and commercialization capabilities;
- our estimates of the markets, their size, characteristics and their potential for Talicia® and any future commercial products and therapeutic candidates and our ability to serve those markets;
- the successful commercialization of products we in-license or acquire;
- our inability to enforce claims relating to a breach of a representation and warranty by a counterparty;
- the hiring and continued employment of executives, sales personnel, and contractors;
- our receipt and timing of regulatory clarity and approvals for Talicia® and any future commercial products and therapeutic candidates, and the timing of other regulatory filings and approvals;
- the initiation, timing, progress, and results of our research, development, manufacturing, preclinical studies, clinical trials, and other commercial efforts and therapeutic candidate development, as well as the extent and number of additional studies that we may be required to conduct;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials;
- our ability to develop or obtain approval for RHB-104/RHB-204 in Crohn's may be adversely impacted if a validated lab test for MAP will not become available;
- our reliance on third parties to conduct key portions of our clinical trials, including data management services and the risk that those third parties may not perform such functions satisfactorily;

- our reliance on third parties to manufacture and supply our therapeutic candidates and their respective active pharmaceutical ingredients with the requisite quality and manufacturing standards in sufficient quantities and within the required timeframes and at an acceptable cost;
- the research, manufacturing, clinical development, commercialization, and market acceptance of our therapeutic candidates;
- the interpretation of the properties and characteristics of Talicia® and any future commercial products or therapeutic candidates and of the results obtained in research, preclinical studies or clinical trials;
- the implementation of our business model, strategic plans for our business, commercial products, and therapeutic candidates;
- the impact of other companies and technologies that compete with us within our industry;
- the scope of protection we are able to establish and maintain for intellectual property rights covering Talicia® and any future commercial products and therapeutic candidates, including from existing or future claims of infringement, and our ability to operate our business without infringing or violating the intellectual property rights of others;
- parties from whom we license or acquire our intellectual property defaulting in their obligations toward us;
- the failure by a licensor or a partner of ours to meet their respective obligations under our acquisition, in-license or other development or commercialization agreements or renegotiate the obligations under such agreements, or if other events occur that are not within our control, such as bankruptcy of a licensor or a partner;
- our reliance on the actions of third parties, including sublicensors and their other sublicensees, to maintain our rights under our in-licenses which are sublicenses;
- the effect of a potential occurrence of patients suffering serious adverse events using investigative drugs under our Expanded Access Program;
- our ability to implement network systems and controls that are effective at preventing cyber-attacks, malware intrusions, malicious viruses and ransomware threats;
- the impact on our business of the political and security situation in Israel, the U.S. and other places in which we operate; and
- other factors discussed in this Annual Report.

We have included important factors in the cautionary statements included in this Annual Report, particularly in “Item 3. Key Information – Risk Factors”, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. No forward-looking statement is a guarantee of future performance.

You should read this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements in this Annual Report represent our views as of the date of this Annual Report. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

Summary of Risk Factors

The following is a summary of some of the principal risks we face. The list below is not exhaustive, and investors should read the "Risk Factors" section included in "Item 3. Key Information – Risk Factors" in full.

- Our financial statements include a going concern reference. We will need to raise significant additional capital to finance our losses and negative cash flows from operations, and if we were to fail to raise sufficient capital on favorable terms and/or successfully conclude a strategic business transaction, we may need to cease operations. Management has substantial doubt about our ability to continue as a going concern.

- Our failure to regain and maintain compliance with Nasdaq's continued listing requirements could result in the delisting of the ADSs.

- We are actively pursuing and in discussions with multiple parties regarding strategic business transactions. There is no assurance that our discussions will result in any strategic business transactions.

- Our current working capital is not sufficient to commercialize Talicia® or to complete the research and development with respect to any or all of our therapeutic candidates. We will need to raise significant additional capital to achieve our strategic objectives and to execute our business plans. Our failure to raise sufficient capital or on favorable terms would significantly impair our ability to fund the commercialization of Talicia®, the further development of our therapeutic candidates, or the products we may commercialize or promote in the future, attract development or commercial partners or retain key personnel, and to fund operations.

- We may not successfully continue the commercialization of Talicia®.

- If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of the ADSs.

- If we or our future development or commercialization partners are unable to obtain or maintain the FDA or other foreign regulatory clearance and approval for Talicia® and any future commercial products or therapeutic candidates, we or our commercialization partners will be unable to commercialize Talicia® or future products or therapeutic candidates, upon approval, if any.

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should carefully consider the risks we describe below, in addition to the other information set forth elsewhere in this Annual Report, including our financial statements and the related notes beginning on page F-1, before you decide to buy our securities. The risks and uncertainties described below in this Annual Report for the year ended December 31, 2024, are not the only risks facing us. We may face additional risks and uncertainties not currently known to us or that we currently deem to be immaterial. Any of the risks described below or incorporated by reference in this Form 20-F, and any such additional risks, could materially adversely affect our reputation, business, financial condition or results of operations. In such case, you may lose all or part of your original investment.

Risks Related to Our Business

Our financial statements include a going concern reference. We will need to raise significant additional capital to finance our losses and negative cash flows from operations, and if we were to fail to raise sufficient capital on favorable terms and/or successfully conclude a strategic business transaction, we may need to cease operations. Management has substantial doubt about our ability to continue as a going concern.

Our consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. During the year ended December 31, 2024, our net cash used in operating activities was $9.4 million leaving a cash balance of $4.8 million as of December 31, 2024. Because we do not have sufficient resources to fund our operations for the next twelve months from the date of this filing, management has substantial doubt about our ability to continue as a going concern. We have determined that the Company's available cash on December 31, 2024, together with proceeds from our at-the-market offering facility with H.C. Wainwright & Co., LLC in the first quarter of 2025, are not sufficient to fund our operations and satisfy our payment obligations for a period exceeding one year from the date of this Annual Report. Our operational costs include payment of pre-closing liabilities relating to Movantik®, which our subsidiary, RedHill U.S., retained under our agreement with HCR Collateral Management, LLC ("HCRM") for the extinguishment of all our debt obligations under the Credit Agreement, dated February 23, 2020, as amended (the "Credit Agreement") in exchange for the transfer of our rights in Movantik® to an affiliate of HCRM. As of December 31, 2024, estimated remaining pre-closing liabilities relating to Movantik® were approximately $3.0 million, substantially all of which are included in the allowance for deductions from revenue balance in the consolidated statements of financial position for the year ended December 31, 2024 included elsewhere in this Annual Report. In addition, we assumed obligations under the Global Termination Agreement with Movantik Acquisition Co., Valinor Pharma, LLC, and HCR Redhill SPV, LLC (the "Global Termination Agreement"). As of December 31, 2024, our estimated obligations relating to this agreement were $6.7 million, which are included in accrued expenses and other current liabilities in the consolidated statements of financial position for the year ended December 31, 2024 included elsewhere in this Annual Report. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources – Term Loan Facility". The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should we be unable to continue as a going concern.

We will need to raise significant additional capital to finance our losses and negative cash flows from operations and continue as a going concern. We are also actively pursuing and in discussions with multiple parties regarding strategic business transactions. If we were to fail to raise sufficient capital or on favorable terms or successfully conclude a strategic business transaction, we may need to cease operations. There are no assurances that we will be able to raise significant additional capital on terms favorable to us or at all, particularly given the current difficult conditions in the capital markets and very low market capitalization which makes it more difficult to raise significant amounts of capital. If we are unsuccessful in achieving sufficient commercial sales of our products or in raising sufficient capital, or successfully concluding a strategic business transaction, we will need to reduce activities and curtail or cease operations.

In addition, our business plan and our ability to continue as a going concern is largely dependent on our ability to defer payments we owe to the following year. However, we do not currently have any formal payment plans in place and there can be no assurance that any counter-party to whom we owe payments will agree to such payment deferrals. Actual payment schedules could differ significantly and adversely from our current contemplated payment schedules, which may have a material adverse effect on our ability to continue to operate as a going concern.

We are actively pursuing and in discussions with multiple parties regarding strategic business transactions. There is no assurance that our discussions will result in any strategic business transactions.

We are actively pursuing and in discussions with multiple parties regarding strategic business transactions. The success of any such strategic business transactions is subject to various uncertainties, including but not limited to, market and other conditions, negotiations with potential buyers, regulatory approvals, and other factors beyond our control. There is no assurance that our discussions will result in any strategic business transactions. If we are unable to successfully complete strategic business transactions on favorable terms to us, or at all, our ability to strengthen our balance sheet and enhance our strategic focus could be impacted and could have a material adverse effect on our ability to continue to operate as a going concern.

Even if we are able to complete a strategic business transaction, any such strategic business transaction may require us to incur non-recurring or other charges, increase our expenditures, pose significant integration or implementation challenges or disrupt our management or business. These transactions could entail numerous operational and financial risks, including exposure to unknown liabilities, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and have a material adverse effect on our business, results of operations, financial condition and prospects. Conversely, any failure to enter any collaboration or other strategic transaction that would be beneficial to us could delay and make more expensive the development and potential commercialization of our therapeutic candidates and have a negative impact on the competitiveness of any therapeutic candidate that reaches market.

Following our 2023 sale of our rights to Movantik®, our revenue, business' size and scope, market share and opportunities in certain markets, and our ability to compete in certain markets and therapeutic categories was reduced. We may never achieve levels of revenue we achieved through Movantik®, which could have a material adverse effect on our ability to operate as a going concern.

Following the consummation of our sale of our rights to Movantik® in February 2023, our revenue generated from Movantik® sales was eliminated and our business' size and scope, market share and opportunities in certain markets, and our ability to compete in certain markets and therapeutic categories were substantially reduced. Our ability to realize any value from Movantik® beyond its price in an asset sale was permanently lost. Additionally, following the sale of our rights to Movantik®, we lost our primary revenue source and our ability to operate as a financially viable commercial business has been significantly more difficult. We also lost economies of scale in our commercial operations that we were able to benefit from by having Movantik® as a core commercial product. As a result, we have downsized our commercial operations and taken other steps to better align our expenses and revenues, which has adversely affected our ability to sell Talicia®. This could have a material adverse effect on our ability to continue to operate as a going concern. In addition, in the event we are not able to achieve sufficient levels of revenues, now that we no longer commercialize Movantik®, we may need to further downsize, or even shut down our commercial operations, which could cause us to incur additional costs and expenses, including severance expenses, and make it more difficult to sell commercial products in the future. See "Item 6. Directors, Senior Management and Employees – B. Compensation – Change in Control Retention Plan and Agreements; Severance Arrangements."

Our current working capital is not sufficient to commercialize Talicia® or to complete the research and development with respect to any or all of our therapeutic candidates. We will need to raise significant additional capital to achieve our strategic objectives and to execute our business plans. Our failure to raise sufficient capital or on favorable terms would significantly impair our ability to fund the commercialization of Talicia®, the further development of our therapeutic candidates, or the products we may commercialize or promote in the future, attract development or commercial partners or retain key personnel, and to fund operations.

As of December 31, 2024, we had cash, cash equivalents, short-term investments and restricted cash of approximately $4.8 million, and as of December 31, 2023, we had cash, cash equivalents and short-term investments of approximately $6.5 million, of which $0.8 million was held in the escrow account. We have funded our operations primarily through public and private offerings of our securities, strategic investments, our Credit Agreement with HCRM, and the Global Termination Agreement. We will need to raise significant additional capital to achieve our strategic objectives of commercializing Talicia® and other products that we may commercialize or promote in the future and acquiring, in-licensing and developing therapeutic candidates. We plan to fund our future operations through commercialization of Talicia®, out-licensing of our therapeutic candidates and commercialization of in-licensed or acquired products, and we will also need to raise significant additional capital through equity or debt financing or non-dilutive financing, including government grants. We are also actively pursuing and in discussions with multiple parties regarding strategic business transactions, which may provide us with additional capital although there is no guarantee that we will complete such a transaction on favorable terms to us, or at all, or that if we do complete such a transaction, it will result in the expected benefits to us. See –"We are actively pursuing and in discussions with multiple parties regarding strategic business transactions. There is no assurance that our discussions will result in any strategic business transactions." We are not yet certain of the financial impact of our commercialization activities, and the amounts we raise may not be sufficient to complete the research and development of all of our therapeutic candidates.

Our business is not yet profitable. As we plan to continue expending funds to commercialize Talicia®, out-license Talicia®, further develop our therapeutic candidates, acquire additional products and therapeutic candidates and expand our efforts in research and development, we will need to raise significant additional capital in the future through equity or debt financing, non-dilutive financing or pursuant to development or commercialization agreements with third parties with respect to particular therapeutic candidates and commercial products approved for sale in the U.S. However, we cannot be certain that we will be able to raise capital on commercially reasonable terms or at all, or that our actual cash requirements will not be greater than anticipated.

We may have difficulty raising needed capital or securing development or commercialization partners in the future as a result of, among other factors, present and future market conditions, the low trading volume of the ADSs, the very low market capitalization of our company which makes it more difficult to make large capital raises, limitations pursuant to General Instruction I.B.5 of Form F-3 and the resulting need to potentially have to raise capital via Form F-1, which may be less appealing to investors and less favorable to us, the need to potentially have to increase our authorized share capital in order to raise amounts sufficient to carry out our business plan, which would be subject to shareholder approval that may not be obtained, unsuccessful commercialization of Talicia® or products that we may commercialize or promote in the future, as well as the inherent business risks associated with our Company, Talicia®, products that we may commercialize or promote in the future and our therapeutic candidates. In addition, our ability to raise capital would be adversely affected if we are not able to regain and maintain compliance with Nasdaq's continued listing requirements. Any financing may also involve significant dilution to our shareholders. We have completed financings in the past which resulted in significant dilution to our shareholders, and we may complete additional financings in the future with similar dilutive effects to our shareholders. To the extent we are able to generate meaningful revenues from Talicia® and any future commercial products, we may still need to raise capital because the revenues from Talicia® and any future commercial products may not be sufficient to cover all of our operating expenses and may not be sufficient to cover our commercial operations expenses. However, the limitations noted above may make future financings difficult or impossible and force us to seek alternative sources of capital such as strategic transactions, licenses, and grants, all of which take a significant amount of time and may not yield the capital we need on favorable terms, if at all. In addition, global and local economic conditions may make it more difficult for us to raise needed capital or secure a development or commercialization partner in the future and may impact our liquidity. The healthcare industry faced a continued challenging market during 2024 and may continue to cause difficulties for healthcare companies to raise capital in the future. If we are unable to obtain sufficient future financing, we will need to reduce activities and curtail or cease operations.

We may not successfully continue the commercialization of Talicia®.

We may not successfully continue the commercialization of Talicia® and our products may not be, or continue to be, commercially successful for various reasons, including but not limited to:

- difficulty in large-scale manufacturing, including yield and quality, and in shipping product internationally;
- low market acceptance by physicians, healthcare payors, patients and the medical community as a result of lower demonstrated clinical safety or efficacy compared to products, prevalence, and severity of adverse side effects, or other potential disadvantages relative to alternative treatment methods;
- changes to the underlying dynamics of the markets for these products;
- infringement on proprietary rights of others for which we or third parties involved in the development or commercialization of our products or potential future therapeutic candidates have not received licenses;
- incompatibility with other marketed products;
- other potential advantages of alternative treatment methods and competitive forces or advancements that may make it more difficult for us to penetrate a particular market segment, if at all;
- ineffective marketing, sales, and distribution activities and support;
- lack of significant competitive advantages over other products on the market;
- lack of cost-effectiveness or unfavorable pricing compared to other alternatives available on the market;
- pressure from commercial payors and government agencies on gross to net margins;
- inability to generate sufficient revenues to sustain our business operations in accordance with our plan from the sale or marketing of a product;
- changes to product labels, indications or other relevant information that may trigger additional regulatory requirements that may have a direct or indirect impact on the commercialization of our products;
- our inability or unwillingness, for cost or other reasons, to commercialize Talicia® to the extent any are approved for commercialization at the time of any such collaboration issues;
- timing of market introduction of competitive products, including from generic competitors; and
- changes in any laws, regulations, or other relevant policies related to drug pricing or other marketing conditions and requirements that may directly or indirectly limit, restrict, or otherwise negatively impact our ability or success in marketing or commercializing.

Physicians, various other healthcare providers, patients, payors or the medical community, in general, may be unwilling to accept, utilize or recommend Talicia®. If we are unable, either on our own or through third parties, to manufacture, commercialize or market Talicia®, we may not achieve or continue to achieve market acceptance or generate meaningful revenues from Talicia®. In addition, in order to support our development product portfolio, we will need to achieve revenues from sales of Talicia® consistent with our business expectations, which may prove more difficult than currently expected. Our reputation, business, financial condition and results of operations may be materially adversely affected by any failure to meet such expectations. See " - We are actively pursuing and in discussions with multiple parties regarding strategic business transactions. There is no assurance that our discussions will result in any strategic business transactions."

If we are unable to successfully continue the commercialization of Talicia®, our business and results of operations will suffer.

We expect our future success will significantly depend upon our ability to successfully commercialize Talicia® in the U.S. or to find a commercialization partner to do so. In addition, there can be no guarantee that we will be able to establish our own manufacturing capabilities, including through third parties, in order to continue the successful commercialization of Talicia®. Our success depends on obtaining reimbursement to patients for our products and there is no guarantee we will be able to secure commercial or government coverage for any of our products. There is significant pressure within the U.S. healthcare reimbursement system to reduce costs of prescription drugs which could adversely affect us. In order to support our growing development product portfolio, we will need to achieve revenues from sales of Talicia® consistent with our business expectations, which may prove more difficult than currently expected. Our reputation, business, financial condition and results of operations may be materially adversely affected by any failure to meet such expectations. See " - We are actively pursuing and in discussions with multiple parties regarding strategic business transactions. There is no assurance that our discussions will result in any strategic business transactions."

Our management conducted an evaluation of the effectiveness of our internal control over financial reporting and concluded that our internal control over financial reporting was not effective as of December 31, 2024. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of the ADSs.

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. Our management is required to assess the effectiveness of our internal controls and procedures and disclose changes in these controls on an annual basis.

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 any applicable requirements of Section 404 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 the ADSs.

Our management conducted an evaluation of the effectiveness of our internal control over financial reporting and concluded that our internal control over financial reporting was not effective as of December 31, 2024. A material weakness in internal control over financial reporting was previously identified in 2022 and disclosed in our Annual Report on Form 20-F for the year ended December 31, 2022 and again in our Annual Report on Form 20-F for the year ended December 31, 2023 relating to lack of sufficient controls which impacted the calculation of allowance for deductions from revenues. We lacked enough financial reporting personnel with an appropriate level of knowledge, experience, and training commensurate with our financial reporting requirements. This control deficiency contributed to the fact that not all data and information available to us was taken into consideration when making the calculation. While we have implemented a remediation plan, as of December 31, 2024, we were not yet able to conclude that the material weakness had been fully remediated. We continue to monitor and assess our internal control environment, and no assurance can be given that significant deficiencies or other material weaknesses will not be identified in the future or that we will be able to remediate such significant deficiencies or other material weaknesses in a timely matter or at all.

Implementation of remediation measures requires validation and testing of the design and operating effectiveness of internal control over a sustained period of financial reporting prior to reaching a determination that the material weakness have been remediated. As we continue to validate and test our internal control over financial reporting, we may determine that additional measures or modifications to the remediation plan are necessary or appropriate. If the steps we take do not remediate the material weaknesses in a timely manner, there could continue to be a reasonable possibility that these control deficiencies or others could result in a material misstatement in our financial statements. Additionally, if significant deficiencies or other material weaknesses are identified in our internal control over financial reporting that we cannot remediate in a timely manner, investors and others may lose confidence in the reliability of our financial statements and the trading price of our securities and ability to obtain any necessary equity or debt financing could suffer. The material weaknesses will not be considered remediated until we have completed implementing the necessary controls and ensured their applicability.

We have made, and will continue to make, changes in these and other areas. In any event, the process of determining whether our existing internal controls are compliant with any applicable requirements under Section 404 and sufficiently effective has required and will continue to require the investment of substantial time and resources, including by our chief financial officer and other members of our senior management. As a result, this process may continue to divert internal resources and may take a significant amount of time and effort to complete. In addition, we cannot predict the outcome of this process and whether we will need to implement remedial actions in order to implement effective controls over financial reporting. The determination of whether or not our internal controls are sufficient and any remedial actions required could result in us incurring additional costs that we did not anticipate, including the hiring of outside consultants. We may also fail to complete our evaluation, testing and any required remediation needed to comply with any applicable requirements under Section 404 in a timely fashion. Irrespective of compliance with any applicable requirements under Section 404, any additional failure of our internal controls could have a material adverse effect on our stated results of operations and harm our reputation. As a result, we may experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes. If we are unable to implement any of the required changes to our internal control over financial reporting effectively or efficiently or are required to do so earlier than anticipated, it could adversely affect our operations, financial reporting or results of operations and could result in an adverse opinion on internal controls from our independent auditors.

Furthermore, if we are unable to certify that our internal control over financial reporting is effective and in compliance with any applicable requirements under Section 404, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or stock exchanges, and we could lose investor confidence in the accuracy and completeness of our financial reports, which could hurt our business, the price of the ADSs and our ability to access the capital markets.

We have a history of operating losses. We may continue to incur significant losses in the coming years.

From our incorporation in 2009 until establishment of our commercial presence in the U.S., we focused primarily on the development and acquisition of late-stage clinical therapeutic candidates, and since we established our commercial presence in the U.S., we have focused primarily on the acquisition and commercialization or promotion of products in the U.S. There is no assurance that we will be able to generate substantial positive cash flow or be profitable in the future.

We plan to further fund our future operations through commercialization and out-licensing of our therapeutic candidates, commercialization of in-licensed or acquired products and raising significant additional capital through equity or debt financing or through non-dilutive financing, including government grants. We are also actively pursuing and in discussions with multiple parties regarding strategic business transactions, which may provide us with additional capital although there is no guarantee that we will complete such a transaction on favorable terms to us, or at all, or that if we do complete such a transaction, it will result in the expected benefits to us. See –"We are actively pursuing and in discussions with multiple parties regarding strategic business transactions. There is no assurance that our discussions will result in any strategic business transactions." Our current cash resources are not sufficient to complete the research and development of any or all of our therapeutic candidates and to fully support our commercial operations until generation of sustainable positive cash flows. We expect that we will incur additional losses as we continue to focus our resources on advancing the development of our therapeutic candidates, as well as advancing our commercial operations, based on a prioritized plan that may result in negative cash flows from operating activities.

Most of our therapeutic candidates are in late-stage clinical development. All of our therapeutic candidates will likely require successful additional clinical and non-clinical trials before we can obtain the regulatory approvals in order to initiate commercial sales of them, if at all. We have incurred losses since inception, principally as a result of research and development, selling, marketing, and business development, and general and administrative expenses in support of our operations. We experienced net loss of approximately $8.3 million in 2024, net income of approximately $23.9 million in 2023, and net loss of approximately $71.7 million in 2022. As of December 31, 2024, we had an accumulated deficit of approximately $414.8 million. Our ability to generate sufficient revenues to sustain our business operations in accordance with our plan and to achieve profitability depends mainly upon our ability, alone and/or with others, to successfully commercialize or promote Talicia® and products that we may acquire or for which we may acquire commercialization rights in the future, develop our therapeutic candidates, obtain the required regulatory approvals in various territories. We may be unable to achieve any or all of these goals with regard to Talicia®, our therapeutic candidates or products we may commercialize or promote in the future. As a result, we may never achieve sufficient revenues to sustain our business operations in accordance with our plan or be profitable.

Our capital requirements are subject to numerous risks.

Our long-term capital requirements are expected to depend on many potential factors, including but not limited to:

- whether we are able to complete a strategic business transaction, including a potential divestment of certain of our assets and/or our commercial operations, on favorable terms to us, or at all;
- the progress, success, and cost of our clinical and non-clinical trials and research and development programs, including manufacturing;
- the number and type of commercial products we commercialize;
- our ability to successfully commercialize Talicia® and products that we may commercialize or promote in the future, including through securing commercialization agreements with third parties and favorable pricing and market share or through our own commercialization capabilities;
- the existence and entrance of generics into the market, including entrances into the market as a result of adverse outcomes in Abbreviated New Drug Application (“ANDA”) litigation, that could compete with our products and erode the profitability of Talicia® and any future commercial products or products that we may commercialize or promote in the future;
- the number and type of therapeutic candidates in development;
- our ability to successfully complete our clinical and non-clinical trials and research and development programs, including recruitment and completion of relevant pediatric and oncology studies, since the pediatric population and the very advanced disease state and poor prognosis of the oncology patients in our oncology studies make it particularly difficult to recruit and successfully treat the patients, and to successfully complete the studies;
- the identification and acquisition of additional therapeutic candidates and commercial products;
- the costs, timing, and outcome of regulatory review and obtaining regulatory clarity and approval of our therapeutic candidates and addressing regulatory and other issues that may arise post-approval;
- the costs of enforcing our issued patents and defending intellectual property-related claims;
- the costs of manufacturing, developing and maintaining sales, marketing, and distribution channels for Talicia® and any future commercial products;
- our consumption of available resources, especially at a more rapid consumption than currently anticipated, resulting in the need for additional funding sooner than anticipated;
- the amount and frequency of any milestone or royalty payments for which we are responsible;
- the ability and interest of investors to invest in our products and activities;
- our partners’ ability to successfully execute the plans to develop and commercialize our products;
- our ability to handle, support and overcome unexpected events including geopolitical, tax, and legal (including litigation) changes and events; and
- the availability and extent of government-supported financings, such as grants and contracts.

We have limited experience achieving regulatory approval or out-licensing our therapeutic candidates, making it difficult to evaluate our business and prospects.

Talicia® is our first and only product that was developed internally and approved for marketing by the FDA. We have limited experience in commercializing products and achieving regulatory approval or out- licensing our therapeutic candidates. Consequently, any predictions about our future performance may not be accurate, and we may not be able to fully assess our ability to commercialize Talicia® or ones we may acquire or develop in the future, complete the development or obtain regulatory approval for our current and future therapeutic candidates or obtain regulatory approvals, reimbursement by third-party payors, achieve market acceptance or competitive pricing of Talicia® or products that we may commercialize or promote in the future.

If we are unable to maintain and train an effective commercial infrastructure, including sales and marketing infrastructure, or maintain compliant and adequate commercial capabilities, we will not be able to successfully commercialize and grow Talicia® and any products we may commercialize or promote in the future.

We and our employees, as well as our contractors, must comply with applicable regulatory requirements and restrictions relating to marketing and advertising. If we are unable to maintain compliant and adequate sales and marketing capabilities, including training our new sales personnel (including sales contractors) regarding applicable regulatory requirements and restrictions, we may not be able to increase our product revenue, may generate increased expenses, and may be subject to regulatory investigations and enforcement actions.

Our commercial efforts, including our sales and marketing efforts, must comply with various laws and regulations. Under applicable FDA marketing regulations, prescription drug promotions must be consistent with and not contrary to labeling, present "fair balance" between risks and benefits, be truthful and not false or misleading, be adequately substantiated (when required), and include adequate directions for use. Additionally, our marketing activities may be subject to enforcement by the Federal Trade Commission, state attorneys general, and consumer class-action liability if we engage in any practices that appear misleading or deceptive to the applicable agencies or consumers. Our sales and marketing practices must also comply with federal and state anti-kickback statutes, the violation of which can result in civil and criminal liability and other penalties.

In addition to the requirements applicable to approved drug products, we may also be subject to enforcement action in connection with any promotion of an investigational new drug. A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, may not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the therapeutic candidate.

If the FDA investigates our marketing and promotional materials or other communications and finds that any of our current or future commercial products are being marketed or promoted in violation of the applicable regulatory restrictions, we could be subject to FDA enforcement action. Any enforcement action (or related lawsuit, which could follow such action) brought against us in connection with alleged violations of applicable drug promotion requirements, or prohibitions, could have an adverse effect on our reputation, business, financial condition or results of operations, as well as the reputation of any approved drug products we may commercialize or promote in the future. In addition, we may also be reliant on third parties' compliance with such regulations.

Moreover, laws and regulations covering commercialization activities in the pharmaceutical industry are constantly changing, and we will need to continually update and adjust our policies and sales and marketing and commercialization activities to meet legal and regulatory requirements. Our ability to comply with legal and regulatory requirements at any time in time does not guarantee we will continue to be able to comply in the future.

In addition to complying with applicable laws and regulations covering commercialization activities in the pharmaceutical industry, we must also comply with various contractual terms governing our use of third-party intellectual property in our commercialization materials.

In order to maintain and potentially increase our commercialization capabilities in the U.S. and outside the U.S., we may need to maintain and potentially expand, among others, our development, regulatory, manufacturing, sales and marketing capabilities, and to maintain or potentially increase our personnel to accommodate sales. We may experience difficulties in managing this growth and integrating new personnel.

To maintain and potentially increase our own commercialization capabilities in the U.S. and outside the U.S. we may need to expand, among others, our development, regulatory, manufacturing, sales and marketing capabilities, and to maintain or potentially increase our personnel to accommodate sales. We may not be able to secure or retain personnel, organizations or vendors that are adequate in number or expertise to successfully and lawfully market and sell our products in the U.S. or outside the U.S. If we are unable to maintain or expand our sales and marketing capabilities, train our sales force or contractors effectively or provide any other capabilities necessary to commercialize products, we may need to contract with third parties to market and sell our products, which, if we are able to sell our products, could have an adverse effect on our financial condition and our results of operations.

We may also have difficulty in integrating into our existing U.S. operations sales and other commercial personnel or contractors that we may hire or engage to support the commercialization of Talicia®. Sales personnel or contractors' productivity may decrease as we hire new, less experienced sales personnel or contractors who are not yet familiar with Talicia® and any future commercial products. In addition, we may be exposed to greater regulatory and compliance risks with an expanded sales force and activities to the extent applicable.

Future growth may impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees or contractors. Our U.S. subsidiary, RedHill U.S., has historically experienced and continues to experience high turnover rates. See "– *Our business could suffer if we are unable to attract and retain key personnel and additional highly qualified personnel*" Below. In addition, management may have to divert a disproportionate amount of its attention away from running our day-to-day activities and devote a substantial amount of time to managing these growth activities.

Any collaborative arrangements that we have established or may establish may not be successful, or we may otherwise not realize the anticipated benefits from these collaborations, including commercialization of Talicia®. We do not control third parties with whom we have or may have collaborative arrangements, and we rely on such third parties to achieve results which may be significant to us. In addition, any current or future collaborative arrangements may place the commercialization of Talicia® or products that we may commercialize or promote in the future or the development of our therapeutic candidates outside our control and may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Each of our collaborative arrangements requires us to rely on external consultants, advisors, and experts for assistance in several key functions, including clinical development, manufacturing, regulatory, market research, intellectual property, and commercialization. We do not control these third parties, but we rely on such third parties to achieve results, which may be significant to us. With respect to RHB-102, we rely on Hyloris Pharmaceuticals NV ("Hyloris"), the party responsible for, among other things, the development, manufacture, registration and commercialization of the product with respect to the territories granted to Hyloris under our exclusive license agreement with Hyloris, dated as of February 25, 2025. With respect to Talicia®, we rely on Recipharm Strängnäs AB ("Recipharm") and other contracting parties for the manufacture of Talicia® and its components, and we rely on Gaelan Medical Trade LLC ("Gaelan Medical") to obtain necessary approvals and commercialize Talicia® in the United Arab Emirates ("UAE").

Relying upon collaborative arrangements to commercialize Talicia® and any other products that we may commercialize or promote in the future and to develop our therapeutic candidates, subjects us to a number of risks, including but not limited to the following:

- we will be responsible for making certain milestones, royalty or other payments under our various in-licenses even if our operating costs exceed the revenues generated from the relevant products;
- our collaborators may default on their obligations to us and we may be forced to either terminate, litigate or renegotiate such arrangements;

- our collaborators may have claims that we breached our obligations to them which may result in termination, renegotiation, litigation or delays in performance of such arrangements;
- we may not be able to control the amount and timing of resources that our collaborators may devote to Talicia®, products that we may commercialize or promote in the future or our therapeutic candidates;
- our collaborators may fail to comply with applicable laws, rules, or regulations when performing services for us, and we could be held liable for such violations;
- our collaborators may experience financial difficulties, making it difficult for them to fulfill their obligations to us, including payment obligations, or they may experience changes in business focus;
- our collaborators' partners may fail to secure adequate commercial supplies for Talicia® or products that we may commercialize or promote;
- our collaborators' partners may have a shortage of qualified personnel;
- we may be required to relinquish important rights, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business or business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- under certain circumstances, a collaborator could move forward with a competing therapeutic candidate or commercial product developed either independently or in collaboration with others, including our competitors;
- collaborative arrangements are often terminated or allowed to expire, which may limit or terminate our rights to commercialize Talicia® or products we may commercialize or promote in the future, or could delay the development and may increase the cost of developing our therapeutic candidates;
- our collaborators may not wish to extend the terms of our agreements related to Talicia® and any future commercial products or therapeutic candidates beyond the existing terms, in which case, we will not have access to existing rights upon the expiration and will therefore not be able to develop such therapeutic candidates or commercialize or promote such products following the initial terms of our agreements; and
- our collaborators may wish to terminate the collaborative arrangements due to any disagreements or conflicts with us, a change in their assessment that the arrangement is no longer valuable, a change in control or in management or in strategy, changes in product development or business strategies of our collaborators.

In addition, our reliance upon our partners in connection with commercial activities subjects us to a number of additional risks, including but not limited to, the following:

- we do not generally control our partners' communications with the FDA or other foreign regulatory authorities, and the FDA or other foreign regulatory authorities may determine not to approve or elect to withdraw the products from the market due to various factors including any action or inaction taken by our partners (see " – Talicia® or products which we may commercialize or promote in the future may be subject to recalls or market withdrawal that could have an adverse effect on our reputation, business, financial condition or results of operations");
- in many instances, we rely on our partners to take enforcement action to protect the IP and regulatory protections, if any, of Talicia® and any future commercial products. Their failure to diligently protect these products could materially affect our commercial success;
- we rely on our partners to be responsible for the manufacture of Talicia®, including through third-party manufacturers with the requisite quality and manufacturing standards as required under applicable laws and regulations, and we also rely on those same partners to supply their respective products and active pharmaceutical ingredients ("APIs"), which may result in us having those respective products and APIs in insufficient quantities or not delivered in as timely a manner as is necessary to achieve adequate or successful promotion and sale of their respective products;
- our partners relating to Talicia® and any future commercial products may significantly create or change reimbursement agreements or increase or decrease the price of their respective products to a level that could adversely affect our sales or revenues;
- our partners may make decisions related to the product and take critical actions to support the product, including with respect to promotion, sales and marketing, medical affairs and pharmacovigilance, and any action or inaction taken by those same partners may adversely affect the approval, promotion and sales of their respective commercial products;

- our partners may terminate their agreements with us after an agreed-upon period for reasons set forth in those same partners' respective agreements with us;
- our partners for future commercial products may change or create new agreements with wholesalers, Pharmacy Benefit Managers or other important stakeholders, which may significantly impact our ability to achieve commercial success, or they may fail to negotiate reimbursement agreements with payors which could also negatively affect our commercial success;
- our partners may change the price of their respective commercial products to a level that could adversely affect our sales or revenues;
- our partners may not be successful in maintaining or expanding reimbursement from government or third-party payors, such as insurance companies, health maintenance organizations and other health plan administrators, which may adversely affect the sales of their respective products; and
- our partners, such as Hyloris, may not pursue their activities under our license agreements, or may not be able to develop, manufacture, register and/or commercialize our products, directly or through third parties, distributors and/or sublicensees.

If any of these or other scenarios materialize, they could have an adverse effect on our reputation, business, financial condition or results of operations.

If we acquire products, technologies, companies or businesses that own rights to, or otherwise acquire commercialization and related rights to, products, such transactions could result in additional costs, integration or operating difficulties, dilution and other adverse consequences. Such acquired products, technologies or businesses that own rights to products may not achieve commercial success or further establish our marketing and commercialization capabilities.

Part of our strategy is to identify and acquire rights to products that have been cleared or approved for marketing in the U.S. or elsewhere, and in particular, those with a therapeutic focus on GI, infectious diseases and oncology or with therapeutic activities which are overlapping or complementary to our existing commercial activities. Management has evaluated, and expects to continue to evaluate, a wide array of potential strategic acquisitions. From time to time, management may engage in discussions regarding potential acquisitions or licensing of rights to certain products that management believes are important to our business. Any one of these transactions could have a material effect on our reputation, business financial condition or results of operations. In connection with these acquisitions or licensing transactions, we may:

- issue equity securities that may substantially dilute our shareholders' percentage of ownership;
- be obligated to make upfront milestones, royalty or other contingent or non-contingent payments;
- incur debt or non-recurring and other charges, or assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs of assets or goodwill or impairment charges.

In addition, the process of integrating an acquired product, technology, company or business may create operating difficulties and expenditures and pose numerous additional risks to our operations, including:

- difficulty and expense in integrating the acquired product, technology, company or business, and personnel in accordance with our business strategy and existing operations, including the failure to achieve the expected benefits and synergies;
- obligations to further develop and commercialize the acquired product, technology, company or business, in particular in jurisdictions outside of those in which we have experience operating;
- higher than anticipated acquisition costs and expenses;
- failure to manufacture or supply, or procure manufacturers or suppliers for, the acquired product, technology, company or business economically or successfully commercialize or achieve market acceptance of the acquired product;

- exposure to liabilities of the acquired product, technology, company or business, including contract terms and conditions that are less favorable to us than our standard contractual terms, known or unknown risks relating to the validity or enforceability of patents, expiration of patents or exclusivity rights, generic competition, product defects or product liability claims, patent and other litigation and clinical, development or other liabilities;
- disruption of our business and diversion of our management's and technical personnel's time and attention from their day-to-day responsibilities;
- adverse effects on our reputation, business, financial condition or results of operations, including due to expenditures or acquisition-related costs, costs of commercialization or amortization or impairment costs for acquired goodwill and other intangible assets;
- impairment of relationships with key suppliers and manufacturers due to changes in management and ownership and difficulty in maintaining existing agreements, licenses and other arrangements or rights on substantially similar terms as existed prior to the acquisition;
- regulatory changes and market dynamics after the acquisition; and
- potential loss of key employees, particularly those of the acquired entity.

If any of the above events (or more) occur, or if we cannot effectively manage or respond to such events following one or more acquisitions, they may have a material adverse effect on our reputation, business, results of operations or financial condition.

Moreover, there can be no assurance that we will accurately or consistently identify products approved or cleared for marketing that will achieve commercial success, that we will be able to successfully acquire or commercialize such products or that such acquisitions would further establish our marketing and commercialization capabilities.

Maintaining and potentially expanding our commercial infrastructure in the U.S., is a significant undertaking that requires substantial financial and managerial resources, and we may encounter setbacks or may not be successful in our efforts.

Maintaining and potentially expanding the necessary commercial capabilities is competitive and time-consuming, and the commercialization of Talicia® requires a significant expenditure of operating, financial and management resources. Even with those investments, we may not be able to effectively commercialize Talicia®, or we may incur more expenditures than anticipated in order to maximize our sales. We cannot guarantee that we will be able to maintain or expand our sales, marketing, distribution, and market access capabilities and enter into and maintain any agreements necessary for commercialization with payors and third-party providers on acceptable terms, if at all. If we are unable to maintain or expand such capabilities, either on our own or by entering into agreements with others, or are unable to do so in an efficient manner or on a timely basis, we will not be able to maximize the commercialization of Talicia® or products that we may commercialize or promote in the future, which would adversely affect our reputation, business, financial condition or results of operations.

Even if the commercialization of Talicia® and any future commercial products is successful, we may fail to further our business strategy as anticipated or to achieve anticipated benefits and success. We may incur higher than expected costs in connection with the commercialization of Talicia®, and we may encounter general economic or business conditions that adversely affect these products.

In addition, if we incur higher than expected costs in connection with the commercialization of Talicia® and any future commercial products, we may need to reduce or terminate our commercial activities, which may have a material adverse effect on our reputation, business, financial condition or results of operations.

We have a limited history of independently commercializing products that we developed and for which we obtained regulatory approval, such as Talicia®, and a limited history of commercializing products in the U.S. Due to our limited experience, we may have difficulty commercializing Talicia® or promoting or commercializing any products for which we may obtain FDA approval or to which we may acquire commercialization or promotion rights in the future.

Compared to competitors in the industry, we have relatively limited experience marketing and selling products in the U.S. In particular, we have limited experience in commercializing products that we developed and for which we obtained regulatory approval, such as Talicia®, which may materially increase our marketing and sales expenses or cause us to be ineffective in these efforts. Talicia® is the first product that we are commercializing that we developed and for which we obtained regulatory approval.

Our prior experience promoting and commercializing several other commercial products in the U.S. that we no longer commercialize or promote was limited and brief.

There can be no assurance we will successfully commercialize Talicia® or any products we may commercialize or promote in the future.

In addition, many companies, both public and private, including well-known pharmaceutical companies and smaller niche-focused companies, are currently selling, marketing and distributing drug products that directly compete with Talicia® and therapeutic candidates that we may seek to commercialize in the future. Many of these companies have significantly greater financial capabilities, marketing, and sales experience and resources than us. As a result, our competitors may be more successful than we are in commercializing products, and we may not be able to generate sufficient revenue to achieve or sustain profitability.

Our failure to accurately forecast demand for Talicia® and any future commercial products, or to quickly adjust to forecast changes, could adversely affect our business and financial results.

Market uncertainty makes it difficult for us to accurately forecast future commercial product demand. We will be setting target levels for the manufacture of Talicia® and any future commercial products in advance of purchases based upon our forecasts of commercial product sales.

If our forecasts exceed demand, we could experience excess inventory of APIs or of Talicia® and any future commercial products, which can increase our inventory costs and result in obsolete inventory. Alternatively, if demand exceeds our forecasts, this may cause a shortage of commercial products, or the APIs used in our products, which could result in an inability to satisfy demand for Talicia® and any future commercial products and a resulting material loss of market share and potential revenue. A failure to accurately predict the level of demand for Talicia® and any future commercial products could adversely affect our revenues and net income.

In addition, some of our suppliers may require extensive advance notice of our requirements in order to produce APIs or commercial products in the quantities we desire. Long lead times may require us to place orders far in advance of the time when the commercial products will be offered for sale, and limitations on our flexibility to change such orders may not only make it difficult for us to accurately forecast demand for Talicia® and any future commercial products, but also expose us to risks relating to shifts in consumer demand and trends and adversely affecting our operating results.

If third parties do not manufacture, our therapeutic candidates, upon approval, if any, or products we may commercialize or promote in the future in sufficient quantities, within the required timeframes, at an acceptable cost and in accordance with applicable quality standards and other regulatory requirements, the commercialization of Talicia® or products we may commercialize or promote in the future may be adversely affected, or clinical development of our therapeutic candidates.

We do not currently own or operate manufacturing facilities. We rely on, and expect to continue to rely on, third parties to manufacture commercial quantities of Talicia® and products that we may commercialize or promote in the future and clinical quantities of our therapeutic candidates. We currently rely on Recipharm and other contracting parties to provide sufficient quantities of Talicia® in the required timeframe. We rely on various third parties to satisfy our supply requirements and there is no guarantee they will be able to do so successfully or in a timely manner. Our reliance on third parties includes our reliance on them for quality assurance related to regulatory compliance. Our current and anticipated future reliance upon others for the manufacture of our therapeutic candidates and any products that we may commercialize or promote may adversely affect our future operations and our ability to commercialize Talicia® and any products that we may commercialize or promote on a timely and competitive basis, and to develop therapeutic candidates.

We may not be able to maintain our existing or future third-party manufacturing arrangements on acceptable terms, if at all. If for some reason our manufacturers or our development or commercialization partners' manufacturers do not perform as agreed or expected or terminate or fail to renew the agreements for any reason, we or our partners may be required to replace them, in which event we may incur added costs and delays in identifying, engaging, qualifying under applicable regulatory requirements and training any such replacements and entering into agreements with such replacements on acceptable terms. In addition, our ability to enter into such alternative arrangements within a reasonable period of time, if at all, may be contractually limited by the terms of our manufacturing agreements existing at that time. Obtaining the necessary FDA or other regulatory approvals or other qualifications required for changes in manufacturing sites, methods or processes under applicable regulatory requirements could result in a significant interruption of supply. In the case of the manufacturer of Talicia®, in particular, the delay in identifying, engaging, qualifying and training its replacement may be extended, leading to a significant interruption of supply. Any such additional costs and delays may adversely impact our ability to obtain regulatory clearances and approvals for our therapeutic candidates or any product we may commercialize or promote or make such commercialization or marketing economically unfeasible.

We rely on third parties to manufacture and supply us with high-quality APIs and their starting materials in the quantities and quality we require on a timely basis.

We currently do not manufacture any APIs ourselves. Instead, we rely on third-party vendors for the development, manufacture, and supply of our APIs that are used to formulate Talicia® and products we may commercialize or promote in the future and our therapeutic candidates. If these suppliers are incapable or unwilling to meet our current or future needs on acceptable terms or at all, we could experience delays in supplying product to market or commercial supply shortages that would adversely affect our sales of products we currently or may commercialize or promote in the future, or delays in obtaining regulatory clearances or approvals for our therapeutic candidates.

While there may be several alternative suppliers of APIs on the market, for most of our products we have yet to conclude extensive investigations into the quality or availability of their APIs. Changing API suppliers or finding and qualifying new API suppliers can be costly and take a significant amount of time. Many APIs require significant lead-time to manufacture. There can also be challenges in maintaining similar quality or technical standards from one manufacturing batch to the next.

If we are not able to find stable, affordable, high quality, or reliable supplies of our APIs, we may not be able to produce enough supplies of Talicia® or products we may commercialize or promote in the future, or of our therapeutic candidates, which could have a material adverse effect on our reputation, business, financial condition or results of operations.

In addition, while to date there have been no significant disruptions to our supply chain, including to the manufacture of our APIs or their starting materials, there may be unfavorable changes in the availability or cost of raw materials, intermediates, and other materials necessary for production, which may result in disruptions in our supply chain.

We anticipate continued reliance on third party manufacturers for Talicia®, and we expect to rely on third-party manufacturers if we are successful in obtaining marketing approval from the FDA and other regulatory agencies for any of our therapeutic candidates.

We rely on, and we expect to continue to rely on, third-party manufacturers to produce commercial quantities of Talicia®. In addition, we expect to rely on third-party manufacturers to produce products that we may commercialize or promote in the future. To date, other than Talicia®, which the FDA has approved for marketing in the U.S., our therapeutic candidates have been manufactured in relatively small quantities for preclinical testing and clinical trials, as well as for other regulatory purposes by third-party manufacturers. If the FDA or other regulatory agencies approve any of our current or future therapeutic candidates for commercial sale, we expect that we would rely, at least initially, on third-party manufacturers to produce commercial quantities of our approved therapeutic candidates. These manufacturers may not be able to successfully increase or maintain the manufacturing capacity for Talicia® or any product we may commercialize or promote in the future or any of our therapeutic candidates that may be approved in the future, in a timely or economic manner, or at all. The significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. Foreign regulatory agencies may also require the approval of additional validation studies for scaling up the manufacturing process of any of our therapeutic candidates or current or future commercial products. If the third-party manufacturers are unable to successfully increase or maintain the manufacturing capacity for a therapeutic candidate, Talicia® or for products that we may commercialize or promote in the future, or if we are unable to secure replacement third-party manufacturers or unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply. A supply disruption from any of our third-party manufacturers could have a material adverse effect on our reputation, business, financial condition or results of operations.

Reliance on third-party manufacturers entails risks, including, but not limited to:

- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our current or future commercial products, including Talicia®, or any future therapeutic candidates, if approved, or otherwise do not satisfactorily perform according to the terms of their agreements with us;
- the possible termination or nonrenewal of manufacturing agreements by the third-party manufacturers at a time that is costly or inconvenient for us;
- the possible breach of manufacturing agreements by third-party manufacturers;
- inability to fulfill all or part of our undertakings and commitments to our current or future commercialization partners in the U.S. and other territories, such as our partners, Gaelen Medical and Hyloris, due to, among other things, delays or lack of supply by manufacturers of commercial products or the supply of such products in quantity or quality which is inadequate or not in line with the required regulatory standards or our agreements;
- delays in obtaining regulatory approval for any future therapeutic candidates, if our third-party manufacturers fail to satisfy FDA inspection requirements in connection with pre-approval inspections or otherwise fail to comply with regulatory requirements; and
- product loss or serious adverse events due to contamination, equipment failure, or improper installation or operation of equipment or operator error.

If we are unable to establish collaborations for our therapeutic candidates or products we may commercialize or promote, or otherwise not be able to raise significant additional capital, we will likely need to alter or abandon our development and commercialization plans.

Our drug development programs and the potential commercialization of our approved products or our therapeutic candidates and products that we may commercialize or promote in the future will require additional cash to fund expenses. As such, our strategy includes either selectively partnering or collaborating with multiple pharmaceutical and biotechnology companies to assist us in furthering the development or potential commercialization of our approved products and therapeutic candidates, if approved, promoting or commercializing products, in whole or in part, in some or all jurisdictions or through our own commercialization capabilities, such as our partnerships with Gaelan Medical and Hyloris. With respect to potential new third-party partners for the development or commercialization of our approved products and therapeutic candidates, if approved, and development or commercialization of products that we may commercialize or promote in the future, we may not be successful in entering into collaborations with third parties on acceptable terms, or at all. In addition, if we fail to negotiate and maintain suitable development, commercialization or promotion agreements or otherwise raise significant additional capital to secure our own commercialization capabilities, we may have to limit the size or scope of our activities or we may have to delay or terminate one or more of our development or commercialization programs. Any failure to enter into (or in the case of Gaelen Medical and Hyloris, any failure to maintain) development or commercialization agreements with respect to the development, marketing and commercialization of any therapeutic candidates or products we may commercialize or promote or failure to develop, market and commercialize such commercial products or therapeutic candidates or products we may commercialize or promote independently may have an adverse effect on our reputation, business, financial condition or results of operations.

We may depend on our ability to identify, consummate and integrate in-licenses or acquire additional therapeutic candidates to achieve commercial success, including products approved or cleared for marketing in the U.S. or elsewhere.

Talicia® and our five clinical-stage development therapeutic candidates were all acquired or licensed by us from third parties and we may in the future pursue in-licenses or acquisitions of additional therapeutic candidates or products and seek to integrate them into our operations as well. We evaluate internally and with external consultants each therapeutic candidate we in-license or acquire. However, there can be no assurance as to our ability to accurately or consistently identify therapeutic candidates or products that have been approved or cleared for marketing in the U.S. or elsewhere that are likely to achieve commercial success. In addition, even if we identify additional therapeutic candidates or products that have been approved or cleared for marketing in the U.S. or elsewhere that are likely to achieve commercial success, there can be no assurance as to our ability to in-license or acquire such therapeutic candidates or products under favorable terms or at all. In-licenses and acquisitions of therapeutic candidates and products involve risks that could adversely affect our future results of operations.

We compete with other entities for some in-license or acquisition opportunities.

As part of our overall strategy, we pursue opportunities to in-license or acquire therapeutic candidates and products that have been approved or cleared for marketing in the U.S. We may compete for in-license and acquisition opportunities with other companies, including established and well-capitalized companies. As a result, we may be unable to in-license or acquire additional therapeutic candidates or products that have been approved or cleared for marketing in the U.S. at all or on favorable terms. Our failure to further in-license or acquire therapeutic candidates or products that have been approved or cleared for marketing in the U.S. in the future may materially hinder our ability to grow and could materially harm our reputation, business, financial condition or results of operations.

If we or a licensor or a partner of ours cannot meet our or their respective obligations under our acquisition, in-license or other development or commercialization agreements or renegotiate the obligations under such agreements, or if other events occur that are not within our control, such as bankruptcy of a licensor or a partner, we could lose the rights to our therapeutic candidates or products we may commercialize or promote, experience delays in developing or commercializing our therapeutic candidates or products we may commercialize or promote or incur additional costs, which could have a material adverse effect on our reputation, business, financial condition or results of operations.

We acquired our rights to Talicia® and RHB-104 from a third party pursuant to an asset purchase agreement. In addition, we in-licensed our rights to three other therapeutic candidates, RHB-102 (Bekinda®), opaganib, and RHB-107 (upamostat), pursuant to license agreements in which we received exclusive perpetual licenses to certain patent rights and know-how related to these therapeutic candidates. These agreements require us to make payments and satisfy various performance obligations in order to maintain our rights and licenses with respect to these marketed products and therapeutic candidates. If we or our collaborators do not meet our or their respective obligations under these or future agreements, or if other events occur that are not within our control, such as the bankruptcy of a licensor, we could lose the rights to commercialize Talicia® and any future commercial products or to our therapeutic candidates, experience delays in developing our therapeutic candidates or incur additional costs.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under these agreements in a timely manner or if other events occur that are not within our control, such as the bankruptcy of a licensor, which impact our ability to prosecute certain patent applications and maintain certain issued patents licensed to us, we could lose the rights to Talicia® and any future commercial products or our therapeutic candidates which could have a material adverse effect on our reputation, business, financial condition or results of operations. We manage a large portfolio of patents and may decide to discontinue maintaining certain patents in certain territories for various reasons, including costs, such as a current belief that the commercial market for the therapeutic candidate will not be large or that there is a near-term patent expiration that may reduce the value of the therapeutic candidate. In the event we discontinue maintaining such patents, we may not be able to enforce rights for our therapeutic candidates or protect our therapeutic candidates from competition in those territories.

Disputes may arise between us and third parties from whom we have acquired assets or commercialization rights, with which we have license agreements or with which we have commercialization agreement. Any conflict, dispute or disagreement with such third parties may result in disruptions to our business relationships, require us to pay damages and incur costs, adversely affect our results of operations and may lead to loss of rights that are important to our business or costly litigation.

Our existing agreements impose, and we expect that future acquisition, commercialization or license agreements will impose, various diligence, milestone payments, royalty or other obligations on us. Such agreements require, or may in the future require, us to remit upfront and royalty payments or performance milestone payments for commercial products that we in-license and to supply and delivery of know-how for products that we out-license. Any failure on our part to perform our obligations could lead to us losing rights under our licenses or commercialization agreements, including rights to certain of the actual products under certain circumstances, and could thereby adversely affect our business. If there is any conflict, dispute, disagreement or issue of non-performance between us and our third-party partners regarding our rights or obligations under the acquisition, commercialization or license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement or to perform certain activities or to adhere to any contractual obligation, we may be liable to pay damages and incur costs, and it could lead to delays in the research, development, collaboration, and commercialization of Talicia®, products we may promote or commercialize in the future or our therapeutic candidates. The resolution of such disputes could require or result in litigation or arbitration, which could be time-consuming and expensive. Such third-party partner may have a right to terminate the affected license or commercialization agreement subject to a dispute. If our existing agreements are terminated, it would have a material adverse effect on our reputation, business, financial condition or results of operations.

Our business could suffer if we are unable to attract and retain key personnel and additional highly qualified personnel.

The loss of the services of members of senior management or other key personnel could delay or otherwise adversely impact the successful completion of our planned clinical trials or the commercialization of Talicia® and therapeutic candidates, if approved, and any product we may commercialize or promote in the future, or otherwise affect our ability to manage our company effectively and to carry out our business plan. These key personnel are Dror Ben-Asher, our Chief Executive Officer, Reza Fathi, Ph.D., our Senior Vice President for Research and Development, Gilead Raday, our Chief Operating Officer, Adi Frish, our Chief Corporate and Business Development Officer, Guy Goldberg, our Chief Business Officer, Razi Ingber, our Chief Financial Officer, Rick D. Scruggs, President, RedHill U.S. and our Chief Commercial Officer, and Dr. Mark Levitt, our Chief Scientific Officer. We do not maintain key-man life insurance. Although we have entered into employment or consultancy agreements with all of the members of our senior management team, members of our senior management team may resign at any time. High demand exists for senior management and other key personnel in the pharmaceutical industry. There can be no assurance that we will be able to continue to retain and attract such personnel.

Our growth and success also depend on our ability to attract and retain additional highly qualified scientific, technical, business development, marketing, sales, managerial and finance personnel. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to liability from their former employers. Our U.S. subsidiary, RedHill U.S., previously experienced high turnover rates. A sustained labor shortage or increased turnover rates within our employee base as a result of general macroeconomic or other factors, could lead to increased costs, such as increased overtime to meet demand and increased wage rates to attract and retain employees, and could negatively affect our ability to efficiently operate our manufacturing and distribution facilities and overall business. If we are unable to hire and retain employees capable of performing at a high-level, or if mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, have unintended negative effects, our business could be adversely affected. An overall labor shortage, lack of skilled labor, increased turnover or labor inflation could have a material adverse impact on our operations, results of operations, liquidity or cash flows.

In addition, so long as we continue to promote Talicia® and in the event we promote additional commercial products we may develop, we need to maintain and may need to expand our marketing and sales capabilities and retain key personnel and talented commercial employees including sales representatives. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have. This has made it more difficult for us to successfully retain and attract key and other personnel that are key to our growth and even the viability of our commercial operations, particularly given the numerous challenges we face, including management's substantial doubt about our ability to continue as a going concern. Many of our sales representatives, including some of our must successful ones, have departed our company over time to pursue more lucrative employment opportunities. We believe this trend may continue in the future and could pose a major challenge to our ability to operate our commercial operations. If we cannot attract and retain sufficiently qualified suitable employees on acceptable terms, we may not be able to develop and commercialize our commercialized products and competitive therapeutic candidates. Further, any failure to effectively integrate new personnel could materially prevent us from successfully growing our company.

We face several risks associated with international business.

We operate our business in multiple international jurisdictions. Such operations could be materially affected by changes in foreign exchange rates, capital and exchange controls, expropriation and other restrictive government actions, changes in intellectual property legal protections and remedies, changes in data privacy laws, trade regulations and procedures and actions affecting approval, production, pricing, and marketing of, reimbursement for and access to, Talicia® and products we may commercialize or promote, or our therapeutic candidates, as well as by political unrest, unstable governments and legal systems, and inter-governmental disputes. For example, although we entered into an exclusive worldwide development and commercialization licensing agreement, excluding North America, with Hyloris for RHB-102 (Bekinda®), an exclusive license agreement with Gaelan Medical for Talicia® in the UAE and the Exclusive License Agreement (as defined herein) for opaganib in South Korea, our licensing partners may not be able to obtain regulatory approval for opaganib in South Korea or for RHB-102 elsewhere (excluding North America), may experience a termination of the agreements, or may be unable to sell the products or sell the products in sufficient quantities to generate meaningful revenues. In addition, we are subject to global events beyond our control, including war, public health crises, such as pandemics and epidemics (as described above), tariffs and trade disputes and other international events. In the UAE, for example, threats to the stability of the Abraham Accords between the UAE, the U.S. and Israel may disrupt our ability to supply Talicia®. Also, given that some of our operations are conducted in Israel, our business and operations are directly affected by economic, political, geopolitical and military conditions in Israel, and any existing conflicts may potentially escalate in the future to more violent events. Any of these changes could have a material adverse effect on our reputation, business, financial condition or results of operations. In addition, the current armed conflict in Ukraine and the subsequent economic sanctions imposed by some countries on Russia and certain territories in Ukraine may negatively impact the supply chain for our commercial product, our R&D activities and our business development activities.

We face risks associated with the lawsuit we initiated against Kukbo. Even if we prevail in the lawsuit against Kukbo, we may need to enforce the judgment in South Korea if Kukbo does not promptly pay the judgment.

On September 2, 2022, we filed a lawsuit against Kukbo Co. Ltd. ("Kukbo") in the Supreme Court of the State of New York, County of New York, Commercial Division, as a result of Kukbo's default in delivering to us $5.0 million under the Subscription Agreement (as defined herein), in exchange for the ADSs we were to issue to Kukbo, and in delivering to us the further payment of $1.5 million due under the Exclusive License Agreement. Kukbo thereafter filed counterclaims alleging breach of contract, misrepresentation, and the breach of the duty of good faith and fair dealing. On December 2, 2024, we were awarded a judgment of approximately $6.5 million in principal and approximately $1.5 million in accrued interest as of the date of the judgment, which interest continues to accrue at a rate of 9% per annum, in a summary judgment by the Supreme Court of the State of New York. In addition, in accordance with the court's ruling that we are entitled to recover attorneys' fees, we filed a motion seeking recovery of approximately $1.8 million in legal fees as of December 31, 2024. The court dismissed the entirety of Kukbo's counterclaims in the case. Kukbo filed a notice of appeal and retains the right to seek an appeal.

We are party to a contingency fee agreement with our legal counsel, Haynes and Boone, LLP, entered into on November 20, 2023, as amended on December 29, 2024. Under this agreement, such firm is entitled to a double-digit percentage of any gross recovery, if and only if the case ends in a final favorable outcome not subject to further appeal. If no collection is made within six months of such an outcome, we are required to pay such firm its standard hourly fees incurred since entering the agreement—approximately $1.1 million as of December 31, 2024—and must pay the full contingency amount if collection occurs later.

We intend to vigorously pursue the recovery of attorneys' fees and the collection of the judgment. Due to the uncertainties of litigation, we can give no assurance that we will ultimately prevail on appeal or succeed in collecting any or all of the amounts awarded to us. If we do not prevail, we will not owe any legal fees under the contingency arrangement; however, if we prevail but are unable to collect in a timely manner, we still may be required to pay the legal fees described above even if we do not receive any recovery. In addition, we may have to pay associated damages and related expenses and legal fees if Kukbo receives a favorable appeal on the judgment (if an appeal is filed). The lawsuit against Kukbo may additionally divert management's attention and resources in preparing for any continued litigation and defending our claim, result in disruptions to our business, and require us to pay legal fees, damages, or associated expenses, all of which could adversely affect our ability to conduct our business.

Risks Related to Regulatory Matters

If we or our future development or commercialization partners are unable to obtain or maintain the FDA or other foreign regulatory clearance and approval for Talicia® and any future commercial products or therapeutic candidates, we or our commercialization partners will be unable to commercialize Talicia® or future products or therapeutic candidates, upon approval, if any.

Talicia® must maintain, and any future products must obtain and maintain, FDA and other foreign regulatory clearance and approval before commercialization.

Talicia® was approved for marketing in the U.S. for the treatment of H. pylori infection in adults in November 2019. Pursuant to our license agreement with Gaelan Medical, Gaelan Medical received marketing approval for Talicia® in the UAE and Gaelan Medical subsequently placed the first commercial order for Talicia®, which was dispatched from the contract manufacturing organization ("CMO") in December 2023. In August 2024, we announced the launch of Talicia in the UAE. However, future regulatory developments may lead to a loss of the right to commercialize Talicia® or any product we may commercialize or promote in the future.

We currently have five therapeutic candidates in development, most of which are in clinical stage development, with the goal of eventually seeking FDA or other foreign regulatory approvals. Our commercial product and therapeutic candidates are subject to extensive governmental laws, regulations, and guidelines relating to the development, clinical trials, manufacturing, marketing, promotion, and commercialization of pre- and post-approval prescription drugs. We may not be able to submit for or obtain marketing approval for any of our therapeutic candidates in a timely manner or at all.

Any material delay in obtaining or maintaining, or the failure to obtain or maintain, required regulatory clearances and approvals will increase our costs and may materially adversely affect our ability to continue to generate meaningful revenues and could adversely impact our reputation, business, financial condition, results of operations or ability to attain or sustain revenues from other markets. We also are, and will be, subject to numerous regulatory requirements from both the FDA and other foreign regulatory authorities that govern the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. Moreover, clearance or approval by one regulatory authority does not ensure clearance or approval by other regulatory authorities in separate jurisdictions. Each jurisdiction may have different approval processes and requirements and may impose additional testing, development and manufacturing requirements for Talicia® and products that we may commercialize or promote in the future and for or our therapeutic candidates.

Additionally, the FDA or other foreign regulatory authorities may require, or companies may pursue, additional clinical trials after a product is approved for marketing. Such postmarketing studies may be mandated by the FDA or other foreign regulatory authorities as conditions for initial or continued approval for marketing. The FDA or other foreign regulatory authorities have expressed statutory authority to require holders of NDAs to conduct postmarketing trials to specifically address safety and other issues identified by the regulatory authority. Failure to comply with postmarketing requirements may result in enforcement actions from the FDA, including, but not limited to, warning letters and/or civil monetary penalties.

Certain changes related to an approved drug, including changes to the product labeling, manufacturing process, indications and other certain specifications set forth within the product's NDA, may not be made until a new NDA or NDA supplement reflecting the applicable changes is submitted to and approved by the FDA. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, including relevant pediatric data, and the FDA typically uses the same procedures and standards in reviewing NDA supplements as it does in reviewing NDAs.

Even if a therapeutic candidate receives regulatory marketing approval, such approval will be limited to a specific disease state(s) and might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution, among other possible restrictions. Further, even after regulatory approval is obtained, later discovery of previously unknown information, such as safety risks, problems with a product or such information, the extent or severity of which were previously unknown, may result in restrictions on the product's ability to be marketed as initially approved or even complete withdrawal of the product's NDA approval and, in effect, its removal from the market.

Additionally, the FDA or other foreign regulatory authorities may change their clearance or approval policies or adopt new laws, regulations or guidelines that materially delay or impair our ability to commercialize Talicia® and products that we may commercialize or promote in the future, or our ability to obtain the necessary regulatory clearances or approvals for any of our current or future therapeutic candidates.

Further, if there are significant reductions in the FDA's workforce, specifically at the Center for Drug Evaluation and Research ("CDER"), there may be unforeseen delays in the review of a future product's NDA or a current or future product's NDA supplement application. A delay in the review of such applications could delay our ability to commercialize and promote any of our future products in the United States.

Talicia® or products which we may commercialize or promote in the future may be subject to recalls or market withdrawal that could have an adverse effect on our reputation, business, financial condition or results of operations.

The FDA and similar foreign governmental authorities have the authority to require the recall of regulated products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the product would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture.

Product manufacturers or owners, as applicable, may, on their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us or one of our collaborators, as applicable, could occur as a result of manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and will have an adverse effect on our reputation, business, financial condition or results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

Regulatory authorities in other jurisdictions may have similar procedures that may subject any product we may commercialize or promote to limitations or withdrawal requests. In addition, the FDA or other foreign regulatory authorities may determine that the chemistry, manufacturing and controls ("CMC") of marketed products that we develop, acquire or to which we acquire commercialization rights, such as Talicia® , is unsatisfactory due to the manufacturing standards of the products. If either of these or any regulatory action is taken, Talicia® or any product we commercialize or promote in the future could be withdrawn from the market at any time. In addition, we may suffer from delays in further commercialization of any product we commercialize or promote.

We and our third-party manufacturers or our partners' manufacturers are, and will be, subject to regulations of the FDA and other foreign regulatory authorities, such as applicable current good manufacturing practices and other quality-based regulations.

We and our third-party manufacturers or our partners' manufacturers are, and will be, required to adhere to laws, regulations, and guidelines of the FDA and other foreign regulatory authorities setting forth current good manufacturing practices ("cGMP"). These laws, regulations, and guidelines cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to Talicia® and any products we may commercialize or promote, and our therapeutic candidates with varying cGMP rigors depending on what phase each of our respective therapeutic candidates is in with respect to its drug development process. We and our third-party manufacturers and our partners' manufacturers may not be able to comply with applicable laws, regulations, and guidelines. We and our third-party manufacturers and our partners' manufacturers are, and will be, subject to unannounced inspections by the FDA, state regulators and similar foreign regulatory authorities outside the U.S. Our failure, or the failure of our third-party manufacturers or our partners' manufacturers, to comply with applicable laws, regulations and guidelines could result in the imposition of sanctions on us, including fines, injunctions, civil penalties, delays or suspension of clinical trials, failure of regulatory authorities to grant marketing approval of our therapeutic candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of Talicia® and any future commercial products and therapeutic candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect regulatory approval and supplies of Talicia® and any future commercial products and therapeutic candidates, and materially and adversely affect our reputation, business, financial condition or results of operations.

Furthermore, changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, will require prior FDA or other regulatory review or approval of the manufacturing process and procedures in accordance with the FDA's regulations or comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch or commercial production of a product. The new facility will also be subject to pre-approval inspection. In addition, we will have to demonstrate that the product made at the new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time-consuming. It is also possible that the FDA may require clinical testing as a way to prove equivalency, which would result in additional costs and delay, and may also result in delays in approval or commercialization of a product or render it unfeasible.

Talicia® , and any product we may commercialize or promote in the future, even if all regulatory clearances and approvals are obtained, will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and applicable foreign laws, regulations, and guidelines, we could lose those clearances and approvals, and our reputation, business, financial condition or results of operations may be materially and adversely affected.

We or our development or commercialization partners, as applicable, are and will be subject to ongoing reporting obligations with respect to Talicia®, RHB-102 and any cleared or approved product that we may develop, commercialize or promote in the future, including pharmacovigilance, and with respect to our therapeutic candidates, even if they receive regulatory clearance or approval. In addition, the manufacturing of Talicia®, the development of RHB-102 and any other product we may develop, commercialize or promote, whether currently or in the future, and our therapeutic candidates, will be subject to continuing regulatory review and approval, including inspections by the FDA and other foreign regulatory authorities. The results of any ongoing review may result in withdrawal from the market of Talicia® , RHB-102 or products we may develop, commercialize or promote in the future, interruption of manufacturing or development operations or imposition of labeling or marketing limitations for such commercial or development products or therapeutic candidate, or other potentially significant enforcement actions. Since many more patients are exposed to drugs following their marketing clearance or approval, serious adverse reactions that were not observed in clinical trials may occur during the commercial marketing of Talicia® , the development of RHB-102 or any product we may develop, commercialize or promote in the future, including therapeutic candidates.

If a product receives regulatory approval, the approval is limited to the specific indications for use identified in the approved marketing application and by any additional requirements, restrictions, and limitations identified at the time of the product's approval or thereafter, which could restrict the commercial value of the product. As a condition of approval or after approval (if the FDA becomes aware of new safety information), the FDA may require us to implement a Risk Evaluation and Mitigation Strategy (REMS), which may include distribution or use restrictions to manage a known or potential serious risk associated with the product. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of a given drug. Once adopted, REMS are subject to periodic assessment and modification. Additionally, the FDA may require post-approval, "Phase 4" clinical trials to generate additional information on safety or efficacy. The results of such postmarketing studies may be negative and could cause the FDA to, among other things, further limit marketing efforts or a product's approved uses or even withdraw approval.

If we or our current or future development or commercialization partners, as applicable, are required to conduct additional clinical trials or other testing of Talicia®, RHB-102 or any other product we may develop, commercialize or promote, or of our therapeutic candidates, we may face substantial additional expenses, be delayed in obtaining marketing clearance or approval, if required by the FDA, or may never obtain marketing clearance or approval for such product we may develop, commercialize or promote or therapeutic candidate.

Third-party manufacturers and the manufacturing facilities that we and our development or commercialization partners use to manufacture Talicia® , develop RHB-102 and any other products that we may develop, commercialize or promote, and therapeutic candidate, will be subject to periodic review and inspection by the FDA and may be subject to similar review by other regulatory authorities. Later discovery of previously unknown problems with Talicia® , RHB-102 and products we may develop, commercialize or promote, or any therapeutic candidate, manufacturer or manufacturing process, or failure to comply with rules and regulatory requirements, may result in actions, including but not limited to the following:

- restrictions on such therapeutic candidate, marketed product, manufacturer or manufacturing process;
- warning letters from the FDA or other foreign regulatory authorities;
- withdrawal of the marketed product from the market;
- withdrawal of the therapeutic candidate from use in a clinical trial;
- suspension or withdrawal of regulatory approvals;
- refusal to approve pending applications or supplements to approved applications that we or our development or commercialization partners submit;
- voluntary or mandatory recall;
- fines;
- refusal to permit the import or export of Talicia® , RHB-102 or products that we may develop, commercialize or promote in the future or our therapeutic candidates;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; and
- adverse publicity.

If we or our current or future development or commercialization partners, suppliers, third-party contractors or clinical investigators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or the adoption of new regulatory requirements or policies, we and our development or commercialization partners may lose marketing clearance or approval for any products already cleared or approved for marketing in any jurisdiction, resulting in decreased or lost revenue from such products and could also result in other civil or criminal sanctions, including fines and penalties, and we may lose marketing clearance or approval of any of our therapeutic candidates, if any of our therapeutic candidates are approved for marketing.

We may encounter delays in receipt of FDA approval, if any, for our therapeutic candidates due to CMC, clinical studies, efficacy, safety, or regulatory or other issues.

We may encounter significant delays in receipt of FDA approval, if any, for our therapeutic candidates. For example, the FDA may determine that the CMC of one of our therapeutic candidates is not satisfactory due to the manufacturing standards of the products or that additional CMC work, information or quality assurances are needed. The FDA may also consider the clinical studies conducted with a therapeutic candidate and the additional information provided to be inadequate, or insufficient, or require us to provide additional information, which may require us to conduct additional studies or otherwise significantly delay potential FDA approval of the potential NDA for a therapeutic candidate, if at all. In addition, we cannot guarantee that potential future manufacturers or other vendors related to manufacturing will be able to perform as required, will not terminate their agreements with us, or otherwise will not perform satisfactorily. The potential delay in identifying, engaging, qualifying and training an alternative manufacturer may be extended, leading to a significant delay. Furthermore, the FDA may also change its clearance or approval policies or adopt new laws, regulations or guidelines in a manner that materially delays or impairs our ability to obtain approval of the potential NDA for a therapeutic candidate, if any.

If any of these or other issues occur, we may face substantial additional expenses and otherwise experience delays in obtaining FDA approval of the NDAs we may file in the future for our therapeutic candidates, including RHB-104/RHB-204 for Crohn's disease, or may never obtain the FDA approval for such NDAs.

Clinical trials and related non-clinical studies may involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We or our development or commercialization partners may not be able to obtain regulatory approvals for our therapeutic candidates or commercialize products we may commercialize or promote without completing such trials in accordance with the applicable regulatory standards, even products that may have already been cleared or approved for marketing.

We have limited resources and experience in conducting and managing the clinical trials that are required to obtain or maintain regulatory approvals and commence or continue commercial sales. Clinical trials and related non-clinical studies are expensive, complex, can take many years and have uncertain outcomes. We cannot predict whether we, independently or through third parties, will encounter problems with any of the completed, ongoing or planned clinical trials that will cause delays, including suspension of a clinical trial, delay of data analysis or release of the final report. The clinical trials of our therapeutic candidates may take significantly longer to complete than estimated. Failure can occur at any stage of the testing, and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could materially delay or prevent the obtainment of a regulatory approval of current or future therapeutic candidates and delay or prevent their commercialization. In addition, clinical trial results are subject to varying interpretations. Even if we consider a clinical trial successful, the FDA may find our data insufficient to support approval of an NDA, which may prevent our products from obtaining regulatory approval or may necessitate additional clinical trials.

In connection with the clinical trials for our therapeutic candidates and other therapeutic candidates that we may seek to develop in the future, either on our own or through licensing or partnering agreements, we face various risks and uncertainties, including but not limited to:

- delays or failure in securing clinical investigators or trial sites for the clinical trials;
- delays or failure in receiving import or other government approvals to ensure appropriate drug supply;
- delays or failure in obtaining institutional review board (IRB) and other regulatory approvals to commence or continue a clinical trial;
- expiration of clinical trial material before or during our trials as a result of delays, including suspension of a clinical trial, degradation of, or other damage to, the clinical trial material;
- negative or inconclusive results or results that are not sufficiently positive from clinical trials;
- the FDA or other foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical studies;
- the FDA or other foreign regulatory authorities may require us to conduct additional clinical trials or studies in connection with therapeutic candidates in development, as well as for products that have already been cleared and approved for marketing;

- inability to monitor patients adequately during or after treatment;
- inability to retain patients;
- lack of technology to support clinical trials results;
- problems with investigator or patient compliance with the trial protocols;
- a therapeutic candidate may not prove safe or efficacious; there may be unexpected or even serious adverse events and side effects from the use of a therapeutic candidate;
- the results with respect to any therapeutic candidate may not confirm the positive results from earlier preclinical studies or clinical trials;
- the results may not meet the level of statistical significance required by the FDA or other foreign regulatory authorities;
- the results may justify only limited or restrictive uses, including the inclusion of warnings and contraindications, which could significantly limit the marketability and profitability of a therapeutic candidate;
- the clinical trials may be delayed or not completed due to the failure to recruit suitable candidates or if there is a lower rate of suitable candidates than anticipated or if there is a delay in recruiting suitable candidates; and
- changes to the current regulatory requirements related to clinical trials, which can delay, hinder or lead to unexpected costs in connection with our receiving the applicable regulatory clearances or approvals.

A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier clinical trials. As such, despite the results reported in earlier clinical trials or related non-clinical studies of our therapeutic candidates, we do not know if we will be able to complete the clinical trials or related non-clinical studies we conduct or if such clinical trials will demonstrate adequate safety and efficacy sufficient to request and obtain regulatory approval to market our therapeutic candidates. If any of the clinical trials or related non-clinical studies of any of our current or future therapeutic candidates do not produce favorable results sufficient to support an application for marketing approval or are found to have been conducted in violation of the FDA's or other regulatory body's standards governing such studies, our ability to request and obtain regulatory approval for the therapeutic candidate may be adversely impacted, which could have a material adverse effect on our reputation, business, financial condition or results of operations.

If a validated lab test for MAP will not become available, our ability to develop or obtain approval for RHB-104/RHB-204 in Crohn's disease may be adversely impacted.

A validated lab test for the detection of MAP bacteria in Crohn's disease patients is likely to be required in order to advance this development program. We do not know if and when such a test for MAP will become available and we depend on third parties' resources and expertise in this area. If such a test for MAP will not become available, our ability to develop or obtain regulatory approval to market RHB-104/RHB-204 may be adversely impacted.

We rely on third parties to conduct our clinical trials and related non-clinical studies and those third parties may not perform satisfactorily, including but not limited to failing to meet established deadlines and compliance with applicable laws and regulations for the completion of such clinical trials.

We currently do not have the ability to independently conduct clinical trials and related non-clinical studies for our therapeutic candidates, and we rely on third parties, such as contract research organizations, medical institutions, contract laboratories, development and commercialization partners, clinical investigators and independent study monitors to perform these functions. Our reliance on these third parties for research and development activities reduces our control over these activities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Although we have, in the ordinary course of business, entered into agreements with such third parties, we continue to be responsible for confirming that each of our clinical trials and related non-clinical studies is conducted in accordance with its general investigational plan and protocol, as well as all applicable laws and regulations. For example, the FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices ("GCP"), for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected, and regulatory authorities in other jurisdictions may have similar responsibilities and requirements. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them or perform such functions independently. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, it may result in a delay of the affected trial and additional costs. Accordingly, we may be materially delayed in obtaining regulatory approvals, if any, for our therapeutic candidates and may be materially delayed in our commercialization efforts for the targeted indications.

In addition, our ability to bring our therapeutic candidates to market depends on the quality and integrity of data that we present to regulatory authorities in order to obtain marketing authorizations. Although we attempt to audit and control the quality of third-party data, we cannot guarantee the authenticity or accuracy of such data, nor can we be certain that such data has not been fraudulently generated. Furthermore, the FDA may consider clinical studies inadequate where steps have not been taken in the design, conduct, reporting, and analysis of the studies to minimize bias. For example, one potential source of bias in clinical studies is a clinical investigator with a financial stake in the outcome of the study. Accordingly, we (or the applicant of the IND or Biologics License Application, as applicable) must submit for all applicable clinical investigators either: (i) a completed Form FDA 3454 attesting to the absence of financial interests and arrangements described in the regulations, dated and signed by the chief financial officer or another responsible corporate official; or (ii) for any investigators for whom a Form FDA 3454 is not submitted, a Form FDA 3455 disclosing completely and accurately the following:

- any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of a covered clinical trial, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;
- any significant payments of other sorts from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;
- any proprietary interest in the tested product held by any clinical investigator involved in a study;
- any significant equity interest in the sponsor of the covered study held by any clinical investigator involved in any study; and
- any steps taken to minimize the potential for bias resulting from any of the disclosed arrangements, interests, or payments.

The FDA may refuse to accept a filing of an NDA that does not contain the required certifications and disclosures or attestations by the applicant that the applicant has acted with due diligence to obtain the information but was unable to do so and stating the reason. Additionally, FDA refusal of an NDA on potential bias grounds may have a material adverse effect on our reputation, business, financial condition or results of operations and the credibility of our other commercial products or therapeutic candidates.

We rely on contract research organizations for the management of clinical data generated from our studies, and such contract research organizations may not perform satisfactorily.

We rely on contract research organizations to provide monitors for and to manage data for our studies. Our reliance on these contract research organizations for data management reduces our control over clinical data management. While we have agreements governing their activities, we have limited influence over their actual performance. If these contract research organizations do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, we may be required to replace them, or our clinical studies may be extended, delayed or terminated. In addition, such failure of our contract research organizations would pose risks to the accuracy and usability of clinical data from our clinical studies. Replacing a contract research organization may result in a delay in our clinical studies and generation of data from such studies. In addition, we face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by contract research organizations, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology.

We may fail to receive or maintain the benefits from the orphan drug and QIDP designations granted by the FDA for our applicable products or therapeutic candidates, as applicable.

In the U.S., under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the U.S. In 2011, the FDA granted to RHB-104 orphan drug designation for the treatment of Crohn's disease in the pediatric population; in 2017, the FDA granted to opaganib orphan drug designation for the treatment of cholangiocarcinoma and granted to RHB-107 (upamostat, formerly Mesupron) orphan drug designation for the treatment of pancreatic cancer; in 2020, the FDA granted orphan drug designation to RHB-204 for the treatment of nontuberculous mycobacteria ("NTM") infections; and in 2024, the FDA granted opaganib orphan drug designation for the treatment of neuroblastoma, a type of childhood cancer.

In the U.S., the orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has the orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the original manufacturer is unable to assure sufficient product quantity.

Exclusive marketing rights from a given orphan drug designation may be limited if we 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 we are unable to assure sufficient quantities of the product to meet the needs of patients with the orphan-designated disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may receive and be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

In addition, in 2017, we announced that RHB-204 had been granted QIDP designation by the FDA for the treatment of pulmonary NTM infections. Like orphan drugs, QIDPs may take advantage of market exclusivity, which in the case of QIDPs is five years (total period of twelve years together with the orphan drug designation). However, the five-year exclusivity extension does not apply to a supplement to an application under Section 505(b) of the FDCA for any QIDP for which an extension is in effect or has expired; a subsequent application submitted with respect to a product approved by the FDA for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength; or a product that does not meet the definition of a QIDP under Section 505(g) based upon its approved uses.

Modifications to Talicia® or to any product that we may commercialize or promote in the future, or our therapeutic candidates, may require new regulatory clearances or approvals or may require us or our development or commercialization partners, as applicable, to recall or cease marketing any of our approved products, or delay further studies of our therapeutic candidates in human subjects until clearances or approvals are obtained.

Modifications to Talicia® and any products we may commercialize or promote, or to our therapeutic candidates, after they have been cleared or approved for marketing, if at all, may require new regulatory clearance or approvals, in particular, if we seek or are required to expand our operations to jurisdictions outside of the U.S., and, if necessitated by a problem with a marketed product, may result in the recall or suspension of marketing of the previously approved and marketed product until clearances or approvals of the modified product are obtained. The FDA and other regulatory authorities require pharmaceutical product and device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine in conformity with applicable laws, regulations, and guidelines that a modification may be implemented without pre-clearance by the FDA or other regulatory authorities. However, the FDA or other regulatory authorities can review a manufacturer's decision and may disagree. The FDA or other regulatory authorities may also, on their own initiative, determine that a new clearance or approval is required. If the FDA or other regulatory authorities require new clearances or approvals of any pharmaceutical product for which we or our partners, including development or commercialization partners, previously received marketing approval, we or our partners, including development or commercialization partners, may be required to recall and stop marketing such marketed product, which could require us or our partners, including development or commercialization partners, to redesign the marketed product and may cause a material adverse effect on our reputation, business, financial condition or results of operations.

Risks Related to Our Industry

The development of opaganib and RHB-107 have been supported by government-funded programs and thus may be subject to federal regulations such as "march-in" rights and certain reporting requirements, and compliance with such regulations may limit our exclusive rights and our ability to contract with manufacturers. In addition, the government is under no obligation to continue to support research and development of our products and can cease such support at any time which could be irreplaceable to the research and development process of our products.

Our intellectual property rights to opaganib, which we in-licensed from Apogee Biotechnology Corporation, have been generated through the use of U.S. federal and state government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in opaganib pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require the licensor to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that (i) adequate steps have not been taken to commercialize the invention, (ii) government action is necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations (also collectively referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if the licensor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. These rights of the government may affect us even though the U.S. government has not previously contacted us with respect to these intellectual property rights. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects. Intellectual property generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources.

In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the U.S. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the U.S. or that under the circumstances domestic manufacture is not commercially feasible. This preference for having products covered by such intellectual property be substantially manufactured in the U.S. may limit our ability to contract with non-U.S. product manufacturers or even U.S. product manufacturers whose manufacturing capacity is offshore.

The research and development of opaganib and RHB-107 has relied on support by the National Institutes of Health and the U.S. Department of Defense and other government bodies. These government bodies can withdraw, reduce or end their support of our products at any time, and this would significantly impair our ability to research and develop them further. In addition, the government is under no obligation to continue to support research and development of our products and can cease such support at any time which could be irreplaceable to the research and development process of our products as well as any current or future preclinical or clinical studies. For example, on January 30, 2025, we were notified that funding from the U.S. Government Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) for the ongoing 300-patient Phase 2 RHB-107 arm of the ACESO PROTECT platform trial for early COVID-19 outpatient treatment is subject to termination, requiring the study to cease enrollment on March 5, 2025, prior to completion. It is estimated that approximately 100 patients have been enrolled out of a fully enrolled target patient population of 300. Due to the reduced number of patients enrolled in this study, the study result may not lead to conclusions regarding the efficacy of RHB-107 in this trial.

Moreover, with the change in presidential administration that recently occurred in the United States, government spending programs have become even more difficult to predict and may be subject to greater risk. Considerable uncertainty exists regarding how future budget and program decisions will unfold, including the spending priorities of the new U.S. presidential administration and Congress and what challenges budget reductions may present for our industry generally or for our Company. In particular, U.S. President Trump recently attempted to place a widespread freeze on most federal grants and loans. Any freeze on government support for our products, programs or studies could significantly impair our research and development activities, business and operations.

The market for Talicia®, for any product we may commercialize or promote in the future and for our therapeutic candidates is rapidly changing and competitive, and new drug delivery mechanisms, drug delivery technologies, new drugs, generic products, treatments and products which may be developed by others could impair our ability to maintain and grow our business and remain competitive.

The pharmaceutical and biotechnology industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching, developing and marketing products designed to address the indications for which we are currently developing therapeutic candidates or may develop therapeutic candidates in the future or for which we may commercialize or promote products. There are various other companies that currently market, are in the process of developing or may develop in the future products that address all of the indications or diseases treated by Talicia®, products that we may commercialize or promote in the future, and our therapeutic candidates.

New drug delivery mechanisms, drug delivery technologies, new drugs and new treatments that have been developed or that are in the process of being developed or will be developed by others may render Talicia®, products we may commercialize or promote in the future and our therapeutic candidates noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic effects compared to Talicia®, products we may commercialize or promote in the future and our therapeutic candidates. In addition, Talicia® and products we may commercialize or promote in the future may compete with products of third parties for market share, and generic drugs or products that treat the same indications as Talicia® or products we may commercialize or promote in the future, which can have an adverse effect on our revenues by reducing our market share or requiring us to reduce the price of the products we market.

Talicia® primarily competes with several branded and generic therapies already approved and used extensively to treat H. pylori.

Technological competition from, and commercial capabilities of, pharmaceutical and biotechnology companies, universities, governmental entities, and others is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities, human resources, and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing, and other resources.

The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our formulations, Talicia® or products we may commercialize or promote in the future, even if commercialized and therapeutic candidates. Many of our targeted diseases and conditions can also be treated by other medications or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use, among other possible advantages. The established use of these competitive drugs may limit the potential for widespread acceptance of Talicia®, products we may commercialize or promote in the future and our therapeutic candidates.

Talicia® or any product for which we may obtain regulatory approval or acquire commercialization rights may not become or continue to be commercially viable products.

Other than Talicia®, none of our therapeutic candidates have been cleared or approved for marketing, and none of our therapeutic candidates are currently being marketed or commercialized in any jurisdiction. Even if any of our therapeutic candidates or any product we may commercialize or promote receives regulatory clearance or approval, such as Talicia®, or do not require regulatory clearance or approval, it may not become a commercially viable product. For example, even if we or our development or commercialization partners receive regulatory clearance or approval to market a therapeutic candidate or receive regulatory clearance or approval to commercialize or promote any product, the clearance or approval may be subject to limitations on the indicated uses or subject to labeling or marketing restrictions, which could materially and adversely affect their marketability and profitability. In addition, a new therapeutic candidate may appear promising at an early stage of development or after clinical trials but never reach the market, or it may reach the market but not result in sufficient product sales, if any. A therapeutic candidate or any product that we may commercialize or promote, may not result in commercial success for various reasons, including but not limited to:

- difficulty in large-scale manufacturing, including yield and quality;
- low market acceptance by physicians, healthcare payors, patients and the medical community as a result of lower demonstrated clinical safety or efficacy compared to products, prevalence, and severity of adverse side effects, or other potential disadvantages relative to alternative treatment methods;
- insufficient or unfavorable levels of reimbursement from government or third-party payors, such as insurance companies, health maintenance organizations and other health plan administrators;
- infringement on proprietary rights of others for which we or our development or commercialization partners have not received licenses;
- incompatibility with other therapeutic candidates or marketed products;
- other potential advantages of alternative treatment methods and competitive forces that may make it more difficult for us to penetrate a particular market segment, if at all;
- ineffective marketing, sales, and distribution activities and support;
- lack of significant competitive advantages over existing products on the market;
- lack of cost-effectiveness or unfavorable pricing compared to other alternatives available on the market;
- inability to generate sufficient revenues to sustain our business operations in accordance with our plan from the sale or marketing of a product in view of the economic arrangements that we have with commercialization or other partners;
- changes to labels, indications or other regulatory requirements as they relate to the commercialization of our products;
- inability to establish collaborations with third-party development or commercialization partners on acceptable terms, or at all, and our inability or unwillingness for cost or other reasons to commercialize the therapeutic candidates or any product we may commercialize or promote on our own; and
- timing of market introduction of competitive products, such as Voquezna.

Physicians, various other healthcare providers, patients, payors or the medical community, in general, may be unwilling to accept, utilize or recommend Talicia® and any product we may commercialize or promote. If we are unable, either on our own or through third parties, to manufacture, commercialize or market Talicia®, our proposed formulations, therapeutic candidates or any product we may commercialize or promote when planned, or to develop them commercially, we may not achieve any market acceptance or generate meaningful revenue.

Unexpected product safety or efficacy concerns may arise and cause any product we may commercialize or promote to fail to gain or lose market acceptance.

Unexpected safety or efficacy concerns can arise with respect to any product we may commercialize or promote, whether or not scientifically justified, potentially resulting in product recalls, withdrawals or declining sales, as well as product liability, consumer fraud or other claims. The market perception and reputation of any product we commercialize or may commercialize or promote in the future, and their safety and efficacy are important to our business and the continued acceptance of any such product. Any negative publicity about any of our current or future commercial products, such as the pricing of any product, discovery of safety issues, adverse events, or even public rumors about such events, could have a material adverse effect on our reputation, business, financial condition or results of operations. In addition, the discovery of one or more significant problems with a product similar to Talicia® or products we may commercialize or promote in the future that implicate (or are perceived to implicate) an entire class of products or the withdrawal or recall of such similar products could have an adverse effect on the current or future commercialization of any product we may commercialize or promote. New data about Talicia® or products that we may commercialize or promote in the future, or products similar to Talicia® or those we may commercialize or promote in the future, could cause us reputational harm and could negatively impact demand for such products due to real or perceived side effects or uncertainty regarding safety or efficacy and, in some cases, could result in product withdrawal. Any of the foregoing could have a material adverse effect on our reputation, business, financial condition or results of operations.

We could be adversely affected if healthcare reform measures substantially change the market for medical care or healthcare coverage in the U.S.

On March 23, 2010, President Obama signed the "Patient Protection and Affordable Care Act" (P.L. 111-148) (the "ACA") and on March 30, 2010, he signed the "Health Care and Education Reconciliation Act" (P.L. 111-152), collectively commonly referred to as the "Healthcare Reform Law." The Healthcare Reform Law included a number of new rules regarding health insurance, the provision of healthcare, conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients, and other healthcare policy reforms. Through the law-making process, substantial changes have been and continue to be made to the current system for paying for healthcare in the U.S., including changes made to extend medical benefits to certain Americans who lacked insurance coverage and to contain or reduce healthcare costs (such as by reducing or conditioning reimbursement amounts for healthcare services and drugs, and imposing additional taxes, fees, and rebate obligations on pharmaceutical and medical device companies). This legislation was one of the most comprehensive and significant reforms ever experienced by the U.S. in the healthcare industry and has significantly changed the way healthcare is financed by both governmental and private insurers. This legislation has impacted the scope of healthcare insurance and incentives for consumers and insurance companies, among others. Additionally, the Healthcare Reform Law's provisions were designed to encourage providers to find cost savings in their clinical operations. Pharmaceuticals represent a significant portion of the cost of providing care. This environment has caused changes in the purchasing habits of consumers and providers and resulted in specific attention to the pricing negotiation, product selection and utilization review surrounding pharmaceuticals. This attention may result in Talicia®, products we may commercialize or promote in the future, and our therapeutic candidates, being chosen less frequently or the pricing being substantially lowered. At this stage, it is difficult to estimate the full extent of the direct or indirect impact of the Healthcare Reform Law on us.

These structural changes could entail further modifications to the existing system of private payors and government programs (such as Medicare, Medicaid, and the Children's Health Insurance Program), creation of government-sponsored healthcare insurance sources, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the U.S. could impact the reimbursement for prescribed drugs and pharmaceuticals, including Talicia®, those we and our development or commercialization partners are currently developing or those that we may commercialize or promote in the future. If reimbursement for the products we currently commercialize or promote, any product we may commercialize or promote, or approved therapeutic candidates is substantially reduced or otherwise adversely affected in the future, or rebate obligations associated with them are substantially increased, it could have a material adverse effect on our reputation, business, financial condition or results of operations.

Extending medical benefits to those who currently lack coverage will likely result in substantial costs to the U.S. federal government, which may force significant additional changes to the healthcare system in the U.S. Much of the funding for expanded healthcare coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of care and increased enforcement activities. Cost of care could be reduced further by decreasing the level of reimbursement for medical services or products (including Talicia®, our development or commercialization partners or any product we may commercialize or promote, or those therapeutic candidates currently being developed by us), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for Talicia®, any product we may commercialize or promote, or any therapeutic candidate, or for which we receive marketing approval in the future, could have a material adverse effect on our reputation, business, financial condition or results of operations.

Several states and private entities initially mounted legal challenges to the Healthcare Reform Law, in particular, the ACA, and they continue to litigate various aspects of the legislation. On June 28, 2012, the U.S. Supreme Court generally upheld the provisions of the ACA at issue as constitutional. However, the U.S. Supreme Court held that the legislation improperly required the states to expand their Medicaid programs to cover more individuals. As a result, states have a choice as to whether they will expand the number of individuals covered by their respective state Medicaid programs. Some states have not expanded their Medicaid programs and have chosen to develop other cost-saving and coverage measures to provide care to currently uninsured individuals. Many of these efforts to date have included the institution of Medicaid-managed care programs. The manner in which these cost-saving and coverage measures are implemented could have a material adverse effect on our reputation, business, financial condition or results of operations.

Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Legislative initiatives to modify, limit, replace, or repeal the ACA and judicial challenges have continued. We cannot predict the impact on our business of future legislative and legal challenges to the ACA or other aspects of the Healthcare Reform Law or other changes to the current laws and regulations. The financial impact of U.S. healthcare reform legislation over the next few years will depend on a number of factors, including the policies reflected in implementing regulations and guidance and changes in sales volumes for therapeutics affected by the legislation. From time to time, legislation is drafted, introduced and passed in the U.S. Congress that could significantly change the statutory provisions governing coverage, reimbursement, and marketing of pharmaceutical products. In addition, third-party payor coverage and reimbursement policies are often revised or interpreted in ways that may significantly affect our business and our products.

During his first term in office, President Trump supported the repeal of all or portions of the ACA. President Trump also issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the ACA and in which he directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the ACA to the maximum extent permitted by law. Congress has enacted legislation that repeals certain portions of the ACA, including but not limited to the Tax Cuts and Jobs Act, passed in December 2017, which included a provision that eliminates the penalty under the ACA's individual mandate, effective January 1, 2019, as well as the Bipartisan Budget Act of 2018, passed in February 2018, which, among other things, repealed the Independent Payment Advisory Board (which was established by the ACA and was intended to reduce the rate of growth in Medicare spending).

Additionally, in December 2018, a district court in Texas held that the individual mandate is unconstitutional and that the rest of the ACA is, therefore, invalid. On appeal, the Fifth Circuit Court of Appeals affirmed the holding on the individual mandate but remanded the case back to the lower court to reassess whether and how such holding affects the validity of the rest of the ACA. The Fifth Circuit's decision on the individual mandate was appealed to the U.S. Supreme Court. On June 17, 2021, the Supreme Court held that the plaintiffs (comprised of the state of Texas, as well as numerous other states and certain individuals) did not have standing to challenge the constitutionality of the ACA's individual mandate and, accordingly, vacated the Fifth Circuit's decision and instructed the district court to dismiss the case. As a result, the ACA will remain in-effect in its current form for the foreseeable future; however, we cannot predict what additional challenges may arise in the future, the outcome thereof, or the impact any such actions may have on our business.

The Biden administration also introduced various measures in 2021 focusing on healthcare and drug pricing, in particular. For example, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. 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. On the legislative front, the American Rescue Plan Act of 2021 was signed into law on March 11, 2021, which, in relevant part, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source drugs and innovator multiple source drugs, which began on January 1, 2024. And, in July 2021, the Biden administration released an executive order entitled, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response, on September 9, 2021, HHS released a "Comprehensive Plan for Addressing High Drug Prices" that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. On August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (which was first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA also authorizes HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. We cannot yet assess the impact that the IRA will have on the pharmaceutical industry, but it will likely be significant.

There is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the U.S. or the effect of any future legislation or regulation, which uncertainty is even greater given the new Trump administration. Furthermore, we cannot predict what actions the Trump administration will implement in connection with the Health Reform Law during President Trump's second term. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the U.S. in the future. For example, any changes that reduce, or impede the ability to obtain, reimbursement for the type of products we currently, or intend to, commercialize in the U.S. or that reduce medical procedure volumes could adversely affect our operations and/or future business plans.

Third-party payors may not adequately reimburse customers for any of our products that we may commercialize or promote, including Talicia®, and may impose coverage restrictions or limitations such as prior authorizations and step edits that affect their use.

Our revenues and profits depend heavily upon the availability of adequate reimbursement for the use of Talicia®, and any products that we may commercialize or promote, from governmental or other third-party payors, both in the U.S. and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that the use of an approved or cleared therapeutic candidate or product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a product that we may commercialize or promote, including Talicia®, from any government, commercial or other third-party payor is a time-consuming and costly process that could require us or our development or commercialization partners to provide supporting scientific, clinical and cost-effectiveness data for the use of our products that we currently, or may, commercialize or promote to each payor. Even when a payor determines that a product that we currently or may commercialize or promote is eligible for reimbursement under its criteria, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or other foreign regulatory authorities, or may impose restrictions, such as prior authorization requirements, or may simply deny coverage altogether. Reimbursement rates may vary according to the use of the product that we commercialize or may commercialize or promote in the future and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for products or services, and may reflect budgetary constraints or imperfections in Medicare, Medicaid or other data used to calculate these rates. In particular, reimbursement for our products may not be available from Medicare or Medicaid, and reimbursement from other third-party payors may be limited, reduced or revoked. Overall, our ability to get reimbursement coverage for our commercial products has historically been limited. Successful commercialization of Talicia® and any future commercial products requires a conducive reimbursement environment. If our products do not receive adequate reimbursement coverage, or if reimbursement coverage is reduced or otherwise adversely affected, then their respective commercial prospects could be severely limited. Although certain payors may currently provide some form of coverage for Talicia®, payors may suspend or discontinue reimbursement at any time, may require or increase co-payments from patients, may impose restrictions or limitations on coverage, or may reduce reimbursement rates for our products. If we fail to establish broad adoption of and reimbursement for Talicia® and any future commercial products, or if we are unable to maintain any existing reimbursement from payors, our ability to generate revenue could be harmed and this could have a material adverse effect on our reputation, business, financial condition or results of operations. In addition to our existing commercial products, any new product we may commercialize or promote in the future may require that we expend substantial time and resources in order to obtain and retain reimbursement, and any of these efforts may not be successful.

In the U.S., there have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for any product that we currently or may commercialize or promote in the U.S. In addition, there is a growing emphasis on comparative effectiveness research, both by private payors and by government agencies. To the extent other drugs or therapies are found to be more effective than our products, payors may elect to cover such therapies in lieu of our products or reimburse our products at a lower rate. Legislation that reduces reimbursement for our current or future commercial products could adversely impact how much or under what circumstances healthcare providers will prescribe or administer those products. This could materially and adversely impact our reputation, business, financial condition or results of operations by reducing our ability to continue to generate meaningful revenue, raise capital, obtain additional collaborators and market share. At this stage, we are unable to estimate the extent of the direct or indirect impact of any such federal and state proposals.

Furthermore, the Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both the Centers for Medicare and Medicaid Services and other third-party payors may have sufficient market power to demand significant price reductions. Price reductions or other significant coverage policies or payment limitations could materially and adversely affect our reputation, business, financial condition or results of operations.

We are subject to U.S. federal and state healthcare laws and regulations relating to our business, and our failure to comply with such laws could have a material adverse effect on our reputation, business, financial condition or results of operations.

We are subject to additional healthcare regulation and enforcement by the U.S. federal government and the states in which we conduct or will conduct our business. Healthcare providers, physicians, and third-party payors play a primary role in the recommendation and prescription of Talicia® or any products we may commercialize or promote in the future. Our arrangements with third-party payors, customers, employees, or others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our products. The laws that may affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under government healthcare programs such as the Medicare and Medicaid programs;
- the federal Anti-Inducement Law (also known as the Civil Monetary Penalties Law), which prohibits a person from offering or transferring remuneration to a Medicare or State healthcare program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State healthcare program;
- the Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients for certain designated health services where that physician or family member has a financial relationship with the entity providing the designated health service, unless an exception applies;
- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government healthcare programs that are false or fraudulent;
- the so-called federal "Sunshine Act", which requires certain pharmaceutical and medical device companies to monitor and report certain financial relationships with physicians and other healthcare providers to the Centers for Medicare and Medicaid Services for disclosure to the public;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and its implementing regulations, which impose obligations on certain covered entities and their business associates with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals, regulatory authorities, and potentially the media of certain breaches of security of individually identifiable health information;
- HIPAA's fraud and abuse provision, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the FDCA, which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Compliance efforts may involve substantial costs, and if our operations or business arrangements with third parties are found to be in violation of any such requirements, we may be subject to penalties, including civil or criminal penalties, monetary damages, the curtailment or restructuring of our operations, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely affect our financial results. Although effective compliance programs can help mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any violation of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, financial condition or results of operations.

The Healthcare Reform Law also imposes reporting requirements on certain medical device and pharmaceutical manufacturers, among others, to make annual public disclosures of certain payments and other transfers of value to physicians (and certain other healthcare providers) and teaching hospitals and ownership or investment interests held by physicians or their immediate family members. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not reported. In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing, medical directorships, and other purposes. Some states impose a legal obligation on companies to adhere to voluntary industry codes of behavior (e.g., the PhRMA Code and the AdvaMed Code of Ethics), which apply to pharmaceutical and medical device companies' interactions with healthcare providers; some mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians, and some states limit or prohibit such gifts.

Most recently, there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in the enactment (or proposal) of federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, several states have passed or introduced bills designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

The scope and enforcement of these laws are uncertain and subject to change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and guidance. We cannot predict the impact that new legislation or any changes in existing legislation will have on our reputation, business, financial condition, or results of operations. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, financial condition or results of operations. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming and could negatively and adversely affect our business or results of operations.

Our marketing, promotional and business practices, including with respect to pricing, as well as the manner in which sales forces interact with purchasers, prescribers and patients, are subject to extensive regulation, including but not limited to, state and federal anti-kickback laws and any material failure to comply could result in significant sanctions against us.

The marketing, promotional, and business practices, including with respect to pricing, of pharmaceutical companies, as well as the manner in which companies' in-house or third-party sales forces interact with purchasers, prescribers, and patients, are subject to extensive regulation, the enforcement of which may result in the imposition of civil or criminal penalties, injunctions, or limitations on marketing practices for some of our products or pricing restrictions or mandated price reductions for some of our products. Many companies have been the subject of claims related to these practices asserted by state or federal authorities. These claims have resulted in fines and other consequences, such as entering into corporate integrity agreements with the U.S. government. Companies may not promote drugs for "off-label" use, that is, uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. A company that is found to have improperly promoted drug products for off-label use may be subject to significant liability, including civil and administrative remedies, as well as criminal sanctions. In addition, enforcement action against us or any of our current or future commercialization partners could cause management's attention to be diverted from our business operations and damage our reputation.

We could be exposed to significant drug product liability claims which could be time-consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage.

The clinical trials that we conduct and the testing, manufacturing, marketing, and commercial sale and use or misuse of our therapeutic candidates and any products we may commercialize or promote, involve and will involve an inherent risk that significant liability claims may be asserted against us or our development or commercial partners. Product liability claims, or other claims related to our therapeutic candidates and any products we may commercialize or promote, regardless of merit or their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. A product liability claim could also significantly harm our reputation and the market price of our shares and decrease demand for Talicia®, products that we commercialize or promote or that are commercialized or promoted by our commercial partners, and delay market acceptance of our therapeutic candidates or products we may commercialize or promote. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for approved products;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- litigation costs;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to receive regulatory approval for and commercialize our therapeutic candidates, upon approval, if any, in the future.

We and our research and development or commercialization partners currently have product-liability policies that include coverage for our clinical trials and our commercial operations. However, our insurance may prove inadequate to cover claims or litigation costs, especially in the case of wrongful death claims. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of Talicia® or products we may commercialize or promote in the future, or the development of our therapeutic candidates.

Our clinical trials may indicate unexpected serious adverse events or other adverse events or undesirable side effects that may harm our reputation, business, financial condition or results of operations. Serious adverse events identified during one of our Expanded Access Programs (EAPs) may present additional risks that may adversely affect our development of the therapeutic candidates involved in the applicable EAP.

As is the case with pharmaceuticals generally, certain side effects and adverse events may emerge as safety risks associated with the use of our therapeutic candidates. Similarly, serious adverse events have occurred and may occur in the future in connection with our clinical trials. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our therapeutic candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug-related side effects could 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 have a material adverse effect on our reputation, business, financial condition or results of operations.

Patients who receive access to investigational new drugs that have not yet received regulatory marketing approval through expanded access programs may be suffering from life-threatening illnesses and poor prognosis and may have exhausted all other available therapies. The risk for serious adverse events in this patient population is high, which could have a negative impact on the prospects of our therapeutic candidates that are provided under the EAP.

Serious adverse events or other undesirable side effects in connection with the use of our therapeutic candidates provided under the EAP could cause significant delays or an inability to successfully develop or commercialize such therapeutic candidates, which could materially harm our business. In particular, any such serious adverse events or other undesirable side effects could cause us or regulatory authorities to interrupt, delay or halt non-clinical studies and clinical trials, or could make it more difficult for us to enroll patients in our clinical trials. If serious adverse events or other undesirable side effects, or unexpected characteristics of our investigational new drugs that have not yet received regulatory marketing approval are observed in patients who were granted expanded access to our investigational new drugs under the EAP, further clinical development of such therapeutic candidate may be delayed or we may not be able to continue development of such therapeutic candidates at all, and the occurrence of these events could have a material adverse effect on our business. Undesirable side effects caused by our therapeutic candidates could also result in the delay or denial of regulatory approval by the FDA or other regulatory authorities or in a more restrictive label than we expect and could cause us to incur additional costs.

Global economic conditions may make it more difficult for us to commercialize Talicia® and any products that we may commercialize or promote in the future and develop our therapeutic candidates.

The pharmaceutical industry, like other industries and businesses, continues to face the effects of the challenging economic environment. Patients experiencing the effects of the challenging economic environment, including increases in co-pays, may switch to generic products, delay treatments, skip doses or use other less effective treatments to reduce their costs. Challenging economic conditions in the U.S. include the demands by payors for substantial rebates and formulary restrictions limiting access to brand-name drugs. In addition, in Europe and in a number of emerging markets there are government-mandated reductions in prices for certain pharmaceutical products, as well as government-imposed access restrictions in certain countries. All of the aforesaid may make it more difficult for us to commercialize Talicia®, any products that we may commercialize or promote, and our therapeutic candidates, upon approval, if any.

Tariff policies and potential countermeasures could increase our costs and disrupt our supply chain, which could negatively impact the results of our operations.

U.S. President Trump has increased, and has indicated his willingness to continue to increase, the use of tariffs by the U.S. to accomplish certain U.S. policy goals. Such tariffs and any countermeasures could increase the cost of raw materials and components necessary for our operations, disrupt our supply chain and create additional operational challenges. Further, it is possible that government policy changes and related uncertainty about policy changes could increase market volatility. Because of these dynamics, we cannot predict the impact of any future changes to the U.S.'s or other countries' trading relationships or the impact of new laws or regulations adopted by the U.S. or other countries on our business. Such changes in tariffs and trade regulations could have a material adverse effect on our financial condition, results of operations and cash flows.

Our business involves risks related to handling regulated substances, which could severely affect our ability to commercialize Talicia® and any products that we may commercialize or promote in the future and to conduct research and development of our therapeutic candidates.

In connection with our or our development or commercialization partners' research and development activities, as well as the manufacture of commercial products, materials, and therapeutic candidates and any products that we may commercialize or promote in the future, we and our development or commercialization partners are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and waste. We and our research and development or commercialization partners may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development, as well as the activities of our commercial and clinical manufacturing and commercialization partners, both now and in the future, may involve the controlled use of hazardous materials, including, but not limited to, certain hazardous chemicals. We cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that could result and any such liability could exceed our resources.

Security breaches, loss of data, and other disruptions could compromise sensitive information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we may collect and store sensitive data, including intellectual property, compliance-related data, research data, our proprietary business information and that of our suppliers and business partners, technical information about our products, clinical trial plans as well as personally identifiable information of patients, clinical trial participants and employees. We also have outsourced elements of our information technology structure, and as a result, we are managing independent vendor relationships with third parties who may or could have access to our confidential information. Similarly, our business partners and other third-party providers possess certain of our sensitive data and confidential information. The secure maintenance of this information is critical to our operations and business strategy. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, cyber-fraud, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

We, our partners, vendors, and other third-party providers could be susceptible to attacks on our and their information security systems, which attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including criminal groups. Any such breach could compromise our and their networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, inappropriate disclosure of confidential or proprietary information or other loss of information, including our data being breached at third-party providers, could result in legal claims or proceedings, liability or financial loss under laws that protect the privacy of personal information, disrupt our operations, or our product development programs and damage our reputation, any of which could adversely affect our business. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store this critical information. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure or modification of confidential information. The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions.

A security breach or privacy violation that leads to disclosure or modification of or prevents access to consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws, require us to verify the correctness of database contents and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer a loss of reputation, financial loss, and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Any such breach or interruption could compromise our networks, and the information stored there could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as HIPAA and the General Data Protection Regulation (GDPR), and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform tests, provide test results, bill facilities or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare Company financial information, provide information about our current and future solutions and other patient and clinician education and outreach efforts through our websites, and manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our reputation, business, financial condition or results of operations. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

In addition, the interpretation and application of consumer, health-related, privacy and data protection laws in the U.S. and elsewhere are often uncertain, contradictory, and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our reputation, business, financial condition or results of operations. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

Risks Related to Our COVID-19 Therapeutic Candidates

Government involvement may limit the commercial success of our COVID-19 therapeutic candidate.

COVID-19 has been previously classified as a pandemic by public health authorities, and it is possible that one or more government entities may take actions that directly or indirectly have the effect of abrogating some of our rights or opportunities. If we were to develop an anti-viral therapeutic to COVID-19, the economic value of such therapeutic to us could be limited.

Separately, various government entities, including the U.S. and or other governments, have offered, and may continue offering incentives, such as those we received, grants and contracts to encourage additional investment by commercial organizations and drug development companies into preventative and therapeutic agents against COVID-19, which may have the effect of increasing the number of competitors and/or providing advantages to competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share for our COVID-19 candidates.

Supply chain and shipping disruptions may result in shipping delays, a significant increase in shipping costs, and could increase product costs and result in lost sales and reputational damage, which may have a material adverse effect on our business, operating results and financial condition.

Our third-party manufacturers and suppliers have experienced in the past, supply chain disruption and shipping disruptions, including disruptions or delays in loading container cargo in ports of origin or off-loading cargo at ports of destination, congestion in port terminal facilities, labor supply and shipping container shortages, inadequate equipment and persons to load, dock and offload container vessels, among others. In addition, recently there have been shipping disruptions in the Red Sea and surrounding waterways due to attacks on marine vessels by the Houthi movement, which controls part of Yemen. These disruptions may impact our ability to receive APIs and other materials and products from our manufacturers and suppliers, to distribute our products to our customers in a cost-effective and timely manner and to meet customer demand, all of which could have an adverse effect on our financial condition and results of operations. There can be no assurance that further unforeseen events impacting the supply chain will not have a material adverse effect on us in the future. Additionally, the impacts that supply chain disruptions have on our third-party manufacturers and suppliers are not within our control. It is not currently possible to predict how long it will take for these supply chain disruptions to cease or ease. Prolonged supply chain disruption that may impact us or our manufacturers and suppliers could interrupt product manufacturing, increase raw material and product lead times, increase raw material and product costs, impact our ability to meet customer demand and result in lost sales and reputational damage, all of which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Intellectual Property

We may be unable to adequately protect or enforce our rights to intellectual property, causing us to lose valuable rights. Loss of patent rights may lead us to lose market share and anticipated profits.

Our success depends, in part, on our ability, and the ability of our commercialization or development partners to obtain patent protection for our therapeutic candidates and any products that we may commercialize or promote, maintain the confidentiality of our trade secrets and know-how, operate without infringing or violating on the proprietary rights of others and prevent others from infringing or violating on our proprietary rights.

We try to protect our proprietary position by, among other things, filing U.S., European, and other patent applications related to our therapeutic candidates, inventions and improvements that may be important to the continuing development of Talicia® and any future commercial products and therapeutic candidates, and we plan to try to do the same with products we may acquire, commercialize or promote in the future, where this is possible.

Because the patent position of pharmaceutical companies involves complex legal and factual questions, we cannot predict the scope, validity or enforceability of patents with certainty. Our issued patents and the issued patents of our commercialization or development partners may not provide us with any competitive advantages, may be held invalid or unenforceable as a result of legal challenges by third parties or could be circumvented. Ownership of the patent rights we in-license from our commercialization or development partners or the patent rights to the products already approved for marketing that we develop, acquire or for which we acquire commercialization rights may be challenged, and as a result, the rights we in-license and the rights to products we acquire may turn out not to be exclusive or we may not actually have rights under the patents despite receiving representations from a commercialization or development partner. Our competitors may also independently develop drug delivery technologies or products similar to ours or design around or otherwise circumvent patents issued to, or licensed by, us. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in patents being issued. If these patents are issued, they may not provide us with proprietary protection or competitive advantages. The degree of future protection to be afforded by 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 our competitive advantage.

In the U.S., Europe, and other jurisdictions, patent applications are typically not published until 18 months after filing. In addition, many companies and universities do not publish their discoveries until after patent filings are made. This makes it difficult to be certain that we were the first to file for protection of the inventions or the first to invent the inventions. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the enforceability and scope of our patents and patent applications in the U.S., Europe, and other jurisdictions are uncertain and unpredictable. Any patents that we own may not provide sufficient protection against competitors and may be of insufficient scope to achieve our business objectives. Additionally, the patent filings of others might act as an impediment to our ability to commercialize our current or future commercial products.

Patent rights are territorial; thus, the patent protection we do have will only extend to those countries in which we have issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the U.S. and the European Union. Competitors may successfully challenge our patents, produce similar drugs or products that do not infringe our patents or produce drugs in countries where we have not applied for patent protection or that do not respect our patents. Furthermore, it is not possible to know the scope of claims that will be allowed in published applications, and it is also not possible to know which claims of granted patents, if any, will be deemed enforceable in a court of law.

In some cases, litigation may be necessary to enforce our patent rights. If we choose to take an infringing third party to court, the third party may challenge the validity or enforceability of our patent rights or may assert that their activities do not infringe our patents. Litigation is expensive and unpredictable, and we may not have the proper resources to pursue such litigation or to protect our patent rights. Moreover, there is the risk that the court will find that our patents are not valid or enforceable, or that the third party does not infringe our rights in these patents. Adverse results in any such litigation could materially impair our patent rights and our ability to prevent generic and other competition for our products. Such results might also materially affect our economics and our ability to require third parties to enter a license with us or to pay us a reasonable royalty for using our technology.

Changes in patent law and regulations in other countries or jurisdictions or changes in governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, in Europe, beginning June 1, 2023, European applications and patents may be subjected to the jurisdiction of the Unified Patent Court (UPC) for a single pan-European infringement action or revocation proceeding. European applications will for now have the option in certain circumstances, upon grant of a patent, of becoming a Unitary Patent that will be subject to the jurisdiction of the UPC. This is a significant change in European patent practice. As the UPC is a new court system with few decisions rendered, there is little precedent for parties to rely on at the court, increasing the uncertainty. The UPC may provide our competitors with a new forum to seek to centrally revoke our European patents if we do not opt our patents out of the UPC where permitted, and allows for the possibility of a competitor to obtain pan-European injunctions with their own UPC-designated European patents. As a single court system can invalidate a European patent, we, where applicable, may opt out of the UPC and as such, each European patent would then need to be challenged in each individual country and each infringement action pursued in each country. We cannot predict how future decisions by the any courts, or the United States Congress, or the USPTO, may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations, and prospects.

After the completion of the development and registration of our patents, third parties may still manufacture or market products in infringement of our patent-protected rights. Such manufacture or market of products in infringement of our patent-protected rights is likely to cause us damage and lead to a reduction in the prices of Talicia®, any product we may commercialize or promote, or any of our therapeutic candidates, thereby reducing our potential profits.

In addition, due to the extensive time needed to develop, test and obtain regulatory approval for our therapeutic candidates or any product we may commercialize or promote, any patents that protect our therapeutic candidate or any product we may commercialize or promote may expire early during commercialization. This may reduce or eliminate any market advantages that such patents may give us. Following patent expiration, we may face increased competition through the entry of generic products into the market and a subsequent decline in market share and profits.

In addition, in some cases, we may rely on our licensors to conduct patent and trademark prosecution, patent and trademark maintenance or patent and trademark defense on our behalf. Therefore, our ability to ensure that these patents and trademarks are properly prosecuted, maintained, or defended may be limited, which may adversely affect our rights in the commercialization of Talicia® and any future commercial products, development of our therapeutic candidates, and potential approval for marketing of our therapeutic products. Any failure by our licensors or commercialization or development partners to properly conduct patent and trademark prosecution, patent and trademark maintenance, patent and trademark enforcement, or patent defense could materially harm our ability to obtain suitable patent protection covering Talicia® and any future commercial products or therapeutic candidates or ensure freedom to commercialize the products in view of third-party patent rights, thereby materially reducing our potential profits.

If we are unable to protect the confidentiality of our inventions, trade secrets or know-how, such proprietary information may be used by others to compete against us.

In addition to filing patents, we generally try to protect our inventions, trade secrets, know-how, and technology by entering into confidentiality or non-disclosure agreements with parties that have access to them, such as our development or commercialization partners, employees, contractors, and consultants. We also enter into agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees, advisors, research collaborators, contractors and consultants while we employ or engage them. However, these agreements can be difficult and costly to enforce or may not provide adequate remedies. Any of these parties may breach the confidentiality agreements and willfully or unintentionally disclose our confidential information, or our competitors might learn of the information in some other way. The disclosure to, or independent development by, a competitor of any trade secret, know-how or other technology not protected by a patent could materially adversely affect any competitive advantage we may have over any such competitor.

To the extent that any of our employees, advisors, research collaborators, contractors or consultants independently develop, or use independently developed, intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises with respect to any proprietary right, enforcement of our rights can be costly and unpredictable, and a court may determine that the right belongs to a third party.

Legal proceedings or third-party claims of intellectual property infringement and other challenges may require us to spend substantial time and money and could prevent us from developing or commercializing Talicia® and any future commercial products and our therapeutic candidates.

The development, manufacture, use, offer for sale, sale or importation of Talicia® and any future commercial products or any of our therapeutic candidates may infringe on the claims of third-party patents or other intellectual property rights. Patentability, invalidity, freedom-to-operate or other opinions may be required to determine the scope and validity of third-party proprietary rights. The nature of claims contained in unpublished patent filings around the world is unknown to us and it is not possible to know which countries patent holders may choose for an extension of their filings under the Patent Cooperation Treaty or other mechanisms. We may also be subject to claims based on the actions of employees and consultants with respect to the usage or disclosure of intellectual property learned at other employers. The cost to us of any intellectual property litigation or other infringement proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation or defense of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may also absorb significant management time. Consequently, we are unable to guarantee that we will be able to manufacture, use, offer for sale, sell or import Talicia® and any future commercial products or of our therapeutic candidates in the event of an infringement action.

In the event of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could potentially limit our competitive advantage. Ultimately, we could be prevented from commercializing a therapeutic candidate and any products that we may commercialize or promote or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement or other claims, we are unable to enter into licenses on acceptable terms. This inability to enter into licenses or the ability to exclude others using proprietary rights could have a material adverse effect on our reputation, business, financial condition or results of operations.

We may be subject to other patent-related litigation or proceedings that could be costly to defend and uncertain in their outcome.

In addition to infringement claims against us, we may become a party to other patent litigation or proceedings before regulatory agencies, including post-grant review, inter parties review, interference or re-examination proceedings filed with the U.S. Patent and Trademark Office or opposition proceedings in other foreign patent offices regarding intellectual property rights with respect to our therapeutic candidates or any products that we may commercialize or promote, as well as other disputes regarding intellectual property rights with development or commercialization partners, or others with whom we have contractual or other business relationships. Post-issuance proceedings challenging patent claims validity are not uncommon, and we or our development or commercialization partners will be required to defend these procedures as a matter of course. Such procedures may be costly, and there is a risk that we may not prevail, which could harm our business significantly.

Risks Related to the ADSs

Our failure to regain and maintain compliance with Nasdaq's continued listing requirements could result in the delisting of the ADSs.

The ADSs are currently listed for trading on Nasdaq. We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum bid price requirement of $1.00 per ADS and a minimum shareholders' equity of $2.5 million, or risk delisting, which would have a material adverse effect on our business.

On March 11, 2024, we received a letter from Nasdaq indicating that for the thirty consecutive business days prior to March 11, 2024, the bid price for the ADSs had closed below the minimum $1.00 per ADS requirement for continued listing on Nasdaq under Nasdaq Listing Rule 5450(a)(1). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until September 9, 2024, to regain compliance. The letter stated that the Nasdaq staff will provide written notification that we have achieved compliance with Rule 5450(a)(1) if at any time before September 9, 2024, the bid price of the ADSs closed at $1.00 per ADS or more for a minimum of ten consecutive business days.

On August 20, 2024, we implemented a ratio change of the ADSs to the Company's non-traded ordinary shares from the previous ratio of one (1) ADS representing four hundred (400) ordinary shares to a new ratio of one (1) ADS representing ten thousand (10,000) ordinary shares. For ADS holders, the ratio change had the same effect as a one-for-25 reverse ADS split. On September 3, 2024, we regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market.

However, we may fail to maintain long-term compliance with such minimum bid price requirement and there is no assurance we would be able to successfully implement another ratio change. Moreover, we previously implemented two ratio changes of the ADSs to the Company's non-traded ordinary shares prior to receiving the letter from Nasdaq in March 2024. If we again fail to comply with such minimum bid price requirement, we may not be able to again implement a ratio change in compliance with applicable Nasdaq rules in the near term. In the event we are able to implement a ratio change, such ratio change could have the effect of causing us to not comply with other listing requirements of Nasdaq, such as the listing requirements related to publicly held shares.

Additionally, in the recent past, we did not meet the continued listing requirement for market value of publicly held shares ("MVPHS"), and only regained compliance with such requirement by transferring the listing of the ADSs to Nasdaq from the Nasdaq Global Market in November 2023. No assurance can be given that the price of the ADSs will not again be in violation of Nasdaq's minimum bid price requirement or the MVPHS requirement in the future.

Lastly, our consolidated financial statements for the year ended December 31, 2024 contained elsewhere in this Annual Report reflect a shareholders' equity of less than $2.5 million, which means we do not currently comply with the continued listing requirement to maintain a minimum shareholders' equity of $2.5 million, and we will be required to cure this non-compliance.

If we are unable to comply with a listing requirement of Nasdaq following a compliance, if any, that shall apply, the ADSs would likely be delisted.

Our failure to meet these requirements may result in our securities being delisted from Nasdaq. A delisting could substantially decrease trading in the ADSs, adversely affect the market liquidity of the ADSs as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws, adversely affect our ability to obtain financing on acceptable terms, if at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. Additionally, the market price of the ADSs may decline further and shareholders may lose some or all of their investment.

U.S. holders of ADSs may suffer adverse tax consequences if we were characterized as a passive foreign investment company.

Based on the current composition of our gross income and assets and on reasonable assumptions and projections no assurance can be given that we will not be treated as a passive foreign investment company (a "PFIC"), for U.S. federal income tax purposes for 2025. If we were characterized as a PFIC, U.S. holders of the ADSs may suffer adverse tax consequences such as (i) having gains realized on the sale of the ADSs treated as ordinary income rather than capital gain, not qualifying for the preferential rate otherwise applicable to dividends received in respect of the ADSs by individuals who are U.S. holders, and (ii) having interest charges apply to certain distributions by us and upon certain sales of the ADSs.

There has been a limited market for the ADSs. We cannot ensure investors that an active market will continue or be sustained for the ADSs on Nasdaq and this may limit the ability of our investors to sell the ADSs.

In the past, there was limited trading in the ADSs, and there is no assurance that an active trading market of the ADSs will continue or will be sustained. Limited or minimal trading in the ADSs has in the past, and may in the future, lead to dramatic fluctuations in market price and investors may not be able to liquidate their investment at all or at a price that reflects the value of the business.

While the ADSs began trading on Nasdaq in December 2012, on the Nasdaq Global Market in July 2018, and on Nasdaq again in December 2023, we cannot assure you that we will maintain compliance with all of the requirements for the ADSs to remain listed. Additionally, there can be no assurance that trading of the ADSs will be sustained or desirable.

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of applicable SEC and Nasdaq Stock Market requirements, which may result in less protection than is accorded to investors under rules applicable to domestic issuers.

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of those otherwise required under the Nasdaq Listing Rules for domestic issuers. For instance, we follow the home country practice in Israel with regard to, among other things, director nomination procedures and quorum at shareholders' meetings. In addition, we follow our home country law, instead of the Nasdaq Listing Rules, which require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity-based compensation plans, an issuance that will result in a change in control, certain transactions other than a public offering involving issuances of a 20% or more interest in us and certain acquisitions of the stock or assets of another company. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. domestic issuer listed on the Nasdaq Stock Market may provide less protection than is accorded to investors under the Nasdaq Listing Rules applicable to domestic issuers.

In addition, as a foreign private issuer, we are exempt from the rules and regulations under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as domestic companies whose securities are registered under the Exchange Act.

We are a non-accelerated filer, and we cannot be certain if the reduced disclosure requirements applicable to us will make the ADSs less attractive to investors.

We are currently a "non-accelerated filer", as that term is defined in the Securities Act. Accordingly, we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not a "non-accelerated filers," in particular, reduced disclosure obligations regarding exemptions from the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting. Decreased disclosures in our SEC filings due to our status as a "non-accelerated filer" may make it harder for investors to analyze our results of operations and financial prospects.

We cannot predict if investors will find the ADSs less attractive if we rely on exemptions applicable to non-accelerated filers. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and our ordinary share price may be more volatile.

We currently do not anticipate paying cash dividends, and accordingly, investors must rely on the appreciation in the ADSs for any return on their investment.

We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of our term loan facility prohibit us from paying dividends. Therefore, the success of an investment in the ADSs will depend upon any future appreciation in their value. There is no guarantee that the ADSs will appreciate in value or even maintain the price at which our investors have purchased their securities.

Investors in the ADSs may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, par value NIS 0.01 per share ("Ordinary Shares"), and, in some limited circumstances, investors in the ADSs may not receive dividends or other distributions on our Ordinary Shares and may not receive any value for them, if it is illegal or impractical to make them available to investors in the ADSs.

The depositary for the ADSs has agreed to pay to investors in the ADSs the cash dividends or other distributions it or the custodian receives on Ordinary Shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. Investors in the ADSs will receive these distributions in proportion to the number of Ordinary Shares such ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act of 1933, as amended, but that is not properly registered or distributed under an applicable exemption from registration. In these cases, the depositary may determine not to distribute such property and hold it as "deposited securities" or may seek to effect a substitute dividend or distribution, including net cash proceeds from the sale of the dividends that the depositary deems an equitable and practicable substitute. We have no obligation to register under U.S. securities laws any ADSs, Ordinary Shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, Ordinary Shares, rights or anything else to holders of ADSs. In addition, the depositary may deduct from such dividends or distributions its fees and may withhold amounts on account of taxes or other governmental charges to the extent the depositary believes it is required to make such withholding. This means that investors in the ADSs may not receive the same distributions or dividends as those we make to the holders of our Ordinary Shares, and, in some limited circumstances, investors in the ADSs may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to investors in the ADSs. These restrictions may cause a material decline in the value of the ADSs.

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

Holders of the ADSs may only exercise the voting rights with respect to the underlying Ordinary Shares in accordance with the provisions of the deposit agreement for the ADSs. Under Israeli law, the minimum notice period required to convene a shareholders' meeting is no less than 35 or 21 calendar days, depending on the proposals on the agenda for the shareholders' meeting. When a shareholders' meeting is convened, holders of the ADSs may not receive sufficient advance notice of a shareholders' meeting to permit them to cancel the ADSs and withdraw their Ordinary Shares to allow them to cast their vote with respect to any specific matter. In addition, the depositary and its agents may not be able to send voting instructions to holders of the ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to holders of the ADSs in a timely manner, but we cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their ADSs. Furthermore, the depositary and its agents are not responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of the ADSs may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they requested. In addition, in the capacity as an ADS holder, they are not able to call a shareholders' meeting.

The depositary for the ADSs gives us a discretionary proxy to vote our Ordinary Shares underlying ADSs if a holder of the ADSs does not give voting instructions, except in limited circumstances.

Under the deposit agreement for the ADSs, the depositary gives us a discretionary proxy to vote our Ordinary Shares underlying ADSs at shareholders' meetings if a holder of the ADSs does not give voting instructions, unless:

- we have instructed the depositary that we do not wish a discretionary proxy to be given;
- we have informed the depositary that there is substantial opposition as to a matter to be voted on at the meeting; or
- we have informed the depositary that a matter to be voted on at the meeting would have a material adverse impact on shareholders.

The effect of this discretionary proxy is that a holder of the ADSs cannot prevent our Ordinary Shares underlying such ADSs from being voted by us at our discretion, absent the situations described above. Holders of our Ordinary Shares are not subject to this discretionary proxy.

Risks Related to our Operations in Israel

We conduct some of our operations in Israel. Conditions in Israel, including the recent attack by Hamas and other terrorist organizations from the Gaza Strip and Israel's war against them, may affect our operations.

Because we are incorporated under the laws of the State of Israel and some of our operations are conducted in Israel, our business and operations are directly affected by economic, political, geopolitical and military conditions in Israel. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries and terrorist organizations active in the region. These conflicts have involved missile strikes, hostile infiltrations and terrorism against civilian targets in various parts of Israel, which have negatively affected business conditions in Israel.

In addition, Israel faces many threats from more distant neighbors, in particular, Iran. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements. Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could adversely affect our operations or results of operations and could make it more difficult for us to raise capital.

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. 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. In addition, since the commencement of these events, there have been continued hostilities along Israel's northern border with Lebanon (with the Hezbollah terror organization) and on other fronts from various extremist groups in the region, such as the Houthis in Yemen and various rebel militia groups in Syria and Iraq. In October 2024, Israel began limited ground operations against Hezbollah in Lebanon, and in November 2024, a ceasefire was brokered between Israel and Hezbollah. In addition, in April 2024 and October 2024, Iran (in concert with other regional actors) launched direct attacks on Israel involving hundreds of drones and missiles and has threatened to continue to attack Israel and is widely believed to be developing nuclear weapons. Such attacks may continue due to continuing tensions in the region. In addition, the collapse of the Assad regime in Syria in December 2024 has led to increased instability in the region. Additionally, Yemeni rebel group, the Houthis, launched a series of attacks on global shipping routes in the Red Sea, causing disruptions of supply chain. Any or all of these situations may potentially escalate in the future to more violent events which may affect Israel and us.

Although we currently do not expect the ongoing conflict to affect our customers, manufacturing, research and development, supply chain, commercialization activities and current clinical studies, which are all located in and/or take place outside of Israel, there can be no assurances that further unforeseen events will not have a material adverse effect on us or our operations in the future.

The Israel Defense Force (the "IDF"), the national military of Israel, is a conscripted military service, subject to certain exceptions. Following the October 7, 2023 attacks, the IDF called up more than 350,000 of its reserve forces to serve. One member of management is currently subject to military service in the IDF and has been called to serve. It is possible that there will be further military reserve duty call-ups in the future, which may affect our business due to a shortage of skilled labor and loss of institutional knowledge, and necessary mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, for example, may have unintended negative effects and adversely impact our results of operations, liquidity or cash flows.

Additionally, five members of our management team and 8 of our non-management employees reside in Israel. Shelter-in-place and work-from-home measures, government-imposed restrictions on movement and travel and other precautions taken to address the ongoing conflict may temporarily disrupt our management and employees' ability to effectively perform their daily tasks.

It is currently not possible to predict the duration or severity of the ongoing conflict or its effects on our business, operations and financial conditions. The ongoing conflict is rapidly evolving and developing, and could disrupt our business and operations, interrupt our sources and availability of supply and hamper our ability to raise additional funds or sell our securities, among others.

Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. The Israeli government is currently committed to cover the reinstatement value of direct damages that are caused by terrorist attacks or acts of war. However, there is no assurance that this government coverage will be maintained, or if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business.

Several countries, principally in the Middle East, restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies. In addition, there have been increased efforts by activists to cause companies and consumers to boycott Israeli goods based on Israeli government policies. Such business restrictions and boycotts, particularly if they become more widespread, may materially and adversely impact our business.

Furthermore, prior to the attacks by Hamas, the Israeli government was pursuing extensive changes to Israel's judicial system. This led to protests at various levels domestically, and investment banks and other investors have voiced concerns that the proposed changes may negatively impact the business environment in Israel. This may, in turn, could slow the flow of international investment and negatively affect our business, financial condition and prospects.

Because a certain portion of our expenses is incurred in currencies other than the U.S. dollar, our results of operations may be harmed by currency fluctuations and inflation.

Our reporting and functional currency is the U.S. dollar. Most of our revenues and royalty payments from our agreements with our development or commercialization partners are in U.S. dollars, and we expect our revenues from future licensing and co-promotion agreements to be denominated mainly in U.S. dollars or in Euros. We pay a substantial portion of our expenses in U.S. dollars; however, a portion of our expenses, including salaries of our employees in Israel and payment to part of our service providers in Israel and other territories, are paid in NIS and in other currencies. In addition, a portion of our financial assets is held in NIS and in other currencies. As a result, we are exposed to currency fluctuation risks. For example, if the NIS strengthens against the U.S. dollar, our reported expenses in U.S. dollars may be higher. In addition, if the NIS weakens against the U.S. dollar, the U.S. dollar value of our financial assets held in NIS will decline.

Provisions of the RedHill Biopharma Ltd. Award Plan, Israeli law, our articles of association and our change in control retention plan may delay, prevent or otherwise impede a merger with, or an acquisition of, our Company, or an acquisition of a significant portion of our shares, which could prevent a change in control, even when the terms of such a transaction are favorable to us and our shareholders.

Our Amended and Restated Award Plan (2010) (the "Award Plan") provides that all options granted by us will be fully accelerated upon a "hostile takeover" of us. A "hostile takeover" is defined in our Award Plan as an event in which any person, entity or group that was not an "interested party", as defined in the Israeli Securities Law – 1968, on the date of the initial public offering of our Ordinary Shares on the TASE, will become a "controlling shareholder" as defined in the Israel Securities Law, 1968, or a "holder," as defined in the Israeli Securities Law – 1968, of 25% or more of our voting rights or any merger or consolidation involving us, in each case without a resolution by our board of directors supporting the transaction. In addition, if a "Significant Event" occurs and following which the employment of a grantee with us or a related company is terminated by us or a related company other than for "Cause", and unless the applicable agreement provides otherwise, all the outstanding options held by or for the benefit of any such grantee will be accelerated and immediately vested and exercisable. A "Significant Event" is defined in our Award Plan as a consolidation or merger with or into another corporation approved by our board of directors in which we are the continuing or surviving corporation or in which the continuing or surviving corporation assumes the option or substitutes it with an appropriate option in the surviving corporation.

The Israeli Companies Law, 1999 (the "Israeli Companies Law"), regulates mergers, requires tender offers for acquisitions of shares or voting rights above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, a majority of each class of securities of the target company must approve a merger. Moreover, the Israeli Companies Law provides that certain purchases of securities of a public company are subject to tender offer rules. As a general rule, the Israeli Companies Law prohibits any acquisition of shares or voting power in a public company that would result in the purchaser holding 25% or more, or more than 45% of the voting power in the company, if there is no other person holding 25% or more, or more than 45% of the voting power in a company, respectively, without conducting a special tender offer. The Israeli Companies Law further provides that a purchase of shares or voting power of a public company or a class of shares of a public company which will result in the purchaser's holding 90% or more of the company's shares, class of shares or voting rights, is prohibited unless the purchaser conducts a full tender offer for all of the company's shares or class of shares. The purchaser will be allowed to purchase all of the company's shares or class of shares (including those shares held by shareholders who did not respond to the offer), if either (i) the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, or (ii) the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class. The shareholders, including those who indicated their acceptance of the tender offer (except if otherwise detailed in the tender offer document), may, at any time within six months following the completion of the tender offer, petition the court to alter the consideration for the acquisition. At the request of an offeree of a full tender offer which was accepted, the court may determine that the consideration for the shares purchased under the tender offer was lower than their fair value and compel the offeror to pay to the offerees the fair value of the shares. Such an application to the court may be filed as a class action.

In addition, the Israeli Companies Law provides for certain limitations on a shareholder that holds more than 90% of the company's shares, or class of shares.

Pursuant to our articles of association, the size of our board of directors may be no less than five persons and no more than eleven, including any external directors whose appointment is required under the law. The directors who are not external directors are divided into three classes, as nearly equal in number as possible. At each annual general meeting, the term of one class of directors expires, and the directors of such class are re-nominated to serve an additional three-year term that expires at the annual general meeting held in the third year following such election. This process continues indefinitely. Such provisions of our articles of association make it more difficult for a third party to effect a change in control or takeover attempt that our management and board of directors oppose.

In addition, we have adopted a change in control employee retention plan and entered into employment agreements providing for compensation to Company officers and employees in the event of a change in control (as defined by the plan and employment agreements), subject to the satisfaction of various conditions. See "Item 6 B. – Compensation – Change in Control Retention Plan."

Furthermore, Israeli tax considerations may, in certain circumstances, make potential transactions unappealing to us or to some of our shareholders. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of numerous conditions, including a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are restricted. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no actual disposition of the shares has occurred.

These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, or an acquisition of a significant portion of our shares, even if such an acquisition or merger would be beneficial to us or to our shareholders.

It may be difficult to enforce a U.S. judgment against us and our directors and officers in Israel or the U.S. or to serve process on our directors and officers.

We are incorporated in Israel. Most of our directors and executive officers reside outside of the U.S., and most of the assets of our directors and executive officers may be located outside of the U.S. Therefore, a judgment obtained against us or most of our executive officers and our directors in the U.S., including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the U.S. and may not be enforced by a U.S. or Israeli court. It may also be difficult to effect service of process on these persons in the U.S. or to assert U.S. securities law claims in original actions instituted in Israel.

The obligations and responsibilities of our shareholders are governed by Israeli law, which may differ in some respects from the obligations and responsibilities of shareholders of U.S. companies. Israeli law may impose obligations and responsibilities on a shareholder of an Israeli company that are not imposed upon shareholders of corporations in the U.S.

We are incorporated under Israeli law. The obligations and responsibilities of the shareholders are governed by our articles of association and Israeli law. These obligations and responsibilities differ in some respects from the obligations and responsibilities of shareholders in typical U.S.-based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith toward the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at the general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and interested party transactions requiring shareholder approval. In addition, a shareholder who knows that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. There is limited case law available to assist us in understanding the implications of these provisions that govern shareholders' actions. These provisions may be interpreted to impose additional obligations and responsibilities on our shareholders that are not typically imposed on shareholders of U.S. corporations.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful shareholder claims against us and may reduce the amount of money available to us.

The Israeli Companies Law and our articles of association permit us to indemnify our directors and officers for acts performed by them in their capacity as directors and officers. The Israeli Companies Law provides that a company may not exempt or indemnify a director or an officer nor enter into an insurance contract, which would provide coverage for any monetary liability incurred as a result of: (a) a breach by the director or officer of his duty of loyalty, except for insurance and indemnification where the director or officer acted in good faith and had a reasonable basis to believe that the act would not prejudice the company; (b) a breach by the director or officer of his duty of care if the breach was done intentionally or recklessly, except if the breach was solely as a result of negligence; (c) any act or omission done with the intent to derive an illegal personal benefit; or (d) any fine, civil fine, monetary sanctions, or forfeit imposed on the officer or director. Our articles of association provide that we may exempt or indemnify a director or an officer to the maximum extent permissible under law.

We have issued letters of indemnification to our directors and officers, pursuant to which we have agreed to indemnify them in advance for any liability or expense imposed on or incurred by them in connection with acts they perform in their capacity as a director or officer, subject to applicable law. The amount of the advance indemnity is limited to the higher of 25% of our then shareholders' equity, per our most recent annual financial statements, or $10 million.

Our indemnification obligations limit the personal liability of our directors and officers for monetary damages for breach of their duties as directors by shifting the burden of such losses and expenses to us. Although we have obtained directors' and officers' liability insurance, certain liabilities or expenses covered by our indemnification obligations may not be covered by such insurance or the coverage limitation amounts may be exceeded. As a result, we may need to use a significant amount of our funds to satisfy our indemnification obligations, which could severely harm our business or financial condition and limit the funds available to those who may choose to bring a claim against us. These provisions and resultant costs may also discourage us from bringing a lawsuit against directors and officers for breaches of their duties and may similarly discourage the filing of derivative litigation by our shareholders against the directors and officers even though such actions, if successful, might otherwise benefit our security holders.

Our Amended and Restated Articles of Association designate courts located either within the State of Israel, or the Federal District Courts of the United States, as the exclusive forum for certain litigation that may be initiated by our shareholders, which could limit our shareholders' ability to bring a favorable or convenient judicial forum for disputes with us.

Our Amended and Restated Articles of Association provide that, unless we consent in writing to the selection of an alternative forum, the Tel Aviv District Court (Economic Division in the State of Israel (or, if the Tel Aviv District Court does not have jurisdiction, and no other Israeli court has jurisdiction, the federal district court for the District of New York) shall be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our shareholders, and (3) any action asserting a claim arising pursuant to any provision of the Companies Law or the Israeli Securities Law 5728-1968, in all cases subject to the court's having personal jurisdiction over the indispensable parties named as defendants. In addition, the federal district courts of the United States for the District of New York shall be the exclusive forum for any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to these provisions.

This forum selection provision may limit shareholders' ability to bring a claim in a judicial forum for disputes that it finds favorable or convenient for disputes with us or our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, a court, including an Israeli court, could find these provisions of our Articles of Association to be inapplicable or unenforceable in respect of one or more of the specified types of actions or proceedings, which may require us to incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

General Risks

We must comply with the U.S. Foreign Corrupt Practices Act.

The U.S. Foreign Corrupt Practices Act (the "FCPA") applies to companies, such as us, with a class of securities registered under the Exchange Act. The FCPA to which various of our operations may be subject generally prohibits companies and their intermediaries from engaging in bribery or making other improper payments to officials for the purpose of obtaining or retaining business. In various jurisdictions, our operations require that we and third parties acting on our behalf routinely interact with government officials, including medical personnel who may be considered government officials for purposes of these laws because they are employees of state-owned or controlled facilities. Our policies mandate compliance with these anti-bribery laws; however, we operate in many parts of the world that have experienced governmental or private corruption to some degree. As a result, the existence and implementation of a robust anti-corruption program cannot eliminate all risks that unauthorized reckless or criminal acts have been or will be committed by our employees or agents. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties. Violations of the FCPA, or allegations of such violations, could disrupt our business and result in a material adverse effect on our reputation, business, financial condition or results of operations.

Future issuances or sales of ADSs could reduce the market price of the ADSs and result in dilution to our shareholders.

As of April 6, 2025, we had outstanding options to purchase up to an aggregate of 26,190,000 Ordinary Shares (equivalent to 2,619 ADSs) under our Award Plan and 98,401 outstanding Restricted Share Units ("RSUs"), each with respect to one ADS, which represents 10,000 of our Ordinary Shares. In addition, as of April 6, 2025, there were 3,001,613,300 Ordinary Shares (equivalent to 300,161 ADSs) reserved for issuance under our Award Plan (including Ordinary Shares subject to outstanding options and RSUs under such plan).

As of April 6, 2025, we also had outstanding warrants to purchase an aggregate of 560,662 ADSs. All warrants are exercisable at any time before April 3, 2029, subject to certain limitations and exceptions. The weighted average exercise price of the warrants is $29.60 per ADS, which is above the current market price of the ADSs, which was $2.05 per ADS based on the closing price of the ADSs on Nasdaq on April 7, 2025. The likelihood that the holders of our warrants will exercise their warrants, and the amount of any cash proceeds that we would receive upon such exercise, is dependent upon the market price of the ADSs. However, there is no guarantee that our outstanding warrants will be in the money prior to their respective expirations, and as such, they may expire worthless.

Future substantial issuance or sale of the ADSs or of securities exercisable, convertible or exchangeable into ADSs, or the perception that such sales may occur in the future, including sales of ADSs issuable upon vesting of RSUs and the exercise of options, warrants or other equity-based securities, may cause the market price of the ADSs to decline. To the extent that our outstanding options or warrants are exercised, additional shares of the ADSs will be issued, which will result in dilution to the holders of the ADSs and increase the number of shares of the ADSs eligible for resale in the public market. Sales of substantial numbers of such shares in the public market or the fact that such outstanding options and warrants may be exercised may cause the market price of the ADSs to decline.

The market price of the ADSs is subject to fluctuation, which could result in substantial losses by our investors. Volatility in the financial market could have a material adverse impact on the market price of the ADSs. This may affect the ability of our investors to sell their ADSs, and the value of an investment in the ADSs may decline.

The stock market in general and the market price of the ADSs on Nasdaq, in particular, are subject to fluctuation, and changes in the price of our securities may be unrelated to our operating performance. The market price of the ADSs on Nasdaq has fluctuated in the past, and we expect they will continue to do so. The market price of the ADSs is and will be subject to a number of factors, including but not limited to:

- our ability to execute our business plan, including commercialization of Talicia® and any future commercial products;
- our ability to satisfy our contractual obligations;
- our continued listing on Nasdaq or another securities exchange;
- announcements of technological innovations or new therapeutic candidates or new products approved for marketing by us or others;
- announcements by us of significant acquisitions, strategic partnerships, in-licensing, out-licensing, joint ventures or capital commitments;
- expiration or terminations of licenses, research contracts or other commercialization or development agreements;
- public concern as to the safety of drugs we, our commercialization or development partners or others market or develop;
- the volatility of market prices for shares of biopharmaceutical companies generally;
- success or failure of research and development projects;
- departure of or major events adversely affecting key personnel;
- developments concerning intellectual property rights or regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if the ADSs are covered by analysts;
- changes in government regulations or patent proceedings and decisions;
- developments by our development or commercialization partners; and

- general market conditions, geopolitical conditions and other factors, including factors unrelated to our operating performance.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of the ADSs and result in substantial losses by our investors.

Additionally, market prices for securities of biotechnology and pharmaceutical companies historically have been very volatile. The market for these securities has from time to time, experienced significant price and volume fluctuations for reasons unrelated to the operating performance of any one company. In the past, the COVID-19 pandemic resulted in significant financial market volatility and uncertainty. A resurgence of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of the ADSs. In the past, following periods of market volatility, shareholders have often instituted securities class action litigation and derivative actions. If we were involved in securities or other litigation, it could have a substantial cost and divert resources and attention of management from our business, even if we are successful.

Our business is subject to cybersecurity risks.

Our operations are increasingly dependent on information technologies and services. Threats to information technology systems associated with cybersecurity risks and cyber incidents or attacks continue to grow, and include, among other things, storms and natural disasters, terrorist attacks, utility outages, theft, viruses, phishing, malware, design defects, human error, and complications encountered as existing systems are maintained, repaired, replaced, or upgraded. Risks associated with these threats include, among other things:

- theft or misappropriation of funds;
- loss, corruption, or misappropriation of intellectual property, or other proprietary, confidential or personally identifiable information (including supplier, clinical data or employee data);
- disruption or impairment of our and our business operations and safety procedures;
- damage to our reputation with our potential partners, patients and the market;
- exposure to litigation;
- increased costs to prevent, respond to or mitigate cybersecurity events.

Although we utilize various procedures and controls to mitigate our exposure to such risk, cybersecurity attacks and other cyber events are evolving and unpredictable. Moreover, we have no control over the information technology systems of third parties conducting our clinical trials, our suppliers, and others with which our systems may connect and communicate. As a result, the occurrence of a cyber incident could go unnoticed for a period of time.

We cannot ensure that we have sufficient means to cover any particular losses we may experience as a result of cyberattacks. Any cyber incident could have a material adverse effect on our business, financial condition and results of operations.

We incur significant costs as a result of the listing of the ADSs on Nasdaq, and we may need to devote substantial time and resources to new and current compliance initiatives and reporting requirements.

As a public company in the U.S., we incur significant accounting, legal and other expenses as a result of the listing of our securities on Nasdaq. These include costs associated with the reporting requirements of the SEC and the requirements of the Nasdaq Listing Rules, as well as any applicable requirements under Section 404 and other provisions of the Sarbanes-Oxley Act. These rules and regulations have increased our legal and financial compliance costs, introduced new costs such as investor relations, travel costs, stock exchange listing fees, and shareholder reporting, and made some activities more time-consuming and costly. Any future changes in the laws and regulations affecting public companies in the U.S. and Israel, including any applicable requirements under Section 404 and other provisions of the Sarbanes-Oxley Act, the rules and regulations adopted by the SEC and the Nasdaq Listing Rules, as well as applicable Israeli reporting requirements, may result in an increase to our costs as we respond to such changes. These laws, rules, and regulations could make it more difficult and costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers and may require us to pay more for such positions.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our legal and commercial name is RedHill Biopharma Ltd. Our company was incorporated on August 3, 2009, and was registered as a private company limited by shares under the laws of the State of Israel. Our principal executive offices are located at 21 Ha'arba'a Street, Tel-Aviv, Israel, and our telephone number is 972-3-541-3131.

In February 2011, we completed our initial public offering in Israel, pursuant to which we issued 14,302,300 Ordinary Shares, and 7,151,150 tradable Series 1 Warrants to purchase 7,151,150 Ordinary Shares for aggregate gross proceeds of approximately $14 million. On December 27, 2012, we completed the listing of ADSs on Nasdaq, and on July 20, 2018, the ADSs were listed on the Nasdaq Global Market. On February 13, 2020, our Ordinary Shares were voluntarily delisted from trading on the Tel-Aviv Stock Exchange. On November 15, 2023, the ADSs were transferred from the Nasdaq Global Market to Nasdaq. The ADSs are currently traded on Nasdaq under the symbol "RDHL."

The Securities and Exchange Commission (the "SEC"), maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at http://www.sec.gov.

Our website address is http://www.redhillbio.com. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report.

Our capital expenditures for the years ended December 31, 2024, 2023, and 2022, were approximately $8,700, $9,500 and $25,000, respectively. Our current capital expenditures involve basic equipment and leasehold improvements.

B. Business Overview

We are a specialty biopharmaceutical company, primarily focused on GI, infectious diseases and oncology. Our primary goal is to become a leading specialty biopharmaceutical company.

We are currently focused primarily on the advancement of our development pipeline of clinical-stage therapeutic candidates. We also commercialize in the U.S. our GI-related product, Talicia® (omeprazole, amoxicillin, and rifabutin), and continue to explore our strategic plans for other potential products and activities.

Among our therapeutic candidates, we are exploring opaganib as a potential treatment for various conditions, including GI-ARS, viral infections such as COVID-19, Ebola virus disease and additional viruses as part of pandemic preparedness, several cancers and diabetes and obesity-related disorders. Furthermore, we are investigating RHB-107 (upamostat) as a potential treatment for COVID-19 and other viruses as part of pandemic preparedness, including the Ebola virus.

Our current pipeline consists of five therapeutic candidates, part of which are in late stage clinical development. We generate our pipeline of therapeutic candidates by identifying, validating and in-licensing or acquiring products that are consistent with our product and corporate strategy and that have the potential to exhibit a favorable probability of therapeutic and commercial success. We have one product, Talicia®, that we primarily developed internally which has been approved for marketing and, to date, none of our other therapeutic candidates has generated revenues. We have out-licensed our commercial product, Talicia®, for specific territories outside the U.S., and one of our therapeutic candidates, RHB-102, worldwide (except for the U.S., Canada, and Mexico). Furthermore, we plan to commercialize our therapeutic candidates, upon approval, if any, through licensing and other commercialization arrangements with pharmaceutical companies on a global and territorial basis or independently with a dedicated commercial operation or in potential partnership with other commercial-stage companies. We also evaluate, on a case-by-case basis, co-development, co-promotion, licensing, acquisitions and similar arrangements.

Our Strategy

Our goal is to become a leading specialty pharmaceutical company in the commercialization and development of pharmaceuticals for the treatment of GI, infectious diseases and oncology.

Key elements of our strategy are to:

- Identify and enter into out-licensing or collaborative agreements with third parties to develop and/or commercialize Talicia® and any future commercial products or therapeutic candidates;
- Enhance existing pharmaceutical products, including broadening their range of indications, or launching innovative and advantageous pharmaceutical products, based on existing active ingredients. Because there is a large knowledge base regarding existing products, the preclinical, clinical and regulatory requirements needed to obtain marketing approval for enhanced formulations are relatively well-defined. In particular, clinical trial designs, inclusion criteria and endpoints previously accepted by regulators may sometimes be re-used. In addition to reducing costs and time to market, we believe that targeting therapeutics with proven safety and efficacy profiles provides us with a better prospect of clinical success;
- Seek creative and resource-efficient ways to advance our pipeline despite liquidity constraints, including through grants, government and institutional partnerships, collaborations, and other funding mechanisms- including opportunistic transactions with entities that have available cash but limited operations - that align with our limited resources;
- Identify and acquire rights to products from pharmaceutical companies facing financial or operational challenges or seeking to divest assets. We focus on products addressing significant clinical needs, with strong market potential and IP protection, and also seek to diversify our portfolio by acquiring products based on different technologies. We source these opportunities through our broad industry network;
- Where applicable, utilize the FDA's 505(b)(2) regulatory pathway to potentially obtain more timely and efficient approval of our formulations of previously approved products. Under the 505(b)(2) process, we are able to seek FDA approval of a new dosage form, strength, route of administration, formulation, dosage regimen, or indication of a pharmaceutical product that has previously been approved by the FDA. This process enables us to partially rely on the FDA findings of safety or efficacy for previously approved drugs, thus avoiding the duplication of costly and time-consuming preclinical and various human studies. See "Item 4. Information on the Company – B. Business Overview – Government Regulations – Section 505(b)(2) New Drug Applications";
- Cooperate with third parties to develop or commercialize therapeutic candidates in order to share costs and leverage the expertise of others; and
- Consider potential acquisitions of other companies with or without commercial products, including combinations or strategic partnerships with companies that may have complementary assets, capabilities, or financial resources.

The pharmaceutical and biotechnology industries are intensely competitive. Our therapeutic candidates, if commercialized, and our approved drugs, compete with existing drugs and therapies. In addition, there are many pharmaceutical companies, biotechnology companies, medical device companies, public and private universities, government agencies and research organizations actively engaged in the research and development of products targeting the same markets as our therapeutic candidates. Many of these organizations have substantially greater financial, technical, manufacturing and marketing resources than we do. In certain cases, our competitors may also be able to use alternative technologies that do not infringe upon our patents to formulate the active materials in our therapeutic candidates. They may, therefore, bring to market products that are able to compete with our candidates, or other products that we may develop in the future.

Our Approved and Commercial Product in the U.S.

We have established the headquarters of our U.S. commercial operations in Raleigh, North Carolina. Our U.S. operations currently promote Talicia® for the treatment of H. pylori infection in adults. We are actively evaluating various strategic pathways. In the event of sustained operations, our U.S. operations could potentially serve as the platform for potential launch of our proprietary, late-clinical stage therapeutic candidates in the U.S., if approved by the FDA, and potential in-licensed or acquired commercial-stage products in the U.S.

Our U.S. commercial operations consisted of 11 employees as of December 31, 2024. The net revenues for the fiscal years ended December 31, 2024 and December 31, 2023 from the commercial products were approximately $7.0 million and $6.5 million, respectively. We continue to pursue the acquisition of additional commercial products, including, without limitation, through licensing or promotion transaction, asset purchase, joint venture with, acquisition of, or a merger with or other business combination with, companies with rights to commercial GI and other relevant assets and are continuously working to expand U.S. managed care access and coverage to Talicia®, where appropriate. We plan to pursue such opportunities in the U.S. and, if available, in other jurisdictions; however, we intend to focus our commercial activities in the U.S. We currently promote and commercialize Talicia® in the U.S.

Talicia® (omeprazole magnesium, amoxicillin, and rifabutin) delayed-release capsules 10.3 mg/250 mg/12.5 mg

Talicia® is our proprietary drug approved by the FDA for marketing in the U.S. for the treatment of *H. pylori* infection in adults. Talicia® is a combination of three approved drug products – omeprazole, which is a proton pump inhibitor (it prevents the secretion of hydrogen ions increasing the pH of the stomach), plus amoxicillin and rifabutin, which are antibiotics. Talicia® is administered to patients orally in the form of a fixed-dose, all-in-one capsule. Talicia® is the first product we developed that was approved for marketing in the U.S., which we launched in March 2020 with our dedicated sales force.

Chronic infection with *H. pylori* irritates the mucosal lining of the stomach and small intestine. The original discovery of *H. pylori* bacteria and its association with peptic ulcer disease warranted the Nobel Prize in 2005. *H. pylori* infection has since been associated with a variety of sequalae, including dyspepsia, peptic ulcer disease (duodenal ulcer and gastric ulcer), primary gastric B-cell lymphoma, vitamin B12 deficiency, iron deficiency, anemia, mucosa-associated lymphoid tissue (MALT) lymphoma, and gastric cancer (Vakil et al. J Clin Pharmacol. 2025; Malfertheiner et al. Nat Rev Dis Primers. 2024; National Toxicology Program. Report on Carcinogens, 15th ed. U.S. Dep. of Health and Human Services. 2021. Helicobacter pylori (Chronic Infection)).

Gastric cancer is one of the most prevalent cancers worldwide and one of the most common causes of cancer-related deaths, accounting for approximately 660,000 deaths in 2022, according to the World Health Organization (“WHO”) GLOBOCAN 2022 estimates. Chronic infection with H. pylori is the strongest known risk factor for the development of non-cardia gastric cancer (Moss. Cell Mol Gastroenterol Hepatol. 2017) and is responsible for nearly 90% of all cases (Morgan et al. eClinicalMedicine. 2022). Notably, confirmed eradication of H. pylori infection following treatment has been shown to reduce the risk of gastric cancer by approximately 75% (Kumar et al. Gastroenterology. 2020).

Talicia® is targeting a significantly broader indication than most other existing *H. pylori* therapies, as a treatment for *H. pylori* infection, regardless of ulcer status.

We acquired the rights to Talicia® pursuant to an agreement with Giaconda Limited. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – Acquisition of Talicia®, RHB-104, and RHB-106."

On December 5, 2021, we entered into an exclusive license agreement with Gaelan Medical for Talicia®, in the UAE. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – License Agreement with Gaelan Medical". On August 1, 2023, we announced that Gaelan Medical had received marketing approval for Talicia in the UAE and subsequently placed the first commercial order for Talicia®, which was dispatched from the CMO in December 2023. In August 2024, we announced the launch of Talicia® in the UAE.

In November 2022, we announced post hoc analyses of the Phase 3 clinical trials of Talicia® supporting the efficacy and safety of Talicia® as empiric first-line treatment for *H. pylori* infection in patients regardless of obesity, body mass index (BMI) or diabetic status.

Regulatory Status

On November 1, 2019, Talicia® was approved by the FDA and was granted a total of eight years of U.S. market exclusivity.

In November 2014, Talicia® was granted QIDP designation by the FDA. The QIDP designation was granted under the FDA's Generating Antibiotic Incentives Now (GAIN) Act, which is intended to encourage the development of new antibiotic drugs for the treatment of serious or life-threatening infections that have the potential to pose a serious threat to public health.

In September 2023, we announced that the FDA had approved our supplemental new drug application (sNDA) for Talicia®, allowing a change in dosing to a more flexible regimen, enabling patients to take Talicia® three times daily, at least 4 hours apart with food. This enables patients to follow a convenient "breakfast, lunch and dinner" dosing routine, which may support increased patient adherence and further optimize the potential for successful *H. pylori* eradication.

In November 2023, we announced that the FDA had officially granted Talicia® five years of additional market exclusivity via QIDP designation as provided by the GAIN Act. This grant is on top of the three years' exclusivity granted for the approval of Talicia® under section 505(b)(2). Talicia is protected by a patent portfolio with the latest patent to expire in 2042®.

In January 2024, we announced that U.S. Patent and Trademark Office (USPTO) issued a new patent covering Talicia® as a method for eradicating *H. pylori* regardless of BMI. The new patent is expected to provide protection for Talicia® until May 2042.

In March 2024, we announced that Talicia® had received a new U.S. patent covering its use as an all-in-one treatment for *H. pylori* infection, extending its patent protection until February 2034.

Market and Competition

H. pylori infection is the most common chronic bacterial infection among humans with a global prevalence estimated at over 40% and ranging from 30% to 40% in North America alone (Chey et al. Am J Gastroenterol. 2024). In the U.S., we estimate that approximately 2 million patients per annum are treated for H. pylori eradication, based on a 2021 RedHill-funded market assessment performed by IQVIA.

Resistance to key antibiotics used to treat H. pylori infection – such as clarithromycin, levofloxacin, and metronidazole – has been increasing globally, including in the U.S., leading to high treatment failure rates. In the U.S., it is estimated that resistance rates to clarithromycin, levofloxacin, and metronidazole have reached 31.5%, 37.6%, and 42.1%, respectively, with dual clarithromycin and metronidazole resistance rates reaching 11.7% (Ho J et al. Am J Gastroenterol. 2022). Research indicates that approximately 20% to 30% of patients treated for H. pylori fail first-line treatment in the U.S., with eradication rates falling to as low as 50% to 75% in some countries due to the development of antibiotic resistance (Cortes et al. J Prim Care Community Health. 2021). The newly updated 2024 American College of Gastroenterology (ACG) Guideline for the treatment of H. pylori infection also reports that in the presence of known clarithromycin resistance, the predicted eradication success rate of standard PPI-clarithromycin triple therapy drops below one-third of patients. The Guideline now advises against the use of clarithromycin in any treatment regimen without prior antimicrobial susceptibility testing. Furthermore, the Guideline now lists Talicia® as a first-line treatment option in treatment-naïve and treatment-experienced patients with H. pylori infection. Since Talicia® does not contain clarithromycin, it eliminates concerns regarding potential clarithromycin resistance and the need for prior antimicrobial susceptibility testing.

Talicia® is designed to address the high resistance of *H. pylori* bacteria to the antibiotics commonly used in current standard-of-care therapies. Its antibiotics - amoxicillin and rifabutin - have little to no known resistance in the U.S. (Graham, Ann Intern Med, 2020). Talicia's® approval was supported, in part, by the results of two positive Phase 3 studies in the U.S. for the treatment of *H. pylori*-positive adult patients complaining of epigastric pain and/or discomfort. The confirmatory Phase 3 study of Talicia® demonstrated 84% eradication of *H. pylori* infection with Talicia® vs. 58% in the active comparator (amoxicillin and omeprazole, equivalent to Talicia®, but without rifabutin) arm ($p<0.0001$). Further, in a prespecified subpopulation analysis of data from this study, it was observed that subjects with measurable blood levels of drug at Day 13 had response rates of 90.3% in the Talicia® arm vs. 64.7% in the active comparator arm.

Talicia® faces competition in the U.S. from certain branded prescription therapies indicated for the treatment of *H. pylori* infection including Pylera® (marketed by Juvisé Pharmaceuticals) and Voquezna®, DualPak and TriplePak (marketed by Phathom Pharmaceuticals) as well as from the generic version of Pylera® (first launched by Endo International and Novast Labs), and individual components of certain therapies which include but are not limited to Pylera and PrevPac. Additionally, the individual components of Talicia® are available in generic form, and while rifabutin is not available in an equivalent dose, there is a risk that some physicians may prescribe the individual components of Talicia® in doses that are not equivalent to the approved drug and regimen (Howden et al. Aliment Pharmacol Ther. 2023). We may also be exposed to potentially competitive products that may be under development to treat *H. pylori* infection.

We believe that Talicia® offers a significant benefit over other marketed drugs in part because of the efficacy, safety and tolerability, and resistance profile demonstrated in our Phase 3 program, which showed minimal to zero resistance to amoxicillin and rifabutin and high resistance to clarithromycin and metronidazole. Currently, Talicia® is the only rifabutin-based triple regimen approved by the FDA for the treatment of *H. pylori* infection in adults. Additionally, Talicia® offers an all-in-one capsule, whereas, to our knowledge, no U.S. competitors currently offer all constituents formulated into one capsule.

Aemcolo®

Aemcolo®, containing 194mg of rifamycin, is an orally administered, minimally absorbed antibiotic that is delivered to the colon, approved by the FDA in 2018 for the treatment of travelers' diarrhea caused by non-invasive strains of *E. coli* in adults. In October 2019, we entered into a license agreement, as amended, with a wholly-owned subsidiary of Cosmo Pharmaceuticals N.V. ("Cosmo") pursuant to which we were granted exclusive rights to commercialize Aemcolo® in the U.S. (the "Cosmo License Agreement"). On July 9, 2024, we announced the mutual decision with Cosmo to voluntary terminate the Cosmo License Agreement, and it was officially terminated on October 8, 2024.

Our Therapeutic Candidates

Summary

The ongoing development programs of our five therapeutic candidates, most in clinical development, include "opaganib", "RHB-107" (upamostat), "RHB-104", "RHB-102 (Bekinda®)", "RHB-204", and related research and development programs, the most advanced of which are described below.

Name of Therapeutic Candidate	Proposed Indication	Potential Advantages Over Most Existing Treatments, if Approved	Development Stage	Rights to the Product
Opaganib	Patients hospitalized with SARS-CoV-2 severe COVID-19 pneumonia	Oral administration, first-in-class SK2 selective inhibitor, with anti-inflammatory, antiviral and anti-cancer activities	U.S. Phase 2 study completed and data received; global Phase 2/3 completed and data received and submitted regulatory packages to regulatory authorities	We filed patent applications to protect the proposed commercial use
Opaganib	Prostate cancer	Oral administration, first-in-class SK2 selective inhibitor, sensitizes prostate cancer cells to androgen receptor signal inhibitors (e.g. darolutamide)	Investigator-sponsored Phase 2 study in the U.S patient follow up completed. Investigator-initiated phase 2 study in combination with Bayer's darolutamide – initiated in Australia	Worldwide exclusive license
Opaganib	Nuclear radiation protection	Oral, small molecule pill that is stable with a more than five-year shelf-life, easy to administer and distribute, supporting, if approved, potential central stockpiling by governments	U.S. government-funded in vivo studies completed, and additional validation experiments underway	Worldwide exclusive license
Opaganib	Host Directed anti-Viral	Oral administration, first-in-class SK2 selective inhibitor, with anti-inflammatory and anti-viral activities	BARDA EZ-BAA grant received for Ebola. Pre-clinical collaborations with US gov funded agencies on influenza and Ebola	Worldwide exclusive license
RHB-107 (upamostat; formerly Mesupron)	Outpatients infected with SARS-CoV-2 (COVID-19 disease)	Oral administration, inhibitor of human serine proteases with antiviral activity and established safety profile	Part A of Phase 2/3 study completed Multi-site Phase 2 platform trial ongoing with US governmental funding	We filed patent applications to protect the proposed commercial use
RHB-107 (upamostat; formerly Mesupron) and opaganib	Advanced unresectable cholangiocarcinoma	Combination of (RHB-107 (upamostat)) and (opaganib)	Preclinical	We filed patent applications internationally directed to the proposed commercial use
RHB-104 & RHB-204 (next generation formulation)	Crohn's disease	Novel mechanism of action and improved clinical benefit (targeting suspected underlying cause of Crohn's disease)	First Phase 3 study completed; supportive results from the open-label extension	We filed patent applications internationally directed to the proposed commercial formulation and use
RHB-102 (Bekinda®) 24 mg	Acute gastroenteritis and gastritis	No other approved 5-HT3 serotonin receptor inhibitor for this indication; once-daily dosing	First Phase 3 study in the U.S. completed; confirmatory Phase 3 study in planning	We filed patent applications internationally to protect the proposed commercial formulation and its use
RHB-102 (Bekinda®) 12 mg	IBS-D	Potential 5-HT3 serotonin receptor inhibitor with improved safety, while maintaining efficacy	Phase 2 in the U.S. completed; Phase 3 program in planning	We filed patent applications internationally to protect the proposed commercial formulation and its use
RHB-102 (Bekinda®) 24 mg	Oncology support anti-emetic	Reduced number of drug administrations, improved compliance and adherence	MAA pursued in the U.K Additional data required for U.S.	We filed patent applications internationally to protect the proposed commercial formulation and its use.

Opaganib

Opaganib, a new chemical entity, is a proprietary, first-in-class, orally administered, sphingosine kinase-2 (SK2) selective inhibitor with observed anticancer, anti-inflammatory, and antiviral activities, targeting multiple potential oncology, inflammatory, viral and gastrointestinal indications. The compound originally designated as ABC294640 received an international non-proprietary name, opaganib, in the Recommended INN: List 79, 2018.

Opaganib inhibits SK2, a lipid kinase that catalyzes the formation of the lipid signaling molecule sphingosine 1-phosphate ("S1P"). S1P promotes cancer growth and proliferation and pathological inflammation, including TNFα signaling and other inflammatory cytokine production. Specifically, by inhibiting the SK2 enzyme, opaganib blocks the synthesis of S1P which regulates fundamental biological processes such as cell proliferation, migration, immune cell trafficking and angiogenesis, and is also involved in immune-modulation and suppression of innate immune responses from T cells.

Opaganib's proposed antiviral mechanism, based on pre-clinical studies conducted with the molecule, inhibits the replication of positive-strand single-stranded ribonucleic acid ("RNA") viruses, of which coronavirus, and specifically SARS-CoV-2, is a member. By binding to SK2, opaganib inhibits SK2 recruited to the viral replication-transcription complex and thus blocks the intracellular viral replication process. Because SK2 is a human host factor, opaganib's proposed action is expected to maintain effect against known and emerging SARS-CoV-2 variants of concern irrespective of mutations in the viral spike-protein. Additionally, preclinical in vivo studies have demonstrated opaganib's potential to decrease renal fibrosis, have shown decreased fatality rates from influenza virus infection, and amelioration of bacteria-induced pneumonia lung injury by reducing the levels of IL-6 and TNF-alpha in bronchoalveolar lavage fluids.

On March 30, 2015, we entered into an exclusive worldwide license agreement with Apogee Biotechnology Corporation ("Apogee"), pursuant to which Apogee granted us the exclusive worldwide development and commercialization rights to ABC294640 (which we then renamed to opaganib and, as noted above, received an international non-proprietary name, opaganib, in 2018) and additional intellectual property for all indications. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – License Agreement for opaganib."

In March 2022, we entered into an exclusive license agreement with Kukbo for opaganib for the treatment of COVID-19 in South Korea. See " - Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – License Agreement with Kukbo".

The development of opaganib has been supported by grants and contracts from U.S. federal and state government agencies awarded to Apogee, including from the NCI, the U.S. government's Biomedical Advanced Research and Development Authority ("BARDA"), a center of the Department of Health and Human Services' (HHS) Administration for Strategic Preparedness and Response (ASPR), the U.S. Department of Defense and the FDA's Office of Orphan Products Development.

Phosgene Inhalation Injury

The collaboration focuses on several in vivo studies to evaluate opaganib as a potential medical countermeasure for phosgene inhalation injury. The goal is to assess whether opaganib can progress to further development under the FDA's Animal Rule pathway. Phosgene, a toxic chemical used in industry and as a weapon in World War I, poses a significant risk in the U.S. due to potential exposure from plant malfunctions or bioterrorism. Opaganib may offer a novel treatment, providing a potential antidote for emergency use in future public safety incidents.

Market and Competition

Opaganib is currently being developed for several potential indications, including for the treatment of severe COVID-19 pneumonia, Ebola virus disease and additional viruses as part of pandemic preparedness, several cancers including prostate cancer and cholangiocarcinoma (bile duct cancer), nuclear radiation protection and diabetes and obesity-related disorders.

COVID-19 is a disease caused by a coronavirus virus, SARS-CoV-2. The clinical spectrum has not yet been well defined and ranges from asymptomatic infection to pneumonia and acute respiratory distress syndrome (ARDS) with multiorgan failure, that may lead to death. Patients over 65 years and those with significant comorbidities, such as diabetes, cardiac or pulmonary disease, are more susceptible to developing severe disease and have a relatively higher mortality rate compared to younger, otherwise healthy patients. As of February 2, 2025, there have been over 777 million cumulative confirmed cases of COVID-19 worldwide, including over 7.1 million cumulative reported deaths worldwide according to WHO. Drug treatments for COVID-19 that have been approved by the FDA or authorized for use under emergency use authorization (EUA) include but are not limited to antiviral drugs, immune modulators, monoclonal antibodies and hyperimmune globulins. FDA approved antiviral therapies for COVID-19 include Veklury® (remdesivir, Gilead Sciences) indicated for the treatment of COVID-19 in adults and certain children who are hospitalized or non-hospitalized with mild-to-moderate COVID-19 and who are at high risk of developing severe COVID-19, including hospitalization or death, and is administered intravenously. Paxlovid™ (nirmatrelvir co-packaged with ritonavir, Pfizer Inc.) is another antiviral drug approved by the FDA, and is indicated for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for developing severe COVID-19, including hospitalization or death and is administered orally. Lagevrio™ (molnupiravir, Merck & Co.) has not been approved by the FDA but has been authorized for emergency use by the FDA also for the treatment of adults with mild-to-moderate COVID-19 who are at high risk for developing severe COVID-19, including hospitalization or death and is administered orally. As of the filing of this report, and to the best of our knowledge, no orally administered antiviral therapy has been approved by the FDA to date for treatment of hospitalized patients with severe COVID-19 pneumonia. Several vaccines for SARS-CoV-2 have also been approved by the FDA and other regulatory agencies to date and multiple additional vaccines and drug therapies are currently in development for COVID-19.

Cholangiocarcinoma (bile duct cancer) is a highly lethal malignancy. According to the 2024 American Cancer Society report on bile duct cancer, approximately 8,000 people are diagnosed with intrahepatic and extrahepatic bile duct cancers annually in the U.S., though the report suggests that the actual number of cases may be higher given that these cancers can be difficult to diagnose. Surgery with complete resection is currently known to be the only curative therapy for cholangiocarcinoma; however, only a minority of patients are classified as having a resectable tumor at the time of diagnosis. Additional treatment options include radiation therapy and chemotherapy, but the efficacy of these treatments in cholangiocarcinoma patients is also limited and the prognosis for relapse patients who have failed initial chemotherapy is very poor, with an overall median survival of approximately one year (Valle J, et al. New Eng J, Med 2010).

The FDA has approved several drug therapies for cholangiocarcinoma which largely include kinase inhibitors and checkpoint inhibitors. In April 2020, the FDA approved Pemazyre® (pemigatinib, Incyte Corporation), the first drug approved specifically for cholangiocarcinoma, and indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma whose tumor harbors a mutation in the fibroblast growth factor receptor 2 (FGFR2) gene. Lytgobi (futibatinib, Taiho Oncology Inc) is another orally administered kinase inhibitor approved by the FDA that targets FGFR2 gene mutations in adults with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma. FGFR2 gene fusions are found in patients with intrahepatic cholangiocarcinoma and have a reported incidence rate of 14% to 23% (Prete MG, Explor Target Antitumor Ther., 2021). In August 2021, the FDA approved Tibsovo® (ivosidenib, Servier Pharmaceuticals LLC) for adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation. IDH1 mutations are also found in patients with intrahepatic cholangiocarcinoma and have a reported incidence rate of 7% to 20% (Prete, 2021). In September 2022, the FDA approved the first immunotherapy option, Imfinzi® (durvalumab, AstraZeneca Plc) and later, in October 2023, also approved Keytruda® (pembrolizumab, Merck), which are a programmed death-ligand 1 (PD-L1) blocking antibody and a programmed death receptor-1 (PD-1)-blocking antibody, respectively, and are indicated for the treatment of patients with locally advanced or metastatic biliary tract cancer in combination with gemcitabine and cisplatin.

Additional marketed drugs are available for the treatment of cholangiocarcinoma and others are in development for this indication in the U.S., which may expose us to additional potentially competitive products. The 5-year relative survival rates of intrahepatic and extrahepatic cholangiocarcinoma patients range between 2% to 23%, depending on the tumor type and stage at diagnosis, according to the American Cancer Society. We believe there remains a high unmet medical need for new therapies for the majority of cholangiocarcinoma patients.

Prostate cancer is the second most common cancer and the second leading cause of cancer death in American men. The American Cancer Society estimates that approximately 313,800 new cases of prostate cancer will be diagnosed in the U.S. in 2025. Prostate cancer is more likely to develop in older men, African American men and Caribbean men of African ancestry. Treatment options depend on each case and include surgery, radiotherapy, cryotherapy, chemotherapy, hormone therapy, and immunotherapy. There are several approved drugs indicated for treatment of prostate cancer, as well as several drugs in development for U.S. approval.

GI-ARS is a condition caused by exposure to high doses of ionizing radiation to a large portion of the body and that causes damage to rapidly dividing cells in the gastrointestinal tract, leading to a range of symptoms. The severity of the symptoms can vary depending on the radiation dose absorbed. Although GI-ARS is rare, it is a significant concern in the context of nuclear or radiological incidents that may be intentional (e.g., acts of terrorism) or accidental (e.g. radiation therapy mishaps) as it has the potential to affect large numbers of people. The U.S. Government has recognized the need to develop and expand the availability of suitable medical countermeasures (MCMs) for GI-ARS and has introduced initiatives to support the research and development of these products.

While a number of MCMs have been approved by the FDA for the treatment of Hematopoietic Syndrome of Acute Radiation Syndrome, or Heme-ARS, there remains an unmet need for products that address GI-ARS. Investigational drugs in development for GI-ARS include but may not be limited to MIIST305 being developed by Synedgen Inc. as well as additional products under study by the NIAID RNCP that include other anti-inflammatories, cytokines/cytokine blockers, immunomodulators, cellular therapies, steroids/hormones, anti-apoptotics, anti-microbials, antioxidants, growth factors, and products targeting the microbiome and the vascular endothelium (Winters et al. Radiat Res. 2024). To the best of our knowledge, no products are currently approved for the treatment of GI-ARS.

Ebola virus disease is a viral hemorrhagic fever that occurs in human and nonhuman primates caused by ebola viruses. Although the disease is rare, it is often fatal without treatment and is estimated to have a case fatality rate of around 50% (WHO Ebola Virus Disease Fact Sheet, 2023). Symptoms generally appear anywhere from 2 to 21 days after infection and include fever, fatigue, muscle pain, headache and sore throat, followed by vomiting, diarrhea, rash, and internal and external bleeding. The Ebola virus genus consists of 6 identified species, including Zaire, Bundibugyo, Sudan, Taï Forest, Reston and Bombali.

There are currently two MCMs approved by the FDA for the treatment of Ebola caused by Zaire ebola virus in adults and children, which include Ebanga™ (Ansuvimab-zykl, Ridgeback Biotherapeutics) and Inmazeb® (atoltivimab, maftivimab, and odesivimab-ebgn; Regeneron). Both therapeutics which were developed with BARDA's support are monoclonal antibody treatments and are intravenously administered. The FDA has also approved one vaccine, Ervebo® (Merck) for the prevention of Ebola caused by Zaire ebola virus. Opaganib may be subject to additional potentially competitive products that may be approved or in development for Ebola caused by Zaire and other ebola viruses.

Clinical Development

COVID-19

Preclinical data have demonstrated both anti-inflammatory and antiviral activities of opaganib, with the potential to reduce inflammatory lung disorders, such as pneumonia, and mitigate pulmonary fibrotic damage. In September 2020, we announced that opaganib demonstrated potent inhibition of SARS-CoV-2, the virus that causes COVID-19, achieving complete blockage of viral replication in an *in vitro* model of human lung bronchial tissue. Additionally, preclinical *in vivo* studies have demonstrated that opaganib decreased fatality rates from influenza virus infection and ameliorated Pseudomonas aeruginosa-induced lung injury by reducing the levels of IL-6 and TNF-alpha in bronchoalveolar lavage fluids.

Preliminary results from a preclinical study with opaganib, administered at 250 mg/kg, demonstrated a reduction of thrombosis (blood clotting) in an acute respiratory distress syndrome (ARDS) animal model. The preclinical study was designed to assess the efficacy of opaganib in reducing the incidence of adverse thromboembolic events in situ in the lipopolysaccharide (LPS)-induced model of pulmonary inflammation, a reliable model of ARDS that can mimic COVID-19 inflammation. The preliminary results from our study show opaganib 250 mg/kg reduced blood clot length, weight and total thrombus score in a preclinical model of ARDS. We believe such preliminary results add to the known antiviral and anti-inflammatory activities of opaganib and provide the potential for a unique triple-action effect on the pathophysiological processes associated with COVID-19 disease.

In September 2020, Apogee was awarded a grant from Pennsylvania's COVID-19 Vaccines, Treatments and Therapies Program, which supports the rapid advancement of promising novel COVID-19 therapies.

ABC-201: Global Phase 2/3 Study

In July 2020, we initiated a global Phase 2/3 clinical trial evaluating opaganib in hospitalized patients with severe COVID-19 pneumonia. This global multi-center, randomized, double-blind, parallel-arm, placebo-controlled trial enrolled a total of 475 patients requiring hospitalization and treatment with supplemental oxygen. The study was approved in ten countries.

In September 2021, we reported that preliminary top-line data from the opaganib (ABC294640) global Phase 2/3 study in hospitalized patients with severe COVID-19 pneumonia showed that the study did not meet its primary endpoint. Analysis of the study efficacy endpoints did show trends in favor of the opaganib arm as compared to placebo across multiple endpoints, including the primary endpoint, despite not achieving statistical significance.

In October 2021, we reported new data from a further analysis of this study, showing that treatment with oral opaganib as compared to the placebo-controlled arm resulted in a 62% statistically significant reduction in mortality as well as statistically significant improved outcomes in time to room air and median time to hospital discharge in a group of 251 hospitalized, moderately severe COVID-19 patients, comprising 54% of the study participants.

These results were from a post-hoc analysis of data from the 251 study participants requiring a Fraction of inspired Oxygen (FiO2) up to 60% at baseline. Patients with FiO2 ≤ 60% are still considered to be severely affected and typically require oxygen supplementation via a nasal cannula or face mask.

Analyses of the FiO2 up to 60% patient subset from the opaganib Phase 2/3 study, the median for FiO2 levels in the study, who were treated with either opaganib or placebo in addition to standard-of-care (including dexamethasone and/or remdesivir) demonstrated consistent benefit across endpoints, in this subset of hospitalized moderately severe patients. Given the post-hoc characteristics of this subset, statistical inferences of significance cannot be formally attributed (nominal values presented). We also conducted a sensitivity analysis to account for missing data interpretability:

- **Mortality**: Opaganib treatment resulted in a statistically significant 62% reduction in mortality (7/117 patients treated with opaganib vs. 21/134 for placebo; nominal p-value=0.019, Relative Risk 2.6) (Sensitivity Analysis: 5/117 vs. 16/134, 64% efficacy benefit; nominal p-value=0.033, Relative Risk - 2.8).

A detailed analysis of baseline risk factors and their potential impact on the mortality outcome in the sensitivity analysis group has also been undertaken, showing that the benefit is robustly maintained irrespective of the subgroups/risk factors, confirming that the positive outcome observed is due to opaganib.

- **Reaching Room Air by Day 14 (primary endpoint of the study)**: 77% of opaganib-treated patients reached room air by Day 14 vs. 63.5% for placebo – an efficacy benefit of 21% with opaganib (nominal p-value=0.033).

- **Median time to discharge**: Patients treated with opaganib showed median time of 10 days to discharge vs. 14 days for the placebo arm, resulting in a saving of four days hospitalization per opaganib patient and saving a total of 524 cumulative days of hospitalization across the group by Day 42, nominal p-value=0.0195.

- **Safety**: Overall adverse events were balanced between the opaganib and placebo groups, suggesting good safety, with no new safety signals emerging, further supporting potential use in this patient population and earlier stage populations.

In January 2022, we reported new data from a prespecified analysis of all Phase 2/3 study patients with positive PCR at screening, demonstrating that opaganib improved the median time to viral RNA clearance by at least 4 days. Treatment with opaganib resulted in viral RNA clearance in a median of 10 days while the median for clearance in the placebo arm was not reached by the end of 14-days treatment for placebo (hazard ratio 1.34; nominal p-value=0.043, N=437/463). To the best of our knowledge, opaganib is the first oral novel drug candidate to show improved viral RNA clearance in patients with severe COVID-19 pneumonia. This data provides clinical evidence supporting opaganib's potential antiviral activity.

In February 2022, we reported additional results from two prespecified analyses from the Phase 2/3 study. The first analysis showed that opaganib significantly reduced mortality when given to patients who received remdesivir and corticosteroids, the best available standard-of-care (SoC) for hospitalized patients. This analysis, undertaken for all patients from the study who were receiving remdesivir and corticosteroids at baseline, demonstrated a significant 70.2% mortality benefit for opaganib-treated patients, with a mortality rate of 6.98% (n=3/43) for the opaganib arm + SoC versus 23.4% (n=11/47) for placebo + SoC by Day 42 (p-value=0.034).

The second analysis further showed that opaganib delivered a significant benefit in time to recovery, defined as achieving a score of 1 or less on the WHO Ordinal Scale by Day 14. The prespecified analysis showed opaganib delivered a significant 34% benefit in time to recovery, with 37.4% of opaganib-treated patients (n=86/230) reaching this event versus 27.9% of patients (n=65/233) treated with placebo + SoC (p-value=0.013, Hazard Ratio 1.49).

Safety data for the Phase 2/3 clinical trial showed good tolerability of opaganib, with balanced adverse events between the study arms.

In September 2024, we reported a publication from the Phase 2/3 study published in the peer-reviewed journal, Microorganisms. Data from the post hoc analysis of oral opaganib in COVID-19 pneumonia showed a 62% reduction in mortality and a 21% improvement in time to room air. This analysis, conducted on a sub-group of 251 hospitalized, moderately severe patients, also highlighted FiO2 levels above 60% as a potential biomarker for disease severity.

Guidance on the potential path to approval including the requirement of a confirmatory study for future emergency use approvals has been received from the EU's EMA, the U.S. FDA, UK's MHRA and others.

We are continuing discussions and work with U.S. and other government agencies and non-governmental organizations to support the ongoing development of opaganib in areas of public health interest, including pandemic preparedness and medical countermeasures. These are currently undergoing pre-clinical evaluation. Discussions are also ongoing with potential partners who are interested in the rights to opaganib in various territories.

ABC-110: U.S. Phase 2 Study

In December 2020, we announced that our randomized, double-blind, placebo-controlled U.S. Phase 2 trial with opaganib in patients hospitalized with COVID-19 pneumonia demonstrated positive safety and efficacy data. The trial, which was not powered for statistical significance, enrolled 40 patients requiring hospitalization and supplemental oxygen.

The data from the study was published in May 2022 in Open Forum Infectious Diseases.

ABC-108: Advanced Unresectable Cholangiocarcinoma

A Phase 2a clinical study with opaganib in patients with advanced, unresectable, intrahepatic, perihilar and extrahepatic cholangiocarcinoma is ongoing at Mayo Clinic's major campuses in Arizona and Minnesota, MD Anderson Cancer Center, the Huntsman Cancer Institute, University of Utah Health and at Emory University. In September 2018, we announced that the study achieved its pre-specified efficacy goal for the first stage of the two-stage study design, and as a result, the study has continued to its second stage. Treatment with opaganib, Part 1 of the study, designed to enroll 39 evaluable patients, completed enrollment in January 2020. The primary objective was to determine the response rate (RR) of cholangiocarcinoma defined as objective responses (OR), i.e. complete and partial responses (CR, PR) plus stable disease (SD) of at least four months to treatment with opaganib. Preliminary data from this cohort indicated that 6 of 39 (of 58 total enrolled) patients evaluable for efficacy achieved the primary endpoint of stable disease or better for at least 4 months, with good safety and tolerability heavily pretreated subjects with advanced cholangiocarcinoma.

In October 2019, an expansion cohort for cotreatment of opaganib and hydroxychloroquine sulfate (HCQ), an anti-autophagy agent, was submitted to the FDA. The primary endpoint of this cohort was to determine Durable Disease Control Rate (DDCR), defined as Disease Control Rate (DCR) of at least four months' duration to treatment with opaganib and HCQ. Enrollment of this cotreatment cohort, Part 2 of the study, began in July 2020. The cohort consists of two stages: Stage 1, an accelerated dose escalation run-in with enrollment of up to 15 patients evaluable for safety and tolerability, and Stage 2, treatment of 20 patients evaluable in the Stage 1 determined dose to determine safety and tolerability. In May 2022, RedHill closed the enrollment to the second dose tier, 500 mg BID of opaganib and 200 mg of HCQ BID. The main reason for the study's early closure was a significant slowdown in enrollment since the start of the COVID-19 pandemic. The last patient that was enrolled demonstrated stable disease for 10 cycles and tolerated the treatment very well. Accordingly, RedHill in collaboration with the treating physician in Mayo, AZ, arranged to continue the patient's treatment under a Single Patient IND.

A total of 65 patients have been enrolled in the study, 7 of those in the Phase I safety run-in of Part 2. Of the 7 patients that were enrolled in Part 2 (4 evaluable for efficacy), one subject has demonstrated durable stable disease for 10 months and has transitioned to a Single Patient IND. RedHill is expected to receive the data analysis and the CSR in H1/2023.

The primary objective of Part 1 is to determine the response rate (RR) of cholangiocarcinoma defined as objective responses (OR), i.e. complete and partial responses (CR, PR) plus stable disease (SD) of at least four months to treatment with opaganib. The primary endpoint of Part 2 is to determine Durable Disease Control Rate (DDCR), defined as Disease Control Rate (DCR) of at least four months' duration to treatment with opaganib and HCQ.

In April 2017, the FDA granted to opaganib orphan drug designation for the treatment of cholangiocarcinoma. The orphan drug designation allows us to benefit from various development incentives to develop opaganib for this indication, including tax credits for qualified clinical testing, the waiver of a prescription drug user fee (PDUFA) upon submission of a potential NDA and, if approved, a seven-year marketing exclusivity period (subject to certain exceptions) for the treatment of cholangiocarcinoma.

Neuroblastoma

In August 2024, the FDA granted orphan-drug designation to opaganib for treatment of neuroblastoma, a type of childhood cancer that develops from immature nerve cells and accounts for 15% of all pediatric cancer-related deaths. The neuroblastoma market is expected to reach almost $1.5 billion before mid-2030s.

EAP for the Treatment of Advanced Unresectable Cholangiocarcinoma

An EAP is for eligible participants who do not qualify for participation in, or who are otherwise unable to access, the ongoing clinical trial ABC-108 for advanced unresectable cholangiocarcinoma. This program is designed to provide access to opaganib for the treatment of cholangiocarcinoma prior to approval by the local regulatory agency. As noted in the section above, one subject from study ABC-108 has transitioned to a Single Patient IND with the termination of study ABC-108. We cannot predict how long this program will continue, and we may decide for various reasons, including but not limited to resources and availability of opaganib, not to continue with the EAP.

ABC-101: Advanced Solid Tumors

A Phase 1 study, first-in-man evaluation of opaganib in advanced solid tumors was completed in the summer of 2015. Final results demonstrated that the study, conducted at the Medical University of South Carolina (MUSC), successfully met its primary and secondary endpoints, demonstrating that the compound is well tolerated and can be safely administered to cancer patients at doses predicted to have therapeutic activity.

Twenty-one patients with advanced solid tumors were treated with opaganib in the study, the majority of who were GI cancer patients, including pancreatic, colorectal and cholangiocarcinoma cancers.

The study included the first-ever longitudinal analysis of plasma S1P levels as a potential pharmacodynamic biomarker for activity of a sphingolipid-targeted drug. Administration of opaganib resulted in a rapid and pronounced decrease in levels of S1P with several patients having prolonged stabilization of disease.

The study was supported by grants from the U.S. National Cancer Institute (NCI) awarded to MUSC Hollings Cancer Center, an NCI-Designated Cancer Center, and from the FDA Office of Orphan Products Development (OOPD) awarded to Apogee.

ABC-107: Prostate Cancer

The investigator-sponsored study “A Phase 2 Study of the Addition of opaganib to Androgen Antagonists in Patients with Prostate Cancer Progression on Enzalutamide or Abiraterone” was initiated in March 2020 at MUSC Hollings Cancer Center and at Emory University. The study is led by Dr. Michael B. Lilly. The study is supported by the National Cancer Institute grant awarded to MUSC.

This is a Phase 2 efficacy study of opaganib in patients with metastatic castration-resistant prostate cancer that is progressing during treatment with androgen signaling blockers, abiraterone or enzalutamide. The study will consist of an initial safety “run in” cohort in which patients will receive opaganib along with continuation of prior abiraterone or enzalutamide to document tolerability in this new patient population and to document the effects of opaganib on blood prostate-specific antigen (PSA) levels. Provided that there is no untoward toxicity in these patients, there will be two additional cohorts with up to 27 patients, with each of patients with worsening disease during abiraterone or enzalutamide treatment. These patients will continue previous androgen blocking agents (abiraterone or enzalutamide, and gonadotropin-releasing hormone GnRH receptor agonist/antagonist). The primary objective of the study is to measure the proportion of patients with disease control during opaganib plus abiraterone or enzalutamide treatment using a composite metric based on PSA, bone scan, and RECIST measurements per Prostate Cancer Working Group 3 (PCWG3) criteria.

The first patient was enrolled in March 2020 and the last patient was enrolled in December 2022, completing enrollment of 66 patients: 3 in cohort 1a (abiraterone + opaganib 250 mg BID), 3 in cohort 1b (enzalutamide + opaganib 250 mg BID), 26 in cohort 2 (abiraterone + opaganib 500 mg BID), 34 in cohort 3 (enzalutamide + opaganib 500 mg BID). All patients are now off study. Disease control, the primary endpoint of the study, was defined as progression-free for at least 16 weeks and was assessed primarily in the 500 mg opaganib bid cohorts, cohorts 2 and 3. A total of 11 patients achieved disease control: 3 in the lead-in cohorts combined; 4 (15%; 95% CI 4-35%) in cohort 2 (abiraterone, and 4 (12%; 95% CI 3-27%) in cohort 3 (enzalutamide). Treatment was generally well tolerated; toxicity was similar to that noted in prior studies of opaganib, mainly neuropsychiatric. A new toxicity, subretinal fluid accumulation which manifest as visual disturbance, was noted in one patient who received opaganib and abiraterone. This resolved in several days after the patient stopped taking opaganib. While not previously recognized, this toxicity may have been misinterpreted in the past as visual hallucinations.

On February 4, 2025, we announced that an ensuing investigator initiated phase 2 study has been initiated, to evaluate the efficacy of opaganib in combination with darolutamide in men with metastatic castrate-resistant prostate cancer (mCRPC), financially supported by Bayer (ETR: BAYN) and the Ramsay Hospital Research Foundation.

- The 80-patient placebo-controlled randomized Phase 2 study will evaluate the efficacy of opaganib in combination with Bayer's darolutamide in men with mCRPC, testing the potentially enhancing effect of opaganib in overcoming resistance to standard of care androgen receptor pathway inhibition (ARPI) treatment in patients with a poor prognosis.

- The study is being financially supported by Bayer (ETR: BAYN) and the Ramsay Hospital Research Foundation, and will be led by Professor Lisa Horvath from Chris O'Brien Lifehouse and the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP).

- The study will utilize a companion lipid biomarker test (PCPro) to select mCRPC patients who have a poor prognosis due to standard of care treatment and who may benefit from an opaganib + darolutamide combination treatment approach. Primary endpoint will be improved 12-month radiographic progression-free survival (rPFS).

ABC-104: Oncology Support, Radioprotectant: Prevention of Radiation-Associated Mucositis in the Treatment of Head and Neck Cancer

A Phase 1b study to evaluate opaganib as a radioprotectant in head and neck cancer patients undergoing therapeutic radiotherapy is currently on hold.

Nuclear Radiation Protection Development Program

In November 2022, we announced acceleration of opaganib's nuclear radiation protection development program, with newly published data from eight U.S. government-funded *in vivo* studies, and additional experiments, indicating that opaganib was associated with:

- Protection of normal tissue, including gastrointestinal, from radiation damage due to ionizing radiation exposure or cancer radiotherapy.
- Improvement of antitumor activity, response to chemoradiation, and enhancement of tolerability and survival.

Development of opaganib as a homeland security nuclear medical countermeasure is currently expected to follow the Animal Rule under which human efficacy studies may not be required, and if approved, may be eligible for a Medical Countermeasure Priority Review Voucher.

In February 2023, we announced that the Radiation and Nuclear Countermeasures Program (RNCP), of the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, had selected opaganib for the nuclear medical countermeasures product development pipeline as a potential treatment for ARS. As part of this collaboration, contractors directed and supported by the RNCP will undertake studies, designed in collaboration with us, to test opaganib in established ARS models. Further testing under RNCP has confirmed activity of opaganib in amelioration of GI-ARS and expanded the observed effects from male mice to include also female mice. Discussions with RNCP are underway to continue testing opaganib as a post-exposure GI-ARS ameliorating drug under the Animal Rule, including further mouse studies, testing opaganib in combination with Heme-ARS approved compounds (such as Neulasta) and testing opaganib in a second species, most likely non-human-primates.

In July 2023, we announced that Apogee had been awarded a further $1.7 million in U.S. government funding, via a Small Business Innovation Research grant, which will support research to further the development of opaganib as an MCM for GI-ARS. This grant is in addition and complementary to the multimillion dollar-valued U.S. government RNCP product pipeline development contract awarded to opaganib following its selection by the RNCP for ARS development.

In February 2024, we announced that the International Journal of Molecular Sciences published data demonstrating that opaganib protects against radiation-induced lung inflammation and fibrosis in an *in vivo* mouse model of lung damage following exposure to ionizing radiation.

Ebola

In October 2023, we announced that opaganib delivered a statistically significant increase in survival time when given at 150 mg/kg twice a day (BID) in a United States Army Medical Research Institute of Infectious Diseases (USAMRIID) *in vivo* Ebola virus study, making it the first host-directed molecule to show activity in Ebola virus disease. The U.S. Army study tested three doses of opaganib (50, 100 and 150 mg/kg BID), against an inactive vehicle control arm. The in vivo study results showed a statistically significant survival increase in mean (SE) survival time of 11.2 (2.6) days in the 150 mg/kg opaganib group (p=0.0279) compared to a mean (SE) survival time of 5.5 (0.4) days in the inactive vehicle control group. A 30% mice survival was observed in the 150 mg/kg treated group compared to the vehicle control. A subsequent repeat study showed 20% survival in the vehicle control arm and no statistically significant benefit was observed in the opaganib treated arm. Further work is being considered, in collaboration with BARDA and USAMRIID, to further test opaganib's activity.

In December 2023, we announced opaganib and RHB-107 (upamostat) demonstrated robust synergistic effect when combined individually with remdesivir (a leading COVID-19 therapy sold under the brand name Veklury® by Gilead Sciences, Inc.), significantly improving viral inhibition while maintaining cell viability, in a new U.S. Army-funded and conducted Ebola virus *in vitro* study.

In October 2024, we announced that BARDA had selected opaganib for development to treat exposure to Ebola. Under this cost-sharing contract, BARDA will provide partial funding for us to further advance opaganib to mitigate infection and contain Ebola virus outbreaks.

ABC-105: Moderate to Severe Ulcerative Colitis ("UC")

A Phase 2 study to evaluate the efficacy of opaganib in patients with moderate to severe UC by the proportion of patients who are in remission at the end of treatment is currently on hold.

ABC-109: Food Effect Study in Healthy Subjects

A Phase 1, randomized, open-label, single-dose, 3-treatment, 3-period, 6-sequence crossover study designed primarily to evaluate the effect of a standardized meal on the absorption and bioavailability of opaganib in healthy subjects, was completed in the U.S. in January 2018. The study also evaluated the effect of the administration of a solution of opaganib via nasogastric (NG) tube on the absorption and bioavailability of opaganib. Twenty-three eligible, healthy, male and female adult subjects were randomized to receive opaganib orally in a state of fast, fed or as a solution by NG tube (after tube feeding). Seventeen subjects received all three treatments. All three treatments, though maximum concentration was lower when the drug was given orally in the fed state as compared to fasted, nasogastric administration after tube feeding led to intermediate results. Subjects experienced fewer gastrointestinal side effects when the drug was given in the fed state than fasted, but the pharmacodynamic effect, as reflected in the decrease in sphingosine-1-phosphate, the product of the target enzyme, was no lower after fed than fasted administration. Thus, the results indicated that opaganib may be administered after eating, with improved tolerance and no loss of pharmacodynamic effect.

The following chart summarizes the clinical trial history and status of opaganib:

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Nature and status of the trial	Schedule
ABC-201	Phase 2/3	A study for the treatment of Opaganib in patients with severe COVID-19 pneumonia	Multicenter study	464	Completed	Results reported in 2022
ABC-110	Phase 2	A study for the treatment of opaganib in patients with severe COVID-19 pneumonia	Multicenter study across the U.S.	40	Completed	Results reported in 2021
ABC-108	Phase 2a	A study for the treatment of advanced, unresectable intrahepatic, perihilar and extrahepatic cholangiocarcinoma with opaganib and co-treatment with opaganib and HCQ	Multicenter study across the U.S.	65	Completed	Ended
ABC-107 (103193 MUSC Study ID)	Phase 2	An add-on study for prostate cancer patients who progressed on enzalutamide or abiraterone. The proportion of patients with disease control during treatment with opaganib and enzalutamide or abiraterone will be measured	Medical University of South Carolina, Charleston, U.S. and Emory University, Atlanta, Georgia, U.S.	65	Ongoing	Ended
ABC-103	Phase 1b/2	Safety and efficacy study in patients with refractory or relapsed multiple myeloma that have previously been treated with proteasome inhibitors and immunomodulatory drugs	Duke University, North Carolina, U.S.	Ended	Ended after Phase 1	Ended
ABC-101	Phase 1	Safety, PK and pharmacodynamic study in patients with advanced solid tumors	Medical University of South Carolina, Charleston, U.S.	22	Completed. Final results indicate the study drug is well tolerated and can be safely administered to cancer patients	Completed 2015
ABC-106	Phase 2	Investigator-Sponsored Safety and Efficacy Study in Patients with Advanced Hepatocellular Carcinoma Who Have Progressed on Sorafenib	Medical University of South Carolina, Charleston, U.S. and collaborating sites (Multicenter, U.S.)	From 12 to 39	Withdrawn and replaced with ABC-107 in prostate cancer (103193 MUSC Study ID)	Withdrawn
ABC-104	Phase 1b	Safety and efficacy study in the prevention of mucositis in combination with radiotherapy for treatment of squamous head and neck carcinoma	Multicenter study across the U.S.	Up to 32	TBD	TBD
ABC-105	Phase 2	A study for the treatment of moderate to severe ulcerative colitis	Multicenter study	Up to 94	TBD	TBD
ABC-109	Phase 1	Assessment of the effect of food on the absorption and bioavailability of opaganib; also as a solution via nasogastric (NG) tube under fed conditions	ICON Early Phase Services, San-Antonio, TX, U.S.	23	Completed	Completed 2018

We cannot predict with certainty our development costs, and such costs may be subject to changes. See "Item 3. Key Information – D. Risk Factors – Risks Related to Our Financial Condition and Capital Requirements".

RHB-107 (upamostat; formerly Mesupron)

As mentioned under "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – License Agreement for RHB-107" (upamostat; formerly Mesupron)", on June 30, 2014, we signed an exclusive license agreement with Wilex AG (which later changed its name to Heidelberg Pharma AG) for RHB-107 (INN: upamostat; formerly Mesupron) for all indications and for all uses. Under this agreement, we are responsible for all development, regulatory and commercialization of RHB-107 in the entire world, excluding China, Taiwan, Macao, and Hong Kong.

RHB-107 is a proprietary, first-in-class, orally administered potent inhibitor of several serine proteases, with a unique potency and specificity. In addition to its original development as a potential cancer therapy, work completed by us demonstrated its potential use in inflammatory digestive diseases, inflammatory lung diseases and infectious diseases. Furthermore, RHB-107 shows promise as a potential host-directed anti-viral with applications in pandemic preparedness, including COVID-19 and potentially, Ebola.

Market and Competition

RHB-107 is currently being developed for the treatment of non-hospitalized symptomatic COVID-19 and Ebola virus disease and has previously undergone non-clinical and clinical studies in several oncological indications, including metastatic breast cancer and advanced non-metastatic pancreatic cancer.

Non-Clinical and Clinical Development

Data from non-clinical studies conducted by us indicate that WX-UK1, the active metabolite of RHB-107, is a specific and potent inhibitor of several human serine proteases (e.g., trypsin-3, trypsin-2, trypsin-1, matriptase-1, and trypsin-6), some of which have been shown to play a role in inflammatory digestive diseases and lung diseases. Additional non-clinical studies indicated that several members of the type II transmembrane serine proteases (TTSPs), some of which are important factors in the spread of infectious diseases, were inhibited by WX-UK1.

RHB-107's safety profile has been demonstrated in approximately 350 participants, including in Phase 2 studies in oncology indications and COVID-19.

Oncology

Several Phase 1 studies and two Phase 2 proof-of-concept studies have been completed with RHB-107 in cancer patients. The first Phase 2 trial in locally advanced non-metastatic pancreatic cancer and the second trial in metastatic breast cancer established the therapeutic candidate's safety and tolerability profile. The Phase 2 trials with RHB-107 in both indications failed to demonstrate significant improvement in either progression-free survival or overall survival.

None of the prior studies used any molecular markers to target certain patient populations. Using technologies developed since the original clinical trials were performed, we are currently considering several preclinical studies, including biomarker analysis and mechanism of action studies. We expect that the findings from these studies can help us determine the patient populations to be studied in subsequent clinical trials.

In October 2017, the FDA granted RHB-107 orphan drug designation for the treatment of pancreatic cancer. The orphan drug designation allows us to benefit from various development incentives to develop RHB-107 for this indication, including tax credits for qualified clinical testing, waiver of a PDUFA upon submission of a potential marketing application and, if approved, a seven-year marketing exclusivity period (subject to certain exceptions) for the treatment of pancreatic cancer.

COVID-19

RHB-107 was studied in a 3D tissue model of human bronchial epithelial cells (EpiAirway™) which morphologically and functionally resembles the human airway and is similar to the model used to discover SARS-CoV-2. The study was designed to evaluate the *in vitro* efficacy of RHB-107 in inhibiting SARS-CoV-2 infection and included a positive control of camostat. Results from the study demonstrated strong inhibition of SARS-CoV-2 viral replication.

In October 2022, we announced study results showing preliminary evidence of *in vitro* efficacy against the Omicron COVID-19 sub-variant BA.5 by opaganib and RHB-107.

RHB-107-01: Global Phase 2/3 Study

A 2-part, Phase 2/3 multicenter, randomized, double-blind, placebo-controlled, parallel-group study with RHB-107 randomized its last patient into Part A of the study November 12, 2021. The study aimed at evaluating treatment in patients with symptomatic COVID-19 early in the course of the disease, with a once-daily oral treatment that can be prescribed and used in the non-hospitalized patient population. The Phase 2 part of the study was designed to evaluate safety for dose selection and to provide preliminary assessment of parameters to be used for efficacy evaluation in Part B. A total of 61 patients were enrolled in Part A and randomized on a 1:1:1 basis to receive one of two dose levels of RHB-107 or a placebo control and was predominantly conducted in the U.S. (60/61 patients) as well as South Africa.

RHB-107 was administered once daily for 14 days, with patients receiving follow-up for eight weeks from first dosing. The primary endpoints were time to sustained recovery from symptomatic illness compared to placebo, as well as safety and tolerability of RHB-107. Several secondary and exploratory endpoints are also being assessed. In February 2021, we announced that the first patient had been dosed in the study.

In March 2022, we announced the positive Phase 2 study results of Part A of the Phase 2/3 study. Although not powered for efficacy assessment, the study showed highly promising efficacy results delivering a 100% reduction in hospitalization due to COVID-19, with zero patients on RHB-107 hospitalized with COVID-19 (0/41) compared to 15% on the placebo-controlled arm requiring hospitalization (3/20) (nominal p-value=0.0317). Furthermore, the study showed an 87.8% reduction in reported new severe COVID-19 symptoms, with only one patient on RHB-107 (2.4%, 1/41) compared to 20% (4/20) of patients on the placebo-controlled arm experiencing new COVID-19 related severe symptoms (nominal p-value=0.036).

The study met its primary outcome measure, demonstrating a favorable safety and tolerability profile of RHB-107. Study arms were well balanced with respect to baseline disease severity, risk factors and vaccination status. Patients were also tested for the specific viral strain, with the most common variant being Delta, found in 62.5% of the patients that had next generation sequencing (NGS). The second part of the study was never carried out, as RHB-107 was accepted for testing into the ACESO study described below.

In July 2023, we announced that RHB-107 had been accepted for inclusion in the U.S. Department of Defense- supported Austere environments Consortium for Enhanced Sepsis Outcomes' (ACESO) PROTECT multinational platform trial for early COVID-19 outpatient treatment. The ACESO PROTECT study is funded primarily by the U.S. Department of Defense.

The ACESO PROTECT study is an adaptive, randomized, double blind, multi-site Phase 2 platform trial, being conducted by researchers from ACESO and partner organizations, and administered by the Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF). The study is comparing investigational products to control, in standard to moderate-risk, non-hospitalized adult SARS-CoV-2 infected participants with at least two moderate-severe symptoms at baseline. RHB-107 is the only drug being evaluated in the early treatment arm of the study. The primary efficacy assessment in the early treatment indication will be time to sustained alleviation or resolution of COVID-19 symptoms. Participants will be followed for a period of up to 12 weeks.

ACESO had funding to continue accrual through February 28, 2025, and study enrollment has thus been terminated early. Patients enrolled will now be followed to the conclusion of the study at 12 weeks and results of the trial will then be analyzed. 93 patients have been enrolled out of the originally planned cohort of 300. Due to the reduced number of patients enrolled in this study, the study result may not lead to conclusions regarding the efficacy of RHB-107 in this trial.

Ebola Virus Disease Therapy

In 2022, in collaboration with the Therapeutic Discovery Branch of the USAMRIID (US Army Medical Research Institute of Infectious Diseases) to evaluate opaganib and RHB-107 in high throughput antiviral screening. We completed in-vitro studies against different strains of Ebola virus, including SUDV, Sudan ebolavirus (Boniface), Ebola Virus Disease, EBOV (Makona), and additional viral infectious diseases, including Marburg virus disease, MARV (Ci67), and Rift Valley fever RVFZ (ZH-501). Initial data from high-content imaging assays, provided further support for activities of Redhill candidates against these viral diseases.

In December 2023, we announced opaganib and RHB-107 demonstrated robust synergistic effect when combined individually with remdesivir (a leading COVID-19 therapy sold under the brand name Veklury® by Gilead Sciences, Inc.), significantly improving viral inhibition while maintaining cell viability, in a new U.S. Army-funded and conducted Ebola virus in vitro study.

RHB-104

Crohn's Disease

RHB-104 is an investigational new drug intended to treat Crohn's disease, which is a serious inflammatory disease of the GI system that may cause severe abdominal pain and bloody diarrhea, malnutrition and potentially life-threatening complications.

RHB-104 is a patented combination of clarithromycin, clofazimine, and rifabutin, three generic antibiotic ingredients, in a single capsule. The compound was developed to treat MAP infections in Crohn's disease.

To date, Crohn's disease has been considered an autoimmune disease, but the exact pathological mechanism is unclear. Dr. Robert J. Greenstein suggested in *The Lancet Infectious Diseases*, 2003, that Crohn's disease is caused by MAP, the same organism responsible for causing a major disease in animal agriculture production, domestic and wild animals. This hypothesis is supported by an expanding number of scientific and clinical studies published in peer-reviewed journals since a National Institute of Allergy and Infectious Diseases conference that focused on MAP in Crohn's disease took place in 1998. Specific genetic loci like NOD2/CARD15 have been implicated in the pathogenesis of Crohn's disease with mutations in NOD2 suspected of leading to defective recognition of MAP and increased compensatory immune activation in patients with Crohn's disease. Advances in diagnostic technology have led to increasingly higher identification of MAP, with studies, such as Naser S *et al.* The Lancet, 2004, Bull TJ *et al.* J Clin Microbiol, 2003 and Shafran I *et al.* Dig Dis Sci, 2002, demonstrating a high prevalence of MAP in Crohn's disease patients. However, there is currently no FDA-approved commercial diagnostic test for MAP.

In 2011, we obtained FDA "Orphan Drug" status for RHB-104 for the treatment of Crohn's disease in the pediatric population. See "Item 4. Information on the Company – B. Business Overview – Government Regulations – Orphan Drug Designation."

The formulation for RHB-104 and manufacturing of the all-in-one capsules for our clinical trials have been completed. Multiple batches of RHB-104 hard shell capsules packaged in 250 cc bottles with a cap and induction seal child resistant closure have been evaluated in long-term and accelerated stability studies under International Conference on Harmonization ("ICH") specified conditions.

We acquired the rights to RHB-104 pursuant to an asset purchase agreement with Giaconda Limited, an Australian company. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – Acquisition of Talicia®, RHB-104, and RHB-106."

We are likely to require a validated lab test for the detection of MAP bacteria in Crohn's disease patients. Efforts to develop one are in part based on reliably detecting the presence of MAP bacterial DNA in human biological specimens. We do not know if or when such a diagnostic test would become available.

Market and Competition

According to GlobalData, a provider of market intelligence for the pharmaceutical sector, there were approximately 4.1 million diagnosed prevalent cases of Crohn's disease in the sixteen major pharmaceutical markets (the U.S., France, Germany, Italy, Spain, the UK, Japan, Australia, Brazil, Canada, China, India, Mexico, Russia, South Africa and South Korea) in 2024.

Therapeutic interventions in Crohn's disease patients are based on the disease location, severity, and associated complications. Therapeutic approaches for the treatment of Crohn's disease are individualized according to the patient's symptomatic response and tolerance to the prescribed treatment. Since the existing treatments are not curative, the current therapeutic approaches are sequential and involve treatment of an acute disease or inducing clinical remission followed by maintenance of the response or remission to improve the patient's quality of life.

Currently, available drugs on the market for the treatment of Crohn's disease offer symptomatic relief, the effects of which are largely temporary or partial and are accompanied by numerous adverse effects. Marketed treatments for Crohn's disease include 5-Aminosalicylates (5-ASA, such as mesalamine), corticosteroids (such as prednisone), antibiotics, immunomodulators (such as azathioprine and methotrexate) and biologic agents, including TNF-α inhibitors (such as Remicade®, Humira®, and Cimzia®), integrin receptor antagonists (such as Tysabri® and Entyvio®) and interleukin-12 (IL-12) and/or -23 (IL-23) antagonists (such as Stelara® and Skyrizi). In May 2023, the FDA approved Rinvoq® (upadacitinib), a Janus kinase (JAK) inhibitor indicated for the treatment of adults with moderately to severely active Crohn's disease limiting it to patients who have had an inadequate response or intolerance to treatment with one or more TNF blockers. Additionally, the Rinvoq® label includes an FDA black box warning against serious infections, mortality, malignancy, major adverse cardiovascular events and thrombosis. Furthermore, several companies have developed or are in the process of developing biosimilar drugs to compete with approved biologic agents once their patents expire.

There are other companies currently conducting clinical trials with drug candidates in Crohn's disease. We may also be exposed to potentially competitive products, which may be under development or have already been approved to treat Crohn's disease, including new biological therapies, biosimilars and other types of therapies.

Unlike drugs currently on the market for the treatment of Crohn's disease, RHB- 104 is intended to address the suspected cause of the disease - MAP bacterial infection. To the best of our knowledge, there are no drugs approved for marketing that target infections caused by MAP bacteria in Crohn's disease patients.

Clinical Development

A Phase 3 clinical trial for RHB-104 was conducted in Australia, sponsored by Pharmacia, a Swedish company (which merged with Pfizer), with the primary endpoint of evaluating the ratio of patients with recurrent symptoms of Crohn's disease following the initial induction of remission with 16 weeks of treatment with prednisolone initiated at 40 mg/day and weaned over the 16-week period. Subjects were subsequently assessed at 52, 104 and 156 weeks. The main secondary objective was the percentage of patients who achieved clinical remission at 16 weeks. The results of the trial were published by Professor Warwick Selby *et al.* in 2007 in the medical journal *Gastroenterology*. Although the study did not meet the main objective of showing a difference in relapse rate with long-term treatment, there was a statistically significant difference between the treatment groups in the percentage of subjects in remission at week 16. Professor Marcel Behr and Professor James Hanley from McGill University published a re-analysis of the study in *The Lancet Infectious Diseases* in June 2008, based on the intent-to-treat (ITT) principle and found that there was a significant statistical advantage for the active therapy over the placebo throughout the two-year period of administration that disappeared once the active therapy was discontinued.

In June 2011, we entered into an agreement with our Canadian service provider, which entered into a back-to-back agreement with PharmaNet Canada Inc. for the provision of clinical trial services for the RHB-104 adult studies in North America and Europe. PharmaNet was subsequently acquired by inVentiv Health which became Syneos Health ("Syneos"), and our agreements were transferred to Syneos.

In October 2012, we entered into an agreement with our Canadian service provider, which, in turn, entered into a back-to-back agreement with a Canadian manufacturer to complete the manufacturing and supply of RHB-104 for our clinical trials. In addition, we entered into additional manufacturing agreements directly with the Canadian manufacturer.

In July 2018, we announced positive top-line results from the first Phase 3 study with RHB-104 for Crohn's disease (the "MAP US study"), a randomized, double-blind, placebo-controlled first Phase 3 study with RHB-104 for Crohn's disease. The Phase 3 study enrolled 331 subjects with moderately to severely active Crohn's disease (defined as Crohn's Disease Active Index ("CDAI") between 220 and 450) in the U.S., Canada, Europe, Australia, New Zealand, and Israel. Subjects were randomized 1:1 to receive RHB-104 or placebo as an add-on therapy to baseline standard-of-care medications, including 5-ASAs, corticosteroids, immunomodulators or anti-TNF agents.

Our MAP US study successfully met its primary endpoint, as well as key secondary endpoints. Top-line results in the intent-to-treat (ITT) population demonstrated superiority of RHB-104 over placebo in achieving remission at week 26, defined as CDAI value of less than 150, the primary endpoint of the study. The proportion of patients meeting the primary endpoint was significantly greater in the RHB-104 group compared to placebo at week 26 (37% vs. 23%, p= 0.007). Moreover, while the secondary endpoints were not powered for significance in this induction of remission trial, key secondary endpoints were nevertheless met with statistically and clinically meaningful outcomes, demonstrating consistent benefit to Crohn's disease patients treated with RHB-104. RHB-104 was found to be generally safe and well tolerated.

In October 2018, we reported additional positive data from the MAP US study, including subgroup analysis of treatment with and without anti-TNF agents, presented at the United European Gastroenterology Week 2018.

In October 2019, we announced full week 52 results of blinded treatment in the MAP US study at the American College of Gastroenterology, which were consistent with the previously reported interim positive outcomes from the study. The study continued to meet its primary endpoint of clinical remission, defined as CDAI value of less than 150, at week 26 (36.7% vs. 22.4%, p=0.0048), key secondary endpoints of maintenance of remission at weeks 16 and 52 (25.9% vs. 12.1%, p=0.0016) and, notably, durable clinical remission on all visits, week 16 through 52 (18.7% vs. 8.5%, p=0.0077) (in all cases, data presented as RHB-104 vs. placebo).

RHB-104 was found to be generally safe and well tolerated, with an overall balance in the type and frequency of adverse events between RHB-104 and placebo. RHB-104 was associated with a lower incidence of Clostridiodies (Clostridium) difficile infections compared with placebo. In the analysis of the complete safety information for the study, a top-line electrocardiogram monitoring report for the MAP US study, which was shared with the FDA, demonstrated evidence of progressive prolongation of the QTcF (corrected QT interval by Frederica's formula) interval across visits, with the largest mean placebo-corrected ΔQTcF (ΔΔQTcF) of 30.6ms at week 52 of treatment. Clofazimine, as well as clarithromycin (another active component of RHB-104), are known to be associated with QT prolongation.

In October 2019, we also announced supportive top-line results from an open-label extension Phase 3 study (the "MAP US2 study"), which was conducted to evaluate the safety and efficacy of RHB-104 in subjects who remain with active Crohn's disease (CDAI ≥ 150) after 26 weeks of blinded study therapy in the Phase 3 MAP US study. These subjects had the opportunity to receive treatment with RHB-104 for a 52-week period in the open-label MAP US2 study. A total of 54 subjects entered the open-label extension study in the U.S., Canada, Europe, Israel, and New Zealand, and 30 subjects completed 52 weeks of treatment with RHB-104. The MAP US2 study's primary endpoint is disease remission at week 16, defined as CDAI of less than 150. Top-line results from the MAP US2 study demonstrated 28% clinical remission with RHB-104 at week 16 and 22% remission at week 52. Of the MAP US2 subjects who were previously randomized to the placebo arm (as an add-on to standard-of-care therapies) in the MAP US study and treated with RHB-104 for the first time in the MAP US2 study, 32% achieved remission at week 16.

We further announced in September 2019 that following additional guidance received from the FDA on the path for potential approval of RHB-104 for the treatment of Crohn's disease, we have intensified our collaborations with leading laboratories in the field of detection of MAP bacteria in Crohn's disease patients. We do not know if and when a validated lab test for MAP would become available. Additional FDA guidance on the potential path to approval of RHB-104 is to be obtained prior to initiation of further clinical studies.

We have conducted several supportive studies with the current formulation of RHB-104, including a population pharmacokinetic study that was conducted as part of the Phase 3 MAP US study.

We believe that additional clinical studies will be required to support an NDA for RHB-104, if filed.

The following chart summarizes the clinical trial history and status of RHB-104 studies and its earlier individual active agents:

Clinical trial author/designation	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Nature and status of the trial	Schedule
Borody 2002	Phase 2a	Examining the effect of the treatment on Crohn's disease patients	Center for Digestive Disease, Australia	12	Performed	Completed 2002
Borody 2005	Phase 2	Examining the effect of the treatment on Crohn's disease patients	Center for Digestive Disease, Australia	52	Performed	Completed 2005
Selby	Phase 3	Examining the effect of the treatment with the product on Crohn's disease patients	20 clinical centers in Australia	213	The trial was performed and indicated promising improvement rates, although it did not meet the main trial objective, as defined	Published in 2007
Biovail PK Study 2007	PK Study	Optimize the formulation of RHB-104 on a PK basis	Toronto, Ontario	24	The trial compared two formulations to determine the optimum formulation for RHB-104	Completed 2007
MAP US Study	Phase 3	Assess the safety and efficacy of RHB-104 in Crohn's disease patients	U.S., Canada. Israel, Australia, New Zealand, and Europe	331	Completed	Completed 2020
MAP US2 Study	Phase 3	Assess the safety and efficacy of RHB-104 in Crohn's disease patients	U.S., Canada, Israel, New Zealand, and Europe	54	Completed	Completed 2021
Drug-Drug Interaction Study	PK Study	To assess the net PK effect of multiple doses of RHB-104 on CYP3A4 enzymes in healthy volunteers	Algorithme Pharma, Canada	36	Ended	Ended 2014
Food Effect Study	PK Study	Determine the effect of food on the bioavailability of RHB-104 in healthy volunteers	Algorithme Pharma, Canada	84	Completed	Completed 2014

We cannot predict with certainty our development costs, and such costs may be subject to change. See "Item 3. Key Information – D. Risk Factors – Risks Related to Our Financial Condition and Capital Requirements."

Multiple Sclerosis ("MS")

MS is an inflammatory, demyelinating, and neurodegenerative disease of the central nervous system of uncertain etiology that exhibits characteristics of both infectious and autoimmune pathology.

We had previously conducted a Phase 2a proof-of-concept study with RHB-104 for relapsing-remitting multiple sclerosis. At the current stage, we have no intention to pursue the development of RHB-104 for this indication.

RHB-102 (Bekinda®)

RHB-102 (Bekinda®) is an investigational, once-daily, bi-modal release, oral formulation of ondansetron, a leading member of the family of 5-HT3 serotonin receptor inhibitors. RHB-102 (Bekinda®) is under development in multiple dosage strengths for the intended use in the following indications, which are novel and not yet FDA-approved indications for ondansetron targeting large potential markets:

1) Acute gastroenteritis and gastritis – 24 mg strength

2) Irritable Bowel Syndrome with Diarrhea (IBS-D) – lower dose strength, at 12 mg for long-term administration

3) Oncology support (management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy, also referred to as CINV and RINV) – 24 mg strength

On February 16, 2023, the Company announced that following a positive pre-MAA meeting and subject to manufacturing-related activities it is considering plans and path to submit a Marketing Authorisation Application (MAA) to the UK Medicines & Healthcare products Regulatory Agency (MHRA) seeking approval for RHB-102 (Bekinda®) for oncology support in adults and children over the age of 12. Data to support the submission was generated from several clinical studies, including the successful U.S. Phase III GUARD study with RHB-102 24 mg for acute gastroenteritis and gastritis.

On February 25, 2025, we announced that we entered into an exclusive worldwide development and commercialization licensing agreement, excluding North America, with Hyloris for RHB-102 (Bekinda®). We intend to continue the development for FDA approval in the U.S, if granted, for RHB-102. Hyloris will be responsible for all development, regulatory, and commercialization activities related to RHB-102 in its territories across all indications including acute gastroenteritis and gastritis, IBS-D, and oncology support. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – License Agreement with Hyloris Pharmaceuticals".

RHB-102 (Bekinda®) utilizes a technology called CDT® that uses salts to provide an extended-release of ondansetron. The CDT® platform enables extended drug release (i.e., the measured rate of introduction of active drug) at a relatively low manufacturing cost. The proposed commercial formulation and its use are protected by Company-filed patents and pending patent applications and are being pursued internationally.

Acute Gastroenteritis and Gastritis

Acute gastroenteritis and gastritis both involve inflammation of the mucous membranes of the GI tract. Symptoms of gastroenteritis and gastritis include nausea, vomiting, diarrhea, and abdominal pain. Acute gastroenteritis and gastritis are major causes of emergency room visits, particularly for pediatrics. If approved, RHB-102 (Bekinda®) could potentially decrease the number of emergency room visits for patients suffering from acute gastroenteritis and gastritis by offering them an effective and long-lasting treatment, which can be taken in the comfort of their home.

Market and Competition

A single dose of RHB-102 (Bekinda®) is intended to treat nausea and vomiting over a time window of approximately 24 hours. If approved for such use, this would be potentially advantageous for acute gastroenteritis and gastritis patients as it could help eliminate the need to take additional drugs (tablets) during the day or receiving intravenously administered drugs.

If RHB-102 (Bekinda®) is approved for the treatment of acute gastroenteritis and gastritis, it could potentially hold substantial advantages over existing treatments. If approved, RHB-102 (Bekinda®) could be prescribed by primary care physicians to patients early on, potentially preventing emergency room visits, dehydration and the need to provide IV fluids. There are an estimated 685 million global cases of acute gastroenteritis caused by Norovirus annually (CDC – Norovirus Facts and Stats, 2024).

To the best of our knowledge, there are no other 5-HT3 serotonin receptor inhibitors indicated or in the advanced clinical stage of development in the U.S. for this indication. Patients presenting at hospitals with gastroenteritis and gastritis are often treated primarily in IV administration with antiemetic drugs not indicated or approved for this condition, off-label, including 5-HT3 serotonin receptor inhibitors. If approved, RHB-102 (Bekinda®) will compete with several prescription and OTC antiemetic drugs, including but not limited to, dimenhydrinate, Nauzene®, and Emetrol®, as well as off-label use of ondansetron and other 5-HT3 inhibitors.

We may also be exposed to potentially competitive products which may be under development to treat acute gastroenteritis. To the best of our knowledge, a product that potentially directly competes with RHB-102 (Bekinda®) is EUR-1025 for controlled release of ondansetron, based on a different technology of controlled release originally developed by Eurand N.V. (now owned by Adare Pharma Solutions) and which completed two pivotal pharmacokinetic studies intended to establish the bioequivalence of EUR-1025 versus Zofran® (ondansetron hydrochloride). To the best of our knowledge, there has not been further clinical development of EUR-1025 since the completion of the above-mentioned pharmacokinetic studies.

Clinical Development

In June 2017, we announced positive top-line results from the randomized, double-blind, placebo-controlled Phase 3 study (the "GUARD study") with RHB-102 (Bekinda®) 24 mg for acute gastroenteritis and gastritis. The study successfully met its primary endpoint and RHB-102 (Bekinda®) 24 mg was found to be safe and well tolerated in this indication. The GUARD study evaluated the efficacy and safety of RHB-102 (Bekinda®) 24 mg in treating acute gastroenteritis and gastritis in 321 adults and children over the age of 12. The primary endpoint of the study was the proportion of patients without further vomiting, without rescue medication, and who were not given intravenous hydration from 30 minutes post first dose of the study drug until 24 hours post-dose, compared to placebo. In September 2017, we met with the FDA to discuss the study results and the clinical and regulatory path toward potential marketing approval of RHB-102 (Bekinda®) 24 mg in the U.S. Following the guidance provided at the meeting and additional guidance provided thereafter, we are currently advancing preparations toward a confirmatory Phase 3 study to support a potential NDA with RHB-102 (Bekinda®) 24 mg for acute gastroenteritis and gastritis.

Final results from the GUARD study showed improvement to the primary efficacy outcome by 21% in the ITT population; 65.6% of RHB-102 (Bekinda®) treated patients as compared to 54.3% of placebo patients (p=0.04; n=192 in the RHB-102 (Bekinda®) group and n=129 in the placebo group). In the Per Protocol (PP) population, which included patients who met all protocol entry criteria and for which the diagnosis of gastroenteritis was confirmed (n=177 in the RHB-102 (Bekinda®) group and n=122 in the placebo group), RHB-102 (Bekinda®) improved the efficacy outcome by 27%; 69.5% of patients in the RHB-102 (Bekinda®) group vs. 54.9% in the placebo group, (p=0.01). An imbalance in baseline nausea was noted, with worse nausea in the RHB-102 (Bekinda®) treated group. In a post hoc analysis, when results were adjusted for baseline nausea, the p-value for the ITT population was 0.0152, and for the PP population was 0.0037. RHB-102 (Bekinda®) 24 mg was also shown to be safe and well tolerated; electrocardiogram results showed no adverse changes with treatment. The benefit observed with RHB-102 (Bekinda®) is evident across the spectrum of severity of nausea at baseline, including in patients with very severe nausea, suggesting that the drug works regardless of the initial severity of gastroenteritis.

The lead investigator for the Phase 3 study was Dr. Robert A. Silverman, MD, MS, Associate Professor at the Hofstra North Shore-LIJ School of Medicine and an emergency medicine specialist.

In September 2019, we had a follow-up meeting with the FDA regarding our efforts to design a study acceptable to the agency to seek the FDA's approval for pediatric labeling for RHB-102 (Bekinda®), as required by the FDA pursuant to the Pediatric Research Equity Act.

The following chart summarizes the clinical trial history and status of RHB-102 (Bekinda®) for gastroenteritis and gastritis:

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Nature and status of the trial	Schedule
GUARD Study	Phase 3	Randomized double-blind placebo-controlled Phase 3 study in acute gastroenteritis and gastritis	21 sites in the U.S.	321	Evaluated the safety and efficacy of RHB-102 (Bekinda®) in acute gastroenteritis and gastritis	Completed 2017
TBD	Confirmatory Phase 3	Support a potential NDA with RHB-102 (Bekinda®) 24 mg for acute gastroenteritis and gastritis	TBD	TBD	TBD	TBD

We cannot predict with certainty our development costs, and such costs may be subject to changes. See "Item 3. Key Information – D. Risk Factors – Risks Related to Our Financial Condition and Capital Requirements."

Irritable Bowel Syndrome with Diarrhea (IBS-D)

Irritable bowel syndrome (IBS) is a multifactorial disorder marked by recurrent abdominal pain or discomfort and altered bowel function. According to the Mayo Clinic, certain factors that alter GI function can contribute to IBS symptoms, including stress, prior gastroenteritis, and changes in the gut microbiome, bile acids and short-chain fatty acids, which may stimulate 5-HT3 serotonin release and increase colonic permeability and motility.

In preliminary studies, ondansetron has demonstrated activity in IBS-D (Garsed K, Chernova J, Hastings M, et al. Gut Published Online First December 12, 2013). Unlike alosetron (a currently approved 5-HT3 antagonist in IBS-D), ondansetron has not been noted to cause ischemic colitis (FDA labeling for Lotronex® (alosetron), 2010; FDA labeling for Zofran® (ondansetron), 2014).

In light of the activity of ondansetron demonstrated in the preliminary studies described above, and because of its extended-release properties and once-daily dosing, we believe RHB-102 (Bekinda®) is a promising candidate for the treatment of IBS-D.

Market and Competition

IBS is one of the most common GI disorders. According to GlobalData, there were approximately 76 million diagnosed prevalent cases of IBS (age>=18) in the 16 major pharmaceutical markets (the U.S., France, Germany, Italy, Spain, the UK, Japan, Australia, Brazil, Canada, China, India, Mexico, Russia, South Africa and South Korea) in 2024. Of the three subtypes of IBS, IBS-D is the most prevalent diagnosed subtype according to Pimentel M (Am J Manag Care, 2018), accounting for 40% of the patient population.

To the best of our knowledge, there is one other 5-HT3 serotonin receptor inhibitor indicated for this indication in the U.S. known as alosetron marketed under the brand name Lotronex® by Sebela Pharmaceuticals and is also available in generic versions marketed by other companies. However, alosetron is approved only for the treatment of IBS in women with severe chronic IBS-D and has been associated with serious gastrointestinal side effects. The active ingredient in RHB-102 (Bekinda®), ondansetron, is approved by the U.S. FDA as an oncology support antiemetic and has a good safety profile. Therefore, we believe that RHB-102 (Bekinda®), if approved for the treatment of IBS-D in the U.S., may provide improved safety while maintaining efficacy and has the potential to be a preferred 5-HT3 serotonin receptor inhibitor treatment for patients suffering from IBS-D. Ramosetron, another 5-HT3 serotonin receptor inhibitor is marketed for the treatment of IBS in Japan, South Korea, China and India (marketed under the brand name Irribow® by Astellas Pharma Inc. in Japan and is available in generic versions marketed by other companies in South Korea, China and India). Ramosetron is also marketed for the treatment of chemotherapy-induced nausea and vomiting in Japan, South Korea, China, India and Indonesia and for postoperative nausea and vomiting in South Korea and India. To the best of our knowledge, there is currently no clinical development of ramosetron for marketing approval in the U.S. for any indication.

If approved, RHB-102 (Bekinda®) will compete with several prescription drugs indicated for IBS-D, including but not limited to Xifaxan® (rifaximin), marketed in the U.S. by Salix Pharmaceuticals, and Viberzi® (eluxadoline), marketed in the U.S. by Allergan plc., now AbbVie Inc, as well as additional prescription drugs, generic drugs, and over-the-counter products indicated for IBS-D or for symptomatic relief of diarrhea and pain.

In addition, we may also be exposed to potentially competitive products that may be under development or that have already been approved by other companies to treat IBS-D in the U.S.

Clinical Development

In January 2018, we announced positive final results from the Phase 2 clinical study of RHB-102 (Bekinda®) 12 mg for the treatment of IBS-D. The randomized, double-blind, placebo-controlled Phase 2 study evaluated the efficacy and safety of RHB-102 (Bekinda®) 12 mg in 126 subjects over 18 years old at 16 clinical sites in the U.S. The study successfully met its primary endpoint, improving the primary efficacy outcome of stool consistency.

RHB-102 (Bekinda®) was also shown to be safe and well tolerated in this indication. No serious adverse events or new or unexpected safety issues were noted in the study. In September 2018, we announced that we concluded a positive End-of-Phase 2 Type B meeting with the FDA discussing the clinical and regulatory pathway toward potential FDA approval of RHB-102 (Bekinda®) for the treatment of IBS-D, which requires the conduct of two pivotal Phase 3 studies with RHB-102 (Bekinda®) for the treatment of IBS-D.

The primary endpoint of the trial was the proportion of patients in each treatment group with response in stool consistency on study drug as compared to baseline. Response was defined as per FDA guidelines for the indication. Additional endpoints were analyzed including:

- proportion of patients in each treatment group who are pain responders, per FDA guidance definition;
- proportion of patients in each treatment group who are overall responders, per FDA guidance definition; and
- differences between treatment groups in:
  - abdominal pain,
  - abdominal discomfort,
  - frequency of defecation, and
  - incidence and severity of adverse events.

The RHB-102 (Bekinda®)12 mg Phase 2 study successfully met its primary endpoint, improving the primary efficacy outcome of stool consistency response (in accordance with the FDA guidance definition) by an absolute difference of 20.7%, with 56.0% responders of subjects treated with RHB-102 (Bekinda®) (n=75) vs. 35.3% responders of the placebo subjects (n=51) (p=0.036). While not powered for statistical significance of the secondary efficacy endpoints, the study suggested clinically meaningful improvement in both secondary efficacy endpoints of abdominal pain response and overall response (combined stool consistency and abdominal pain response). Final results from the Phase 2 study demonstrated that RHB-102 (Bekinda®) 12 mg improved the overall worst abdominal pain response rate by 11.5% vs. placebo (50.7% with RHB-102 (Bekinda®) 12 mg (n=75) vs. 39.2% with placebo (n=51); (p=0.278)) and the overall response improved by an absolute difference of 14.5% in favor of the RHB-102 (Bekinda®) 12 mg arm (40.0% with RHB-102 (Bekinda®) 12 mg (n=75) vs. 25.5% with placebo (n=51); (p=0.135)).

RHB-102 (Bekinda®) 12 mg was also shown to be safe and well tolerated. No serious adverse events or new or unexpected safety issues were noted in the study. In September 2018, we announced that we concluded a positive End-of-Phase 2/Pre-Phase 3 (Type B) meeting with the FDA discussing the clinical and regulatory pathway toward potential FDA approval of RHB-102 (Bekinda®) 12 mg for the treatment of IBS-D, which requires the conduct of two pivotal Phase 3 studies with RHB-102 (Bekinda®) for the treatment of IBS-D.

We have initiated formulation work to formulate RHB-102 at lower dosages to help support planned pediatric studies. In December 2019, we received confirmation from the FDA that it has agreed with our Initial Pediatric Study Plan (iPSP).

The following chart summarizes the clinical trial history and status of RHB-102 (Bekinda®) for IBS-D:

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Nature and status of the trial	Schedule
-	Phase 2	Randomized double-blind placebo-controlled Phase 2 study in IBS-D	16 sites in the U.S.	126	Evaluating the safety and efficacy of RHB-102 (Bekinda®) 12 mg in IBS-D	Completed 2018
TBD	Phase 3	Randomized double-blind placebo-controlled Phase 3 study in IBS-D	TBD	TBD	TBD	TBD

We cannot predict with certainty our development costs and such costs may be subject to change. See “Item 3. Key Information – D. Risk Factors – Risks Related to Our Financial Condition and Capital Requirements.”

RHB-204

Nontuberculous Mycobacteria Infections

In November 2020, we initiated a Phase 3 study in RHB-204 for the treatment of pulmonary Mycobacterium avium complex (MAC) disease in adults with nodular bronchiectasis (also referred to hereafter as pulmonary NTM disease caused by MAC).

The study was intended to assess the efficacy and safety of RHB-204 as a potential first-line, stand-alone treatment for pulmonary NTM infections caused by MAC. In May 2023, we announced the termination of the study due to a very low accrual rate, and the shifting of our resources to advance once-daily, oral RHB-107’s late-stage development for outpatient treatment of COVID-19. We continue to explore potential partnerships for RHB-204 and are also expanding the planned indications to be pursued with RHB-204 to Crohn’s disease.

In January 2017, we announced that RHB-204 had been granted QIDP designation by the FDA for the treatment of pulmonary NTM infections, including eligibility for Accelerated Approval and Priority Review and an extended market exclusivity period, if approved for marketing in the U.S.

In October 2020, we announced that RHB-204 had been granted Orphan Drug designation by the FDA for the treatment of pulmonary NTM infections which would extend market exclusivity period to a total of 12 years, if approved for marketing in the U.S.

In January 2021 we announced that the FDA granted RHB-204 Fast Track designation, allowing RedHill access to early and frequent communications with the FDA, to expedite the RHB-204 development program, and to a rolling review of an NDA.

In August 2022, we announced that the European Commission granted Orphan Drug Designation to RHB-204 for the treatment of NTM disease, following a positive opinion recommendation by the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP), providing eligibility for 10 years post-approval EU market exclusivity.

RHB-204 is a patented fixed-dose combination product of three antibiotics intended to simplify administration and optimize compliance, selected based on modelling to provide optimal balance of the potential safety and efficacy. Each capsule contains the same three antibiotics as RHB-104 (clarithromycin, clofazimine, and rifabutin), but at doses unique from RHB-104. Clarithromycin and rifabutin were selected because mycobacteria live within host cells, and these agents have intracellular activity against MAC. Further, rifabutin enhances the antimicrobial activity of clarithromycin due to increased levels of clarithromycin's active metabolite. Selection of clofazimine was based on its activity against MAC, preferential accumulation in macrophages and bactericidal activity demonstrated in a mouse model of tuberculosis. Moreover, the inclusion of rifabutin and clofazimine has shown to mitigate the emergence of resistance to clarithromycin compared to clarithromycin alone or in combination with only rifabutin or clofazimine in a clarithromycin- susceptible M.avium lung infection mouse model as well as exhibiting significant reductions in bacterial counts in the lung after four and eight weeks of treatment.

Market and Competition

Pulmonary NTM is an orphan disease and is expected to affect approximately 111,000 patients in the U.S. in 2025, according to a 2021 analysis by Foster Rosenblatt. Although rare, the incidence and number of deaths from NTM disease have been steadily increasing globally, according to Ratnatunga CN et al. (Front. Immunol. 2020), with a rise in the number of globally documented NTM infections leading to NTM being recognized as an emerging threat causing significant morbidity and mortality in both immune competent and immune compromised populations. Treatment options remain limited, lengthy and challenging (Ryu YJ et al. Tuberc Respir Dis, 2016; Ratnatunga CN et al. Front. Immunol. 2020).

NTM are naturally occurring organisms found in water and soil, which can cause chronic pulmonary infection. According to Prevots DR (Am J Respir Crit Care Med, 2010) and Winthrop KL (Am J Respir Crit Care Med, 2010), approximately 80% of pulmonary NTM cases in the U.S. are associated with MAC. In some people, infection with NTM may lead to a progressive lung disease characterized by fever, weight loss, chest pain, and blood in sputum. NTM disease is more common in the older adult population and individuals with a compromised immune system or underlying lung disease.

According to the American Lung Association, NTM are relatively resistant to antibiotics and can become more resistant if only one antibiotic is used. Effective treatment of NTM caused by MAC requires three drugs for at least 12 months of treatment. Currently recommended treatment regimens, drug resistance patterns, and treatment outcomes differ according to the NTM species, and management is a lengthy complicated process with limited therapeutic options (Ryu YJ et al. 2016). There is currently no approved first-line therapy for NTM lung disease. Treatment is determined based on guidelines and includes multi- drug regimens with antibiotics not approved for NTM. Adherence to the guidelines for treating NTM lung disease is suboptimal, and potentially harmful antibiotic regimens are commonly prescribed. Management of NTM disease requires prolonged use of costly combinations of multiple drugs with a significant potential for toxicity.

In September 2018, the FDA approved Arikayce® (amikacin liposome inhalation suspension), a new drug developed by Insmed Incorporated, for the treatment of lung disease caused by MAC in a limited population of refractory patients which does not respond to conventional treatment. To the best of our knowledge, this is the first treatment approved specifically for pulmonary NTM infections caused by MAC. Arikayce® is indicated as a second-line therapy in refractory patients as part of a combination antibacterial drug regimen. The Arikayce® prescribing information includes a Boxed Warning regarding the increased risk of respiratory conditions, including hypersensitivity pneumonitis, bronchospasm, exacerbation of underlying lung disease and hemoptysis that have led to hospitalizations in some cases.

Several investigational drugs are in development for the treatment of NTM infections, including but not limited to, epetraborole (AN2 Therapeutics), an oral antibiotic agent, LungFit® GO (Beyond Air Inc.), an inhaled Nitric Oxide, MNKD-101 (MannKind), a clofazimine inhalation suspension and Nuzyra® (Paratek Pharmaceuticals), an oral antibacterial agent. Additionally, Insmed Incorporated is conducting a clinical trial program with Arikayce® as a first-line treatment for patients with MAC lung disease. According to www.clinicaltrials.gov, there are several additional ongoing clinical studies evaluating treatments for NTM infections.

Clinical Development

Although each of the three components of RHB-204 is approved individually and has been tested extensively in humans (e.g. see RHB-104), the formulation and doses represented by RHB-204 is novel and has not previously been tested in humans. Initiation of the trial for pulmonary NTM lung infections was in November 2020, and in May 2023, we announced the termination of the study due to a very low accrual rate, and the shifting of our resources to advance once-daily, oral RHB-107's late-stage development for outpatient treatment of COVID-19.

The following chart summarizes the development history and status of RHB-204:

Trial name	Development phase	Purpose of the trial	Clinical trial sites	Planned number of subjects of the trial	Status of the trial
CleaR-MAC Trial	Phase 3	Evaluate the efficacy and safety of RHB-204 in adult subjects with documented MAC lung infection.	Up to 40	125	Terminated

Preclinical studies

In September 2021, we announced results of a preclinical study demonstrating opaganib's efficacy in significantly decreasing renal fibrosis in a unilateral ureteral obstruction-induced renal interstitial fibrosis model. Reports suggest that over 20% of hospitalized COVID-19 patients experience acute renal failure. The aim of the *in vivo* efficacy study was to verify the effect of opaganib on kidney inflammation and fibrosis in a unilateral ureteral obstruction (UUO) model – a well characterized model for renal fibrosis. Results from the study showed that opaganib significantly decreased renal fibrosis.

Opaganib demonstrated potent antiviral activity against SARS-CoV-2, the virus that causes COVID-19, completely inhibiting viral replication in an *in vitro* model of human lung bronchial tissue. In June 2021, we announced that preliminary results from a preclinical study demonstrated potent inhibition of the Beta and Gamma COVID-19 variants of concern by opaganib at non-cytotoxic doses. We further announced in August 2021 that opaganib demonstrated strong inhibition of the Delta variant replication while maintaining cell viability at relevant concentrations in a 3D tissue model of human bronchial epithelial cells. Based on opaganib's unique host-targeted mechanism and the preliminary results of this study, we believe opaganib is likely to also maintain its activity against emerging variants of COVID-19.

In April 2022, we announced study results in which opaganib was observed to have potent *in vitro* efficacy against the *Omicron* SARS-CoV-2 variant, while maintaining host cell viability, and in October 2022, we announced study results showing preliminary evidence of *in vitro* efficacy against the Omicron COVID-19 sub-variant BA.5 by opaganib and RHB-107.

In an in-vitro study sponsored by NIAID, opaganib demonstrated activity against Influenza A H1N1 in a human airway epithelial cell line. Upon successful completion of the above assay, further in-vivo studies of opaganib for treatment of influenza A/CA/04/2009 (H1N1pdm) virus infection in C57BL/6 mice were initiated at Utah State University to determine the efficacy of opaganib. The experiment was technically flawed, as the positive control was also only minimally effective. Following discussion with NIAID to repeat the experiment using Balb-C mice and exploring potential synergy with oseltamivir, further repeat and expansion in-vitro testing of H1N1 and H1N5 (bird-flue) strains are underway with anticipated results in the second quarter of 2025.

In October 2023, we announced that opaganib delivered a statistically significant increase in survival time when given at 150 mg/kg twice a day (BID) in a United States Army Medical Research Institute of Infectious Diseases (USAMRIID) in vivo Ebola virus study, making it the first host-directed molecule to show activity in Ebola virus disease. The U.S. Army study tested three doses of opaganib (50, 100 and 150 mg/kg BID), against an inactive vehicle control arm. The in vivo study results showed a statistically significant survival increase in mean (SE) survival time of 11.2 (2.6) days in the 150 mg/kg opaganib group (p=0.0279) compared to a mean (SE) survival time of 5.5 (0.4) days in the inactive vehicle control group. A 30% mice survival benefit was observed in the 150 mg/kg treated group compared to the vehicle control. In December 2023, we further announced that opaganib demonstrated a robust synergistic effect when combined with Veklury® (remdesivir, Gilead Sciences, Inc), significantly improving viral inhibition while maintaining cell viability, in a new U.S. Army-funded and conducted Ebola virus in vitro study.

In August 2024, we announced positive results from multiple in vivo studies of oral opaganib for the treatment of obesity and diabetes. These studies demonstrated the impact of sphingosine kinase-2 (SK2) inhibition in various metabolic disease models, supporting the potential of opaganib therapy for diabetes and obesity-related disorders.

Acquisition, Commercialization and License Agreements

Acquisition of Talicia®, RHB-104, and RHB-106

On August 11, 2010, we entered into an asset purchase agreement with Giaconda Limited, a publicly-traded Australian company, pursuant to which Giaconda Limited transferred all of its patents, tangible assets, production files, regulatory approvals and other data related to the "Heliconda", "Myoconda" and "Picoconda" products to us. We renamed these products Talicia®, RHB-104, and RHB-106, respectively. Giaconda Limited further transferred to us products in process, product samples and raw materials, as well as certain rights of first refusal with respect to intellectual property in relation to digestive condition treatments. The agreement excluded the transfer of the rights to two products of Giaconda Limited that are not related to Talicia®, RHB-104, and RHB-106. However, to the extent that the intellectual property associated with these two other products may be required for the research, development, manufacture, registration, import/export, use, commercialization, distribution, sale or offer for sale of any of Talicia®, RHB-104, and RHB-106, Giaconda Limited granted us an exclusive worldwide assignable right to such intellectual property for such purposes. The closing of this transaction occurred on August 26, 2010.

We paid Giaconda Limited in consideration for the assets purchased by us an initial amount of $500,000. We and Giaconda Limited also agreed that, until the expiration of the last patent transferred to us with respect to each product, we will pay to Giaconda Limited 7% of net sales from the sale of the relevant product/s by us and 20% of the consideration (including royalties received by us) from sublicensees, in each case, only after we recoup the amounts and expenses exceeding an approved budget.

Under the agreement, Giaconda Limited agreed that neither it, nor the developer of the products, nor any of their respective affiliates may compete with us or assist others to compete with us with respect to the products and acquired technology for the period provided for in the agreement.

The agreement provides that, should we elect not to proceed with the registration proceedings, or the maintenance of any patent transferred to us, we will notify Giaconda Limited and Giaconda Limited will have the right to proceed with the registration, maintenance, development and commercialization of such patent at its expense. Should Giaconda Limited exercise such right, it will be entitled to all amounts received in connection with sales relating to such patent.

The agreement also requires us to make a good faith, continuous and commercially reasonable effort to allocate appropriate financial resources to prepare, initiate and complete the clinical development of the products (with the exception of Picoconda by virtue of the Salix license agreement dated February 27, 2014) and file an application for regulatory marketing approval in accordance with industry standards. Development failures, negative regulatory decisions, or other reasons beyond our control will not constitute a breach of this obligation. Should we breach this obligation with respect to the development of any of the products and fail to cure the breach within 90 days from the date that Giaconda Limited sends us a default notice, Giaconda Limited may buy back all of the intellectual property rights with respect to such product for the original purchase price, plus the related development costs incurred by us through the date of the buy-back.

In connection with the license agreement with Salix (later acquired by Bausch Health), dated February 27, 2014, described below, we amended the asset purchase agreement and related agreements by excluding from the non-compete undertakings of Giaconda Limited and certain of its affiliate products, technology, and related activities in the purgative field and excluded from such non-compete undertakings certain of Giaconda Limited's affiliates. Subsequently, we recognized revenues in 2014 and paid Giaconda Limited an additional amount of $1 million. On February 27, 2014, we amended the asset purchase agreement with Giaconda Limited to cancel the buyback right and agreed that we would pay Giaconda Limited 20% of all amounts received by us from Bausch Health under the license agreement, without first recouping amounts and expenses and notwithstanding the expiration of any relevant patents.

License Agreement with Hyloris Pharmaceuticals

In February 2025, we entered into an exclusive worldwide development and commercialization licensing agreement, excluding North America, with Hyloris Pharmaceuticals SA ("Hyloris") for RHB-102 (Bekinda®). Under the terms of the agreement, Hyloris will pay us an upfront payment, in addition to up to $60 million in potential milestone payments, contingent upon achieving specified commercial targets, plus up to mid-20s percent royalties on revenues, subject to certain cost recoupments, with minimum annual payments to us, in return for exclusive rights to RHB-102 across all indications and territories outside the United States, Canada, and Mexico. We intend to continue the development for FDA approval in the U.S, if granted, for RHB-102. Hyloris will be responsible for all development, regulatory, and commercialization activities related to RHB-102 in its territories across all indications including acute gastroenteritis and gastritis, IBS-D, and oncology support.

License Agreement with Kukbo

In March 2022, we entered into the Exclusive License Agreement with Kukbo Co. Ltd. ("Kukbo") for opaganib in South Korea. Under the terms of the Exclusive License Agreement, Kukbo was required to pay an upfront payment of $1.5 million and we are also eligible for milestone payments and royalties on net sales of oral opaganib in South Korea.

On September 2, 2022, we filed a lawsuit against Kukbo in the Supreme Court of the State of New York, County of New York, Commercial Division, as a result of Kukbo's default in delivering to us $5.0 million under a subscription agreement, dated October 25, 2021 (the "Subscription Agreement"), in exchange for the ADSs we were to issue to Kukbo, and in delivering to us the $1.5 million due under the Exclusive License Agreement. Kukbo thereafter filed counterclaims with various allegations such as breach of contract, misrepresentation, and the breach of the duty of good faith and fair dealing. On November 20, 2023, we entered into a Contingency Fee Agreement with our legal firm, Haynes and Boone, LLP ("H&B"), under which certain legal costs related to the Kukbo litigation will be assumed by H&B. On December 2, 2024, we were awarded a judgment of approximately $8 million, including $6.5 million in principal and approximately $1.5 million in accrued interest, plus costs, in a summary judgment by the Supreme Court of the State of New York, New York County in our legal proceedings against Kukbo. The Court dismissed the entirety of Kukbo's counterclaims in the case. Kukbo filed a notice of appeal and retains the right to seek an appeal. We intend to vigorously pursue the recovery of attorneys' fees and the collection of the judgment.

License Agreement with Gaelan Medical

In December 2021, we entered into an exclusive license agreement (the "License Agreement") with Gaelan Medical Trade LLC ("Gaelan Medical") for Talicia® in the United Arab Emirates (UAE). Under the terms of the License Agreement, we received in April 2022 an upfront payment of $2 million. In addition, we are eligible for additional milestone payments as well as tiered royalties up to mid-teens on net sales of Talicia® in the UAE. Gaelan Medical received the exclusive rights to commercialize Talicia® in the UAE. Gaelan Medical shall be responsible for obtaining and maintaining regulatory approvals, as well as to conduct any and all required clinical and other studies. In March 2022, we signed an amendment to the License Agreement, according to which Gaelan Medical may sublicense or assign any of its rights or obligations under the License Agreement. In connection with the License Agreement, we and Gaelan Medical entered into a supply agreement, according to which, we will exclusively manufacture (by a third party CMO) and supply Talicia® to Gaelan Medical during the term of the agreement. On August 1, 2023, we announced that Gaelan Medical had received marketing approval for Talicia® in the UAE and that Gaelan Medical has subsequently placed the first commercial order for Talicia®, which was dispatched from the CMO in December 2023. In August 2024, we announced the launch of Talicia® in the UAE.

Additional License Agreement related to MAP diagnostic test for RHB-104

On December 27, 2014, we entered into a license agreement with the University of Minnesota (UoM) pursuant to which we were granted an exclusive license for all indications and medical uses to a patent-protected designation of certain DNA sequencing.

Sale of Movantik® to HCRM

On February 2, 2023, RedHill U.S. and the Company (together, "RedHill Group") entered into an Asset Purchase Agreement (the "APA") and related agreements with HCRM. The APA provides for the sale of RedHill Group's assets exclusively related to RedHill Group's exploitation of Movantik® to an affiliate of HCRM in exchange for the extinguishment and termination of all Obligations (as defined in the Credit Agreement) (other than certain indemnification obligations), including the loans, all accrued and unpaid interest thereon, the revenue interest, the prepayments premiums and exit fees (the "Transaction"). The related agreements, each dated as of February 2, 2023, included the Sixth Amendment to the Credit Agreement and Collateral Documents (the "Collateral Amendment"), the Escrow Agreement (the "Escrow Agreement"), the Transition Services Agreement (the "TSA") and the Supply Agreement (the "Supply Agreement"). The closing of the transaction pursuant to the APA occurred on February 2, 2023 (the "Closing").

Asset Purchase Agreement. HCRM acquired all assets exclusively related to RedHill Group's exploitation of Movantik® and, generally, assumed all liabilities related to the business arising after the Closing (as defined in the APA). Pursuant to the Supply Agreement (described in more detail below), certain supply contracts will either be terminated or assigned to Movantik Acquisition Co., an affiliate of HCRM ("Movantik Acquisition" or "Buyer"), after the Closing. The APA extinguished all Obligations (as defined in the Credit Agreement) under the Credit Agreement (other than certain indemnification obligations that survive the termination) including the loans, all accrued and unpaid interest thereon, the revenue interest, the prepayment premiums, and exit fees.

Collateral Amendment. All Obligations under the Credit Agreement (including the loans, all accrued and unpaid interest thereon, the revenue interest, the prepayment premiums and exit fees) terminated as of the Closing, except for those obligations that were expressly intended to survive termination of the Credit Agreement, including certain indemnification obligations. Upon Closing, collateral, consisting of (i) the Escrow Account, (ii) Talicia®-related assets, (iii) our former Aemcolo®-related assets and (iv) accounts receivable related to Movantik® accrued as of the Closing, continued to secure "Go-Forward Obligations" consisting of indemnification obligations under the APA and the Credit Agreement and scheduled pre-closing liabilities relating to Movantik®. The value of such liens and security interests were capped at the value of our pre-closing liabilities relating to Movantik®, and all such liens and security interests were fully released upon the first to occur of (i) the payment of scheduled pre-closing liabilities related to Movantik® other than certain specified long-dated liabilities and (ii) the first date 90 days after the Closing on which RedHill Israel has at least $16.9 million in cash and cash equivalents on hand. Both HCRM and its affiliates and RedHill Group provided each other with a broad release of any claims they have against each other arising prior to the Closing.

Escrow Agreement. At the Closing, Buyer deposited $16 million, which was equal to the amount of cash collateral against which HCRM exercised remedies under the Credit Agreement, into the Escrow Account overseen by the Bank of New York Mellon, acting as an escrow agent. Additionally, from and after the Closing, RedHill U.S. was required to deposit all cash received from accounts receivable related to Movantik accrued as of the Closing into the Escrow Account. Funds from the Escrow Account could only be used to pay certain scheduled pre-closing liabilities related to Movantik® that were retained by RedHill U.S. under the terms of the APA. RedHill U.S. and Buyer established a "Joint Escrow Committee" to oversee the release of funds from the Escrow Account to pay the scheduled liabilities in an agreed order of priority. Unless earlier terminated by mutual agreement of RedHill U.S. and Buyer, the Escrow Agreement was to remain in effect until the time that all scheduled pre-Closing liabilities relating to Movantik® were paid.

Transition Services Agreement. RedHill U.S. agreed to provide Buyer certain services, including financial services, regulatory services, pharmacovigilance services, medical information services, quality assurance services, commercial services (including calls by sales agents), project management services, contract transfer services and supply chain services. RedHill U.S. received payment of fees for each service type, calculated as a specified FTE rate plus out-of-pocket costs and pass-through costs incurred during the term of the TSA in which services were provided, in addition to certain pre-determined milestone payments. Effective October 1, 2023, all services under the agreement were terminated.

Supply Agreement. RedHill U.S. facilitated supply of Movantik® from third-party suppliers at cost to Buyer on Buyer's behalf to provide Buyer with the opportunity to establish, with the assistance of RedHill U.S., its own manufacturing capabilities and supply chain for Movantik. Effective October 2, 2023, the Supply Agreement was terminated.

On July 15, 2024, we signed a Global Termination Agreement with Movantik Acquisition Co., Valinor Pharma, LLC, and HCR Redhill SPV, LLC, affiliates of HCRM. As a result of the agreement, we received approximately $9.9 million in cash. This amount was in settlement of liabilities related to Movantik® that were allocatable to HCRM and its affiliates under their agreements with us. As the cash received was less than the total net amount of these liabilities (approximately $12.2 million), we recognized a loss of approximately $2.3 million resulting from the termination agreement, presented under "Other expenses" in our consolidated statements of comprehensive income (loss) in our financial statements included elsewhere in this Annual Report. We also gained full control over an additional $0.7 million previously held in a restricted account and settlement of trade balances resulting from the transition services. The agreement terminated all existing credit ties with the agreement parties, removed the lien on Talicia® and restored full control over cash collections back to us.

Expanded Access Program (EAP)

We have adopted an Expanded Access Program ("EAP"), allowing patients with life-threatening diseases potential access to our investigational new drugs that have not yet received regulatory marketing approval. Expanded access (sometimes referred to as "compassionate use") is possible outside of our clinical trials, under certain eligibility criteria, when a certain investigational new drug is needed to treat a life-threatening condition and when there is some clinical evidence suggesting that the drug might be effective for that condition. Patients who qualify for our EAP do not meet the eligibility criteria or are incapable of participating in our clinical trials for such therapeutic candidate or there is no clinical trial accessible to such patients. Following the adoption of the program, we continue to receive patient requests to obtain access to our investigational drugs. Subject to the evaluation of eligibility and all other necessary regulatory, reporting and other conditions and approvals required in all relevant jurisdictions, we provide certain patients with access to an investigational new drug under the EAP.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our technology and therapeutic candidates, its therapeutic applications, and related technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development of our business. We also rely on our trade secrets, know-how, and continuing technological innovation to develop and maintain our proprietary position. We vigorously defend our intellectual property to preserve our rights and gain the benefit of our technological investments.

Patents and Patent Applications

We have rights, either through assignment, asset purchase or in-licensing, to a total of approximately 157 issued patents and 46 patent applications. The patents and patent applications are registered in the U.S. and other key jurisdictions, the details of each family of patents being provided below. In addition, we have licensed rights to various platform technologies on a non-exclusive basis.

The patent positions of companies such as ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted.

Talicia®

The patent portfolio protecting Talicia® currently includes eight U.S. patents, two pending U.S. patent applications, and over 28 foreign patents and patent applications. The patents currently provide patent protection through 2034 and 2042. The Orange Book currently lists seven U.S. patents.

Opaganib - Oncology, inflammatory, viral and GI Indications

We in-licensed several patents from Apogee and also generated new intellectual property. Opaganib is a first-in-class, proprietary SK2 inhibitor. These patents relate to sphingosine kinase inhibitors, pharmaceutical compositions, methods of preparing the inhibitors, methods of treating inflammatory diseases using the inhibitors, methods of treating cancer using the inhibitors, and methods for inhibiting sphingosine kinase.

The patent portfolio covering opaganib includes six U.S. patents and over 28 foreign patents and patent applications, providing patent protection through 2026 and 2030.

A new patent family seeking to protect the use of opaganib plus checkpoint inhibitors to treat cancer is pending in the U.S. as well as 12 foreign jurisdictions. If patents are granted, it will provide protection for the combination treatment through 2040.

SARS-CoV-2

This patent portfolio covers the use of opaganib and RHB-107 for treating or preventing coronavirus infections. The portfolio currently consists of six issued U.S. patents, two pending U.S. patent applications, one foreign patent and 12 pending foreign patent applications, providing patent protection through 2041.

RHB-107 (upamostat; formerly Mesupron) – Oncology

The primary patent portfolio protecting the new chemical entity (WX-UK1), the pro-drug ("WX-671" or "RHB-107" or "upamostat"), formulations comprising upamostat, methods of synthesizing the compounds, and methods of using upamostat to treat cancer, was in-licensed by us from Wilex AG, now known as Heidelberg Pharma AG. RHB-107 is a first-in-class protease inhibitor administered by oral capsule. The portfolio includes three issued U.S. patents and over 28 foreign patents, providing patent protection through 2025 and 2027.

RHB-104 – Inflammatory Bowel Disease

The patent portfolio protecting RHB-104 and its use in treating inflammatory bowel disease currently includes nine U.S. patents and 19 foreign patents, providing patent protection through 2029.

We have also in-licensed U.S. Patent No. 7,867,704 from The University of Minnesota entitled "Mycobacterial Diagnostics", expiring in 2026. The acquired diagnostic technology is intended for the detection of Mycobacterium avium subspecies paratuberculosis (MAP) bacterium.

RHB-104 – Multiple Sclerosis ("MS")

The patent portfolio protecting the use of RHB-104 for treating relapsing-remitting multiple sclerosis includes one U.S. patent and over 11 foreign patents, providing patent protection through 2032.

RHB-102 (Bekinda®) - Gastritis, Gastroenteritis, IBS-D and Oncology support

The patent portfolio protecting RHB-102 (Bekinda®) and its use currently includes three U.S. patents and over 23 foreign patents, providing patent protection through 2035.

RHB-204 – Nontuberculous Mycobacterium (NTM) Infections

The patent portfolio protecting RHB-204 currently includes one U.S. patent and 11 pending international patent applications, providing patent protection through 2041.

Ebola

The patent portfolio covers RedHill's proprietary experimental therapy for the treatment of the Ebola virus disease. The portfolio consists of four U.S. patents, one pending U.S. patent application, four foreign patents and one pending foreign patent application providing patent protection through 2035.

RHB-108 – Combination Cancer Therapy

RedHill has also pursued patent protection in cancer therapy for various combination of drugs with different mechanisms of action which achieve synergistic effects. Currently, the portfolio includes four U.S. patents, two foreign patents and three foreign pending patent applications.

Trademarks

Our principal trademarks, including RedHill, Redhill Biopharma, Talicia®, Bekinda, Yeliva®, and their related logos, are registered or pending with the United States Patent and Trademark Office. We have also filed registration applications for non-U.S. trademarks in other countries in which we do or plan to do business. Brand names appearing in this annual report are trademarks of RedHill Biopharma Ltd. except for:

- trademarks used or that may be or have been used under license by RedHill or its affiliates, such as Aemcolo®, a trademark of Cosmo Technologies Ltd. On July 9, 2024, we announced the mutual decision with Cosmo to voluntary terminate the Cosmo License Agreement, and it was officially terminated on October 8, 2024.
- trademarks used or that may be or have been used under license by RedHill or its affiliates, such as Movantik®, a trademark of AstraZeneca AB.

Not all trademarks related to investigational agents have been authorized as of the date of this annual report by the relevant health authorities; for instance, the Bekinda® and Yeliva® trade names have not been approved by the FDA.

Government Regulations

Pharmaceutical companies are subject to extensive regulation by national, state and local agencies such as the FDA in the U.S., the Ministry of Health in Israel, or the EMA in Europe. The manufacture, clinical trials, distribution, marketing and sale of pharmaceutical products are subject to government regulation in the U.S. and various foreign countries. To manufacture both new therapeutic drug candidates for clinical trials and approved therapeutic drugs for sale and distribution in the U.S., we must follow the rules and regulations in accordance with current cGMP codified in 21 CFR 210 and 211. Additionally, we are responsible for ensuring that the API in each therapeutic drug or therapeutic drug candidate is manufactured in accordance with ICH Q7 guidance that has been adopted by the FDA. Further, we are required to conduct clinical trials that present data indicating that our therapeutic drug candidates are safe and efficacious in accordance with the current good clinical practice and codified in 21 CFR 312. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or not allow us to manufacture or market our products, and we may be criminally prosecuted. We and our contract manufacturers and clinical research organizations may also be subject to regulations under other federal, state and local laws, including, but not limited to, the U.S. Occupational Safety and Health Act, the Resource Conservation and Recovery Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries. Further, the U.S. government has increased its enforcement activity regarding fraud and abuse and illegal marketing practices in the healthcare industry. As a result, pharmaceutical companies must ensure their compliance with the Foreign Corrupt Practices Act and federal healthcare fraud and abuse laws, including the False Claims Act.

These regulatory requirements impact our operations and differ in one country to another, so that securing the applicable regulatory approvals of one country does not imply the approval in another country. However, securing the approval of a more stringent body, i.e., the FDA, may facilitate receiving the approval by a regulatory authority in a different country where the regulatory requirements are similar or less stringent. The approval procedures involve high costs and are manpower intensive, usually extend over many years and require highly skilled and professional resources.

FDA Approval Process for New Molecular Entities

Our therapeutic drug candidates are classified as New Molecular Entities. The steps required to be taken before therapeutic drug candidate may be marketed in the U.S. generally include:

- completion of preclinical laboratory and animal testing;
- the submission to the FDA of an investigational new drug, or IND, application which must be evaluated and found acceptable by the FDA before human clinical trials may commence;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug therapeutic candidate for its intended use; and
- the submission and approval of an NDA.

Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

In all the countries that are signatories of the Helsinki Declaration (including Israel), the prerequisite for conducting clinical trials (on human subjects) is securing the preliminary approval of the competent authorities of that country to conduct medical experiments on human subjects in compliance with the other principles established by the Helsinki Declaration.

The clinical testing of a therapeutic drug candidate generally is conducted in three sequential phases prior to approval, but the phases may overlap or be combined. However, safety information should be submitted before the initiation of a subsequent clinical phase. A fourth, or post-approval phase may include additional clinical studies. The phases are generally as follows:

Phase 1. In Phase 1 clinical studies, the therapeutic drug candidate is tested in a small number of healthy volunteers, though in cases where the therapeutic drug candidate may make the volunteer ill, clinical patients with the targeted condition may be used. These "dose-escalation" studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the therapeutic drug candidate in humans, side effects associated with increasing doses, and, in some cases, to gain early evidence on efficacy. The number of participants included in Phase 1 studies is generally in the range of 20 to 80.

Phase 2. In Phase 2 studies, in addition to safety, the sponsor evaluates the efficacy of the therapeutic drug candidate on targeted indications to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks. Phase 2 studies typically are larger than Phase 1 but smaller than Phase 3 studies and may involve several hundred participants.

Phase 3. Phase 3 studies typically involve an expanded patient population at geographically-dispersed test sites and involve control groups taking a reference compound or a placebo (an inactive compound identical in appearance to the study compound). They are performed after preliminary evidence suggesting the effectiveness of the therapeutic candidate has been obtained and are designed to evaluate clinical safety and efficacy further, to establish the overall benefit-risk relationship of the therapeutic candidate and to provide an adequate basis for a potential product approval. Phase 3 studies usually involve several hundred to several thousand participants.

Phase 4. Phase 4 clinical trials are postmarketing studies designed to collect additional safety data as well as potentially expand a product indication. Postmarketing commitments may be required of, or agreed to by, a sponsor after the FDA has approved a therapeutic drug candidate for marketing. These studies are used to gain additional information from the treatment of patients in the intended therapeutic indication and to verify a clinical benefit in the case of drugs approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement. These clinical trials are often referred to as Phase 4 post-approval or postmarketing commitments. Failure to promptly conduct Phase 4 clinical trials could result in the inability to deliver the product into interstate commerce, misbranding charges, and civil monetary penalties.

Clinical trials must be conducted in accordance with the FDA's GCP requirements. The FDA may order the temporary or permanent discontinuation of a clinical study at any time or impose other sanctions if it believes that the clinical study is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. An institutional review board, or IRB, generally must approve the clinical trial design and patient informed consent at study sites that the IRB oversees and also may halt a study, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. The FDA recommends that a data safety monitoring board should be used to perform regular interim analysis for long-term clinical studies where safety concerns may be unusually high. This group recommends whether or not a trial may move forward at designated checkpoints based on access to certain data from the study. The clinical study sponsor may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

As a therapeutic candidate moves through the clinical testing phases, manufacturing processes are further defined, refined, controlled and validated. The level of control and validation required by the FDA would generally increase as clinical studies progress. We and the third-party manufacturers on which we rely for the manufacture of our therapeutic drugs and therapeutic drug candidates and their respective API are subject to requirements that drugs be manufactured, packaged and labeled in conformity with cGMP. In addition to our third-party API manufacturers, we are responsible for ensuring that our third-party excipient manufacturers conform to cGMP requirements. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, recordkeeping, and other requirements.

Assuming completion of all required testing in accordance with all applicable regulatory requirements, detailed information on the therapeutic candidate is submitted to the FDA in the form of an NDA, requesting approval to market the product for one or more indications, together with payment of a user fee, unless waived. An NDA includes all relevant data available from pertinent nonclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information on the chemistry, manufacture, control and proposed labeling, among other things. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the therapeutic candidate for its intended use to the satisfaction of the FDA.

If an NDA submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Prescription Drug User Fee Act, or PDUFA, the FDA's goal is to complete its initial review and respond to the applicant within ten months of a completed submission for 90% of the submissions received, unless the application relates to an unmet medical need in a serious or life-threatening indication, in which case the goal may be within six months of a completed NDA submission. However, PDUFA goal dates are not legal mandates, and the FDA response may occur several months beyond the original PDUFA goal date. Further, the review process and the target response date under PDUFA may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the NDA. The NDA review process can, accordingly, be very lengthy. During its review of an NDA, the FDA may refer the application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. Data from clinical studies are not always conclusive, and the FDA or any advisory committee it appoints may interpret data differently than the applicant.

After the FDA evaluates the NDA and conducts a pre-approval inspection of all manufacturing facilities where the drug therapeutic candidate or its API will be produced, it will either approve commercial marketing of the drug therapeutic candidate with prescribing information for specific indications or issue a complete response letter indicating that the application is not ready for approval and stating the conditions that must be met in order to secure approval of the NDA. If the complete response letter requires additional data and the applicant subsequently submits that data, the FDA nevertheless may ultimately decide that the NDA does not satisfy its criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct postmarketing testing. The FDA may also request a Phase 4 clinical trial to further assess and monitor the product's safety and efficacy after approval. Regulatory approval of products for serious or life-threatening indications may require that participants in clinical studies be followed for long periods to determine the overall survival benefit of the drug therapeutic candidate.

If the FDA approves one of our therapeutic drug candidates, we will be required to comply with a number of post-approval regulatory requirements. We would be required to report to the FDA, among other things, certain adverse reactions and production problems, and provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and recordkeeping requirements. If we seek to make certain changes to an approved therapeutic drug, such as certain manufacturing changes, we may need the FDA to review and approve before the change can be implemented. For example, if we change the manufacturer of a product or its API, the FDA may require stability or other data from the new manufacturer, which will take time and is costly to generate, and the delay associated with generating this data may cause interruptions in our ability to meet commercial demand, if any. At their discretion, physicians may prescribe approved pharmaceutical products for indications that pharmaceutical products have not been approved for use by the FDA. However, we may not label or promote pharmaceutical products for an indication that has not been approved. Securing FDA approval for new indications of an approved therapeutic drug requires a Section 505(b)(2) filing, is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product's safety and efficacy in the new indication. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all.

We rely on, and expect to continue to rely on, third parties for the manufacture of clinical and future commercial, quantities of our therapeutic candidates. Future FDA and state inspections may identify compliance issues at these third-party facilities that may disrupt production or distribution or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and may also require the implementation of other risk management measures. Many of the foregoing could limit the commercial value of an approved product or require us to commit substantial additional resources in connection with the approval of a product. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval of new indications or new formulations of previously-approved therapeutic drugs, a company may file a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA, somewhat similar to the process for approval of the original indication or reference drug and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product's safety and efficacy in the new indication. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all. Section 505(b)(2) of the Food, Drug, and Cosmetic Act was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) was enacted to allow a company to avoid duplicative testing by permitting the applicant to leverage previously performed pertinent clinical and non-clinical studies into the current NDA submission. Some examples of therapeutic drug candidates that may be allowed to follow a 505(b)(2) path to approval are candidates that have a new dosage form, strength, route of administration, formulation or indication.

The Hatch-Waxman Amendments permit the applicant to rely upon certain published nonclinical or clinical studies conducted for an approved product or the FDA's conclusions from a prior review of such studies. The FDA may require companies to perform additional studies or measurements to support any changes from the approved product. The FDA may then approve the new product for all or some of the labeled indications for which the reference product has been approved, as well as for any new indication supported by the NDA. While references to nonclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development, process, stability, qualification and validation data related to the manufacturing and quality of the new product must be included in an NDA submitted under Section 505(b)(2).

To the extent that the Section 505(b)(2) applicant is relying on the FDA's conclusions regarding studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book publication. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the reference product has expired. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized.

Orphan Drug Designation

The Orphan Drug Act of 1983, or Orphan Drug Act, encourages manufacturers to seek approval for products intended to treat "rare diseases and conditions" with a prevalence of fewer than 200,000 patients in the U.S. or for which there is no reasonable expectation of recovering the development costs for the product. For products that receive orphan drug designation by the FDA, the Orphan Drug Act provides tax credits for clinical research, FDA assistance with protocol design, eligibility for FDA grants to fund clinical studies, waiver of the FDA application fee, and a period of seven years of marketing exclusivity for the product following FDA marketing approval.

GAIN Act

The FDA's Generating Antibiotic Incentives Now (GAIN) Act is intended to encourage the development of new antibiotic drug therapeutic candidates for the treatment of serious or life-threatening infections. For products that receive QIDP designation under the Act, the Act provides Fast-Track development status with an expedited development pathway and Priority Review status, which potentially provides shorter review time by the FDA of a future potential marketing application. Following FDA approval, an additional five years of U.S. market exclusivity applies, received on top of the standard exclusivity period.

Other Healthcare Laws and Compliance Requirements

In the U.S., we are subject to various federal and state laws and regulations regarding fraud and abuse in the healthcare industry, as well as industry standards and guidance, such as the codes issued by the Pharmaceutical Research and Manufacturers of America (or "PhRMA Codes"), which some states reference or incorporate in their statutes and regulations. These laws, regulations, standards, and guidance may impact, among other things, our sales and marketing activities and our relationships with healthcare providers and patients. In addition, we may be subject to patient privacy regulations by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order, or recommendation of, an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claim Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from the federal government, including Medicare, Medicaid, or other third-party payors, that are false or fraudulent;
- HIPAA, which imposes federal criminal and civil liability for executing, or attempting to execute, a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the federal transparency laws, including the Physician Payments Sunshine Act, that requires applicable manufacturers of covered drugs to disclose payments and other transfers of value provided to physicians and teaching hospitals and physician ownership and investment interests;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, also imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, state laws that require pharmaceutical manufacturers to report certain pricing or payment information, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and are not preempted by HIPAA, thus complicating compliance efforts.

The Healthcare Reform Law broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and certain other criminal healthcare fraud statutes. Specifically, a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Healthcare Reform Law provides that 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 False Claims Act or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only federal healthcare programs such as the Medicare and Medicaid programs.

Due to the breadth of some of these laws, it is possible that some of our current or future practices might be challenged under one or more of these laws. In addition, there can be no assurance that we would not be required to alter one or more of our practices to comply with these laws. Evolving interpretations of current laws or the adoption of new federal or state laws or regulations could adversely affect the arrangements we may have with sales personnel, healthcare providers, and patients. Our risk of being found in violation of these laws is increased by the fact that some of these laws are open to a variety of interpretations. If our past or present operations, practices, or activities are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, damages, fines, disgorgement, contractual remedies, reputational harm, diminished profits, and future earnings, if any, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

C. Organizational Structure

Our wholly-owned and only subsidiary, Redhill Biopharma Inc., was incorporated in Delaware on January 19, 2017.

D. Property, Plant and Equipment

We lease approximately 826 square meters of office space and eleven parking spaces in the "Platinum" building at 21 Ha'arba'a Street, Tel-Aviv, Israel. The projected yearly gross rental expenses are approximately $420,000 per year. Since 2018 until August 2024, we subleased a portion of the office space to a tenant, and the lease payment is approximately $70,000 per year. The term under our lease agreement will expire on January 31, 2026. These offices have served as our corporate headquarters since April 2011.

Our U.S. office lease expired on July 31, 2024, with all related rental obligations fully settled. In June 2023, we terminated another U.S. office lease signed in March 2022 that was originally set to expire on July 31, 2034.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this Annual Report. The following discussion contains forward-looking statements that reflect our plans, estimates, and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly those in "Item 3. Key Information – D. Risk Factors."

Company Overview

We are a specialty biopharmaceutical company, primarily focused on GI, infectious diseases and oncology. Our primary goal is to become a leading specialty biopharmaceutical company.

We are currently focused primarily on the advancement of our development pipeline of clinical-stage therapeutic candidates. We also commercialize in the U.S. our GI-related product, Talicia® (omeprazole, amoxicillin, and rifabutin), and continue to explore our strategic plans for other potential products and activities.

Among our therapeutic candidates, we are exploring opaganib as a potential treatment for various conditions, including GI-ARS, viral infections such as COVID-19, Ebola virus disease and additional viruses as part of pandemic preparedness, several cancers and diabetes and obesity-related disorders. Furthermore, we are investigating RHB-107 (upamostat) as a potential treatment for COVID-19 and other viruses as part of pandemic preparedness, including the Ebola virus.

Our current pipeline consists of five therapeutic candidates, part of which are in late stage clinical development. We generate our pipeline of therapeutic candidates by identifying, validating and in-licensing or acquiring products that are consistent with our product and corporate strategy and that have the potential to exhibit a favorable probability of therapeutic and commercial success. We have one product, Talicia®, that we primarily developed internally which has been approved for marketing and, to date, none of our other therapeutic candidates has generated revenues. We have out-licensed our commercial product, Talicia®, for specific territories outside the U.S., and one of our therapeutic candidates, RHB-102, worldwide (except for the U.S., Canada, and Mexico). Furthermore, we plan to commercialize our therapeutic candidates, upon approval, if any, through licensing and other commercialization arrangements with pharmaceutical companies on a global and territorial basis or independently with a dedicated commercial operation or in potential partnership with other commercial-stage companies. We also evaluate, on a case-by-case basis, co-development, co-promotion, licensing, acquisitions and similar arrangements.

Since inception, we have funded our operations primarily through public and private offerings of our equity securities, loans and revenues from our commercial activity. As of December 31, 2024 and December 31, 2023, we had approximately $4.8 million and $6.5 million, respectively, of cash, cash equivalents, short-term investments and restricted cash.

Sale of Rights in Movantik® and Extinguishment of our Debt Obligations under the Credit Agreement with HCRM

On February 23, 2020, we, through RedHill U.S., entered into a credit agreement (the "Credit Agreement") with HCRM, and the lenders from time to time party thereto. Pursuant to the terms of the Credit Agreement, RedHill U.S. received a $30 million loan following the signing of the Credit Agreement. An additional $50 million tranche was used to fund the acquisition of rights to Movantik® from AstraZeneca. On February 2, 2023, we sold our rights in Movantik® to an affiliate of HCRM and in connection therewith our debt obligations under the Credit Agreement were extinguished. In connection with this sale, RedHill U.S. retained substantially all pre-closing liabilities relating to Movantik®, and $16 million of our cash was deposited into the escrow account to pay pre-closing liabilities related to Movantik®.

Following the sale of our rights to Movantik®, we lost our primary revenue source, and our ability to operate as a financially viable commercial business became significantly more difficult. We are working to replace Movantik® with another commercial product, either internal or external, but this may not occur, and we may never achieve levels of revenue we have achieved through Movantik®. We also lost economies of scale in our commercial operations that we were able to benefit from by having Movantik® as a core commercial product.

In addition, in connection with the sale of Movantik®, the obligation to pay indemnification obligations and scheduled pre-closing liabilities of Movantik® were secured by a lien on Talicia®- related assets and our former Aemcolo®-related assets.

On July 15, 2024, we signed a Global Termination Agreement with Movantik Acquisition Co., Valinor Pharma, LLC, and HCR Redhill SPV, LLC, affiliates of HCRM. This agreement terminated all remaining obligations under the Credit Agreement, including the lien previously placed on our Talicia®-related assets, and restored our control over the restricted escrow account established to cover Movantik® pre-closing liabilities and settlement of trade balances resulting from the transition services. As part of the agreement, we received approximately $9.9 million in cash and regained access to an additional $0.7 million previously held in escrow. The cash received was in settlement of liabilities related to Movantik® that were allocatable to HCRM and its affiliates under their agreements with us. As the cash received was less than the total net amount of these liabilities (approximately $12.2 million), we recognized a loss of approximately $2.3 million resulting from the termination agreement, presented under "Other expenses" in our consolidated statements of comprehensive income (loss) in our financial statements included elsewhere in this Annual Report. The agreement also terminated the transition services arrangement previously in place.

Our financial statements include a going concern reference. We will need to raise significant additional capital to finance our losses and negative cash flows from operations, and if we were to fail to raise sufficient capital or on favorable terms and/or divest assets on favorable terms or at all, we may need to cease operations. Management has substantial doubt about our ability to continue as a going concern.

Description of our Products

The following is a description of our current commercial product and five therapeutic candidates, most of which are in late-stage clinical development:

Commercial Product

Talicia® is our proprietary drug approved by the FDA for marketing in the U.S. for the treatment of *H. pylori* bacterial infection in adults. Talicia® is a combination of three approved drugs, omeprazole, which is a proton pump inhibitor (it prevents the secretion of hydrogen ions increasing the PH of the stomach), amoxicillin and rifabutin, which are antibiotics. Talicia® is administered to patients orally in the form of a fixed-dose, all-in-one capsule. On November 1, 2019, the FDA approved Talicia® for marketing in the U.S. for the treatment of *H. pylori* infection in adults and we launched Talicia® in the U.S. in March 2020. Talicia® is expected to receive a total of eight years of U.S. market exclusivity. Talicia® is the first therapeutic candidate we developed to be approved by the FDA.

Therapeutic Candidates

RHB-204 is a patented fixed-dose combination product of three antibiotics that will simplify administration and optimize compliance. Each capsule contains the same components as RHB-104 (clarithromycin, clofazimine, and rifabutin) but at unique doses, selected based on modeling to provide optimal balance of the potential safety and efficacy in the treatment of NTM infection.

Opaganib is an investigational new drug that is proprietary, first-in-class, orally administered SK2 selective inhibitor, with anti-viral, anti-inflammatory and anti-cancer activities, targeting multiple potential oncology, inflammatory, viral and GI indications. On March 30, 2015, we entered into an exclusive worldwide license agreement with Apogee, pursuant to which Apogee granted us the exclusive worldwide development and commercialization rights to ABC294640 (which we then renamed to ABC294640 (Yeliva®)) and as noted above, received an international non-proprietary name, opaganib, in 2018) and additional intellectual property for all indications. Under the terms of the agreement, as amended, we agreed to pay Apogee initial milestone payments of $3 million, of which the total amount has been paid, as well as up to $2 million in potential development milestone payments, and tiered royalties starting in the low double-digits. For more information regarding this agreement, see "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – License Agreement for opaganib." In March 2022, we entered into an exclusive license agreement (the "Exclusive License Agreement") with Kukbo for opaganib in South Korea. Under the terms of the Exclusive License Agreement, Kukbo was required to pay an upfront payment of $1.5 million, and we are also eligible milestone payments and royalties on net sales of oral opaganib. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements - License Agreement with Kukbo" and "Legal Proceedings".

RHB-107 (upamostat; formerly Mesupron) (INN: upamostat) is a proprietary small molecule, first-in-class, potent serine protease inhibitor administered by oral capsule. RHB-107 is being investigated as a potential treatment for COVID-19 outpatients and other viruses as part of pandemic preparedness, including the Ebola virus. Additional indications in the area of inflammatory digestive diseases and inflammatory lung diseases could be targeted. On June 30, 2014, we acquired from Heidelberg the exclusive development and commercialization rights to RHB-107, excluding China, Hong Kong, Taiwan, and Macao, for all indications. We made an upfront payment to Heidelberg of $1.0 million with potential tiered royalties on net revenues, ranging from mid-teens up to 30%. We are responsible for all development, regulatory and commercialization of RHB-107. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – License Agreement for RHB-107."

RHB-104 is an investigational new drug intended to treat Crohn's disease, which is a serious inflammatory disease of the GI system that may cause severe abdominal pain and bloody diarrhea, malnutrition and potentially life-threatening complications. RHB-104 is a patented combination of clarithromycin, clofazimine, and rifabutin, three generic antibiotic ingredients, in a single capsule. The compound was developed to treat Crohn's disease through the targeting of MAP infection.

RHB-102 (Bekinda®) is an investigational once-daily bi-modal extended-release oral formulation of ondansetron, a leading member of the family of 5-HT3 serotonin receptor inhibitors, intended to treat nausea, vomiting and diarrhea symptoms experienced in some people suffering from acute gastroenteritis, gastritis, and IBS-D.

Components of Statements of Comprehensive Loss

Revenues

Revenues are with respect to commercialization and licensing of our commercial products.

Cost of Revenues

Direct costs related to the revenues, such as cost of goods sold and royalties to third parties. Additionally, includes intangible assets amortization and impairment.

Research and Development Expenses

See "Item 5. Operating and Financial Review and Prospects – C. Research and Development, Patents and Licenses" below.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees, directors and consultants and professional services. Other significant general and administrative expenses include medical affairs, office-related expenses, travel, conferences, and others.

Selling, Marketing and Business Development Expenses

Selling, Marketing and Business Development expenses consist primarily of compensation for employees and consultants dedicated to marketing activities with the Company's commercialized and promoted products and professional services. Other significant selling, marketing and business development expenses include market research, market access, advertising, printed and digital media, product samples, car fleet, travel, conferences, office-related expenses, and others.

Financial Income and Expenses

Financial income and expenses consist of non-cash financing expenses in connection with changes in the fair value of derivative financial instruments, interest earned on our cash, cash equivalents, and short-term bank deposits, bank fees, interest, and finance changes for lease liabilities and other transactional costs and expense or income resulting from fluctuations of the U.S. dollar against other currencies, in which a portion of our assets and liabilities are denominated like NIS, for example, as well as losses from the Global Termination Agreement. In addition, as it relates to the extinguishment of all debt obligations of RedHill U.S. under the Credit Agreement in exchange for the transfer of its rights in Movantik®, the portion of the gain from the debt extinguishment, resulting from the difference between the carrying amount (the amortized cost) of the financial liability to HCRM and the fair value of the assets transferred, is included within financial income.

Other income

Incorporates the portion of the gain from the sale of Movantik® resulting from the difference between the carrying value and fair value of the assets transferred to HCRM. Additionally, includes service fees relating to transition services provided as part of the sale of Movantik®.

A. Operating Results

History of Losses

Since inception in 2009, we have generated significant losses in connection with the research and development of our therapeutic candidates and from our commercial operations. We may continue to incur additional losses as we continue our commercial activities and expand our research and development activities over time. As a result, we expect to continue incurring operating losses, which may be substantial over the next several years, and we will need to obtain substantial additional funds. As of December 31, 2024 and December 31, 2023, we had an accumulated deficit of approximately $414.8 million and $407.7 million, respectively.

We expect to continue to fund our operations over the next several years through revenues generated from the commercialization of our commercial products, public or private equity offerings, debt financings, non-dilutive financings, including government grants, commercialization of our therapeutic candidates, if approved, or products we may commercialize or promote in the future. Concurrently, we are actively engaged in discussions to explore strategic business transactions, including potential divestment of certain Company assets.

Going Concern

Our consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. During the year ended December 31, 2024, our net cash used in operating activities was $9.4 million leaving a cash balance of $4.8 million. Because we do not have sufficient resources to fund our operations for the next twelve months from the date of this filing, management has substantial doubt of our ability to continue as a going concern. We have determined that the Company's available cash on December 31, 2024, together with proceeds raised pursuant to the Wainwright Sales Agreement (as defined below) during the first quarter of 2025, will not be sufficient to fund current liabilities and capital expenditure requirements for a period exceeding one year from the date of this Annual Report. Our operational costs include the payment of substantially all pre-closing liabilities relating to Movantik®, which our subsidiary, RedHill U.S., retained under our agreement with HCRM for the extinguishment of all our debt obligations under the Credit Agreement in exchange for the transfer of our rights in Movantik® to an affiliate of HCRM. As of December 31, 2024, the estimated pre-closing liabilities relating to Movantik® were approximately $3.0 million. In addition, we assumed obligations under the Global Termination Agreement. As of December 31, 2024, the estimated obligations relating to the Global Termination Agreement were $6.7 million. See "See "– Term Loan Facility" and "Additional Cash Requirements", below. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should we be unable to continue as a going concern.

We will need to raise significant additional capital to finance our losses and negative cash flows from operations. We are also actively pursuing and in discussions with multiple parties regarding strategic business transactions. If we were to fail to raise sufficient capital on favorable terms or at all, we may need to cease operations. There are no assurances that we will be able to raise significant additional capital on terms favorable to us or at all, particularly given the current difficult conditions in the capital markets and very low market capitalization which makes it more difficult to raise significant amounts of capital. In addition, following the sale of our rights to Movantik® in 2023, we lost our primary revenue source and our ability to operate as a financially viable commercial business has been significantly more difficult. If we are unsuccessful in achieving sufficient commercial sales of our products, or in raising sufficient capital, we will need to reduce activities and curtail or cease operations.

Comparison of the Year Ended December 31, 2024, to the Year Ended December 31, 2023

Net Revenues

Net Revenues for the year ended December 31, 2024, were $8.0 million, compared to $6.5 million for the year ended December 31, 2023. Talicia® net revenues for the year ended December 31, 2024, increased to $9.0 million from $8.8 million for the year ended December 31, 2023, driven by approximately $1.0 million of revenues generated from the UAE partnership with Gaelan Medical. Net revenues for the years ended December 31, 2024 and December 31, 2023, included Movantik® contra-revenues of $0.9 million and $2.6 million for Movantik®, respectively, mainly due to product returns.

Cost of Revenues

Cost of Revenues for the year ended December 31, 2024, was $3.2 million, compared to $3.5 million for the year ended December 31, 2023. The decrease was primarily due to lower inventory write-downs, which totaled $0.2 million in 2024 compared to $1.3 million in 2023. This decrease was partially offset by higher Movantik® negative cost of revenues recognized in the previous year, reflecting the higher contra revenues recognized in 2023.

Gross Profit

Gross Profit for the year ended December 31, 2024, was $4.9 million, compared to $3.1 million for the year ended December 31, 2023, reflecting the increase in net revenues and the lower level of inventory write-downs in 2024.

Research and Development Expenses

Research and Development Expenses were $1.6 million for the year ended December 31, 2024, as compared to $3.5 million for the year ended December 31, 2023. The decrease was attributable to the costs from closing the RHB-204 clinical trial, which were recognized in 2023, as well as ongoing cost-reduction measures.

Selling, Marketing and General and Administrative Expenses

Selling, Marketing and General and Administrative Expenses for the year ended December 31, 2024, were $15.5 million, as compared to $31.0 million for the year ended December 31, 2023. The reduction was primarily attributable to ongoing cost-reduction measures and the divestiture of Movantik® in 2023, which led to workforce downsizing and other related expense reductions.

Other Income/Expenses

Other Expense for the year ended December 31, 2024 was $2.3 million, recognized as part of the Global Termination Agreement, as compared to Other Income of $44.1 million for the year ended December 31, 2023. The other income in 2023 was comprised of (i) $35.5 million from the divestiture of Movantik®, calculated as the difference between the fair value of the rights and the carrying amount of this asset and (ii) $8.6 million from transitional services provided to the buyer of Movantik®.

Operating Income (Loss)

Operating Loss for the year ended December 31, 2024, was $14.6 million, compared to Operating Income of $12.6 million for the year ended December 31, 2023. The difference is primarily attributable to the changes resulting from the divestiture of Movantik® partially offset by the decrease in operating expenses as detailed above.

Financial Income (Expenses), net

Financial Income, net for the year ended December 31, 2024, was $6.3 million, compared to Financial Income, net of $11.3 million for the year ended December 31, 2023. The income recognized for the year ended December 31, 2024, was primarily driven by the revaluation of financial instruments, partially offset by other financing expenses. The income recognized in the year ended December 31, 2023, was primarily attributable to gain resulting from the extinguishment of the HCRM debt in exchange for the transfer of rights to Movantik®, calculated as the difference between the carrying amount of the financial liability and the fair value of the rights transferred partially offset by financial expenses related to the financial instruments and other financial expenses.

Net Income (Loss)

Net Loss was $8.3 million for the year ended December 31, 2024, as compared to Net Income of $23.9 million for the year ended December 31, 2023. The change was primarily attributable to the impact of the Movantik® divestiture in 2023, partially offset by reduction in operating expenses resulting from ongoing cost-reduction measures, as detailed above.

Total Assets

Total Assets as of December 31, 2024, were $18.0 million, as compared to $23.0 million as of December 31, 2023. The decrease was primarily attributable to the decrease in cash balance, reduced inventory and a decline in prepaid expenses and other receivables, consistent with the Company's scaled-down operations, as well as impact of balances settled as part of the Global Termination Agreement, and a reduction in right-of-use assets following the termination of vehicle leases during 2024.

Total Liabilities

Total Liabilities as of December 31, 2024, were $22.7 million, as compared to $21.0 million as of December 31, 2023. The increase primarily reflects the impact of the Global Termination Agreement, under which the Company incurred liabilities related to Movantik® that were allocatable to HCRM and its affiliates under their agreements with the Company, offset by payments made toward these liabilities during the period. Additionally, there was an increase in derivative financial instruments associated with warrant liabilities from offerings made during 2024. This was partially offset by a decrease in accounts payable and allowance from deductions from revenues, consistent with the Company's scaled-down operations, as well as a reduction in lease liabilities due to the termination of car leases.

Comparison of the Year Ended December 31, 2023, to the Year Ended December 31, 2022

This analysis can be found in Item 5 of the Annual Report on Form 20-F for the year ended December 31, 2023, filed with the SEC on April 8, 2024.

Non-IFRS Financial Measures

In addition to our financial results reported in accordance with IFRS, we believe that Adjusted EBITDA, which is a non-IFRS financial measure, is useful in evaluating the performance of our business. See tables below for a discussion regarding our use of Adjusted EBITDA, including its limitations, and a reconciliation to the most directly comparable IFRS financial measure.

Adjusted EBITDA

We define Adjusted EBITDA as Consolidated Comprehensive Income (Loss) plus depreciation, amortization and impairment of intangible assets, share based compensation, financial (income) expenses, minus gains from early termination of leases, and other income, which includes income from service provided to HCRM and gain from the sale of Movantik®. Our management believes Adjusted EBITDA is indicative of operational performance and ongoing profitability and uses Adjusted EBITDA to evaluate the operating performance and for planning and forecasting purposes. Non-IFRS financial measures have limitations as analytical tools and should not be considered in isolation or as substitutes for financial information presented under IFRS. There are a number of limitations related to the use of non-IFRS financial measures versus comparable financial measures determined under IFRS. For example, other companies in our industry may calculate the non-IFRS financial measures that we use differently or may use other measures to evaluate their performance. All of these limitations could reduce the usefulness of our non-IFRS financial measures as analytical tools. Investors are encouraged to review the related IFRS financial measure, Consolidated Comprehensive Income (Loss), and the reconciliations of Adjusted EBITDA provided below to Consolidated Comprehensive Income (Loss) and to not rely on any single financial measure to evaluate our business.

The following table sets forth our Adjusted EBITDA for the years ended December 31, 2024, 2023 and 2022:

	Year Ended December 31,		
	2024	2023	2022
	U.S. dollars in thousands		
Adjusted EBITDA	(10,993)	(28,338)	(29,015)

The following table provides a reconciliation of adjusted EBITDA to Consolidated Comprehensive Income (Loss) for the periods indicated:

	Year Ended December 31,		
	2024	2023	2022
	U.S. dollars in thousands		
Consolidated Comprehensive Income (Loss)	(8,268)	23,916	(71,669)
Depreciation	588	1,445	2,136
Amortization and impairment of intangible assets	31	545	6,018
Share-based compensation to employees and service providers	665	1,647	5,675
Gain from early termination of lease, net	(22)	(543)	—
Other income	2,359	(44,064)	—
Financial (income) expenses, net	(6,346)	(11,284)	28,825
Adjusted EBITDA	(10,993)	(28,338)	(29,015)

B. Liquidity and Capital Resources

Liquidity and Capital Resources

Since inception, we have funded our operations primarily through public and private offerings of our equity securities, loans and revenues from our commercial activity. Other potential sources of liquidity in the future may include government grants or subordinated indebtedness, other non-dilutive financings, or divestment of certain Company assets. As of December 31, 2024, we had approximately $4.8 million of cash, cash equivalents, short-term investments and restricted cash.

Through our U.S. subsidiary, we currently commercialize Talicia®. However, our ability to generate profits from the commercialization of commercial products still remains uncertain. To date, our commercial operations are still generating operational losses. Other than Talicia®, our therapeutic candidates are in research and development stage, and therefore do not yet generate revenues.

Until our sale to HCRM on February 2, 2023, we also commercialized Movantik® (naloxegol), and until October 8, 2024, we also commercialized Aemcolo®. Following the sale of Movantik®, we lost our primary revenue source which will make it more difficult for us to satisfy our payment obligations. See "- Sale of Rights in Movantik® and Extinguishment of our Debt Obligations under the Credit Agreement with HCRM". On July 9, 2024, we announced the mutual decision with Cosmo to voluntary terminate the Cosmo License Agreement with respect to Aemcolo®, and it was officially terminated on October 8, 2024.

On August 9, 2024, we filed a registration statement on Form F-3 (File No. 333-281417) with the SEC. As of the filing date of this Annual Report, we are subject to the limitations of General Instruction I.B.5 of Form F-3, which limits the amount of funds we can raise through primary public offerings of securities in any twelve-calendar month period using a registration statement on Form F-3 to one-third of the aggregate market value of our ordinary shares held by non-affiliates. Therefore, we will be limited in the amount of proceeds we are able to raise by selling our securities using Form F-3, until such time as our public float held by non-affiliates exceeds $75.0 million.

Going Concern

Our consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. During the year ended December 31, 2024, our net cash used in operating activities was $9.4 million leaving a cash balance of $4.8 million. Because we do not have sufficient resources to fund our operations for the next twelve months from the date of this filing, management has substantial doubt of our ability to continue as a going concern. See "– B. Operating Results – Going Concern".

Financing Activities

On March 29, 2024, we entered into a securities purchase agreement with certain investors, pursuant to which we agreed to issue and sell, in a registered direct offering directly to such investors, (i) 85,779 ADSs and (ii) warrants to purchase up to an aggregate of 85,779 ADSs, at a combined purchase price of $14.57 per ADS and accompanying warrant (the "April 2024 Offering"). The warrants have an exercise price of $18.75 per ADS, are immediately exercisable upon issuance and have a term of five years following the issuance date. The April 2024 Offering closed on April 3, 2024. The gross proceeds to us were approximately $1.25 million, before deducting offering expenses payable by us.

On January 26, 2024, we issued (i) in a registered direct offering 400,000 ADSs at a purchase price of $20.00 per ADS and (ii) in a concurrent private offering, warrants (the "January 2024 Warrants") to acquire 400,000 ADSs in the aggregate at an exercise price of $25.00 per ADS (the "January 2024 Offering"). The gross proceeds were approximately $8.0 million, before fees and expenses. The January 2024 Warrants are exercisable immediately after the issuance date and have a term of five years following the issuance date. After the mentioned offerings and the November 2023 warrants' exercise described below, as of January 31, 2024, the Company's share capital included 1,188,121 ADSs, the January 2024 Warrants, December 2022 Warrants to purchase 30,234 ADSs (as defined below), and placement agent warrants to purchase 44,649 ADSs. These placement agent warrants have exercise prices ranging from $14.6875 per ADS to $125.00 per ADS and expire between April 3, 2028, and January 25, 2029. These warrants were issued to the placement agent as part of the compensation for the offerings conducted in April, July, and September 2023, as well as January 2024.

Between November 27, 2023, and November 29, 2023, the September 2023 Reload Warrants (as defined below) were exercised for a total of approximately $4.0 million gross proceeds to the Company.

On September 28, 2023, we entered into a warrant reprice and reload letter with holders of (i) the May 2022 Warrants (as defined below), as amended as described below, (ii) the December 2022 Warrants (as defined below), as amended as described below, (iii) warrants issued on April 3, 2023 (as amended, the "Class B Warrants"), and (iv) warrants issued on July 25, 2023 (the "July 2023 Warrants", and together with the May 2022 Warrants, the December 2022 Warrants and the Class B Warrants, the "Existing Warrants") to purchase up to an aggregate of 172,076 ADSs, pursuant to which such holders agreed to exercise their Existing Warrants in full at a reduced exercise price of $11.75 per ADS for aggregate gross proceeds of approximately $2.0 million, before deducting the fees and expenses. In exchange, the exercising holders received new unregistered warrants to purchase up to an aggregate of 344,154 ADSs (the "September 2023 Reload Warrants") at an exercise price of $11.75 per ADS and with exercise terms ranging from eighteen months to five years.

On July 25, 2023, we issued in a registered direct offering 43,397 ADSs and pre-funded warrants to purchase 8,680 ADSs for aggregate gross proceeds to us, together with the proceeds of the concurrent Reload Agreement described below, of approximately $3.8 million, before deducting fees and expenses. In connection with the offering, on July 21, 2023, we entered into a warrant reprice and reload letter (the "Reload Agreement") with a certain holder of Series A Warrants to purchase up to an aggregate of 60,000 ADSs and Series B Warrants to purchase up to an aggregate of 60,000 ADSs, each issued in April 2023, pursuant to which: (i) such holder exercised its Series A Warrants in full at a reduced exercise price of $33.75 per ADS (the "Series A Warrant Exercise") in exchange for new unregistered warrants to purchase up to an aggregate of 60,000 ADSs at an exercise price of $45.00 per ADS exercisable until April 3, 2028 (the "Reload Warrant"), and (ii) the exercise price of the Series B Warrants was reduced to $45.00 per ADS. We also agreed to reduce the exercise price of (i) the May 2022 Warrants (as defined below), as amended as described below, and (ii) the December 2022 Warrants (defined below) to purchase up to an aggregate of 38,873 ADSs, at an exercise price of $45.00 per ADS (the "Warrant Amendment").

On April 3, 2023, we issued in a registered direct offering (i) 10,800 ADSs and pre-funded warrants to purchase 49,200 ADSs, (ii) Series A Warrants to purchase up to an aggregate of 60,000 ADSs, and (iii) Series B Warrants to purchase up to an aggregate of 60,000 ADSs at a combined offering price of $100.00 per ADS (or pre-funded warrant) and accompanying Series A Warrant and Series B Warrant. The Series A Warrants had an initial exercise price of $118.75 per ADS (subsequently reduced to $33.75 per ADS as described above), were exercisable immediately and had a term of five years following issuance. The Series B Warrants had an initial exercise price of $100.00 per ADS (subsequently reduced to $45.00 as described above), were exercisable immediately and had a term of nine months following issuance. The gross proceeds were approximately $6.0 million, before fees and expenses.

In connection with the April 2023 offering, we reduced the exercise price of the May 2022 Warrants (defined below) to $118.75 per ADS and amended the termination date to April 3, 2028 (subsequently amended in July 2023 as described above).

During the year ended December 31, 2023, we sold 105 ADSs under an at-the-market program (the "ATM program") for total gross proceeds of approximately $20,000. During the year ended December 31, 2022, we sold 1,223 ADSs under the ATM program for total gross proceeds of approximately $2.0 million. We terminated the ATM program effective as of April 4, 2024. See "ATM Program with Cantor", below.

On December 6, 2022, we consummated an underwritten offering of 21,775 ADSs and pre-funded warrants to purchase 10,225 ADSs for gross proceeds of approximately $8.0 million after deducting the underwriting discounts and commissions and estimated offering expenses payable by us in connection with the offering. In addition, the investors in this financing received warrants to purchase 69,107 ADSs with an exercise price of $115.7625 per ADS (following a reset on March 31, 2023, in connection with the ratio change of the ADSs to the Company's ordinary shares) (the "December 2022 Warrants").

On May 11, 2022, we issued (i) in a registered direct offering a total of 5,059 ADSs and pre-funded warrants to purchase 5,503 ADSs and (ii) in a concurrent private placement, warrants to acquire 13,204 ADSs at a purchase price of $1,480.00 per ADS ("May 2022 Warrants"). The gross proceeds were approximately $15.0 million, before fees and expenses. The warrants were exercisable six months after the issuance date and had a term of five and one-half years.

Term Loan Facility

On February 23, 2020, we, through our wholly-owned subsidiary, RedHill U.S., entered into the Credit Agreement with HCRM, as Administrative Agent, and the lenders from time to time party thereto. Pursuant to the terms of the Credit Agreement, RedHill U.S. received a $30 million loan following the signing of the Credit Agreement. An additional $50 million tranche was used to fund the acquisition of rights to Movantik® from AstraZeneca. See "Item 4. Information on the Company – B. Business Overview – Sale of Movantik® to HCRM."

We also entered into a Security Agreement, a Pledge Agreement, an Israeli-law governed Fixed Charge Debenture and an Israeli-law governed Floating Charge Debenture in favor of HCRM, pursuant to which our obligations under the Credit Agreement (and those of RedHill U.S.) were secured by a pledge of all of our holdings of the capital stock of RedHill U.S., substantially all of the assets of RedHill U.S., and all of our assets relating in any material respect to Talicia®.

On February 2, 2023, we reached an agreement with HCRM for the extinguishment of all our debt obligations under the Credit Agreement in connection with the transfer of our rights in Movantik® to Movantik Acquisition Co., an affiliate of HCRM. HCRM assumed substantially all post-closing liabilities relating to Movantik®, with RedHill U.S. retaining substantially all pre-closing liabilities relating to Movantik®. These collateral documents were amended to provide HCRM with security interests in (i) an escrow account ("Escrow Account") established to pay pre-closing liabilities related to Movantik® that were retained by RedHill U.S. under the terms of the asset purchase agreement, (ii) Talicia®-related assets, (iii) our former Aemcolo®-related assets and (iv) accounts receivable related to Movantik® accrued as of the Closing (as defined in the APA) to secure "Go-Forward Obligations" consisting of indemnification obligations under the APA and the Credit Agreement and scheduled pre-closing liabilities relating to Movantik® until substantially all pre-closing liabilities relating to Movantik® were paid or other specific conditions were met.

On July 15, 2024, we signed a Global Termination Agreement with Movantik Acquisition Co., Valinor Pharma, LLC, and HCR Redhill SPV, LLC, affiliates of HCRM. As a result of the agreement, we received approximately $9.9 million in cash. This amount was in settlement of liabilities related to Movantik® that were allocatable to HCRM and its affiliates under their agreements with us. As the cash received was less than the total net amount of these liabilities (approximately $12.2 million), we recognized a loss of approximately $2.3 million resulting from the termination agreement, presented under "Other expenses" in our consolidated statements of comprehensive income (loss) in our financial statements included elsewhere in this Annual Report. We also gained full control over an additional $0.7 million previously held in a restricted account and settlement of trade balances resulting from the transition services. The agreement terminated all existing credit ties with the agreement parties, removed the lien on Talicia® and restored full control over cash collections back to us.

ATM Program with Cantor Fitzgerald & Co. and SVB Leerink LLD

On July 29, 2021, we entered into the sales agreement (the "Cantor – SVB Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") and SVB Leerink LLC ("SVB"), for the sale of ADSs, pursuant to which we were able to offer and sell, from time to time, ADSs through our ATM program, with SVB and Cantor acting as our agents. Under the prospectus supplement relating to the ATM program and the accompanying base prospectus, we offered and were permitted to sell ADSs having an aggregate offering price of up to $100.0 million from time to time through SVB and Cantor, acting as our agents, in accordance with the Cantor – SVB Sales Agreement. On November 3, 2022, we received notice from SVB notifying us and Cantor of SVB's termination of the Cantor – SVB Sales Agreement with respect to itself. On April 4, 2024, we delivered written notice to Cantor and terminated the Cantor – SVB Sales Agreement. Prior to termination, we sold 1,378 ADSs at a weighted average offering price of $1,871.07 per ADS for approximate aggregate net proceeds of approximately $2.5 million pursuant to the Cantor – SVB Sales Agreement and related prospectus supplement and accompanying base prospectus since the launch of the ATM program in July 2021.

ATM Program with H.C. Wainwright & Co., LLC

On February 3, 2025, we entered into a sales agreement (the "Wainwright Sales Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), for the sale of ADSs, pursuant to which we are able to offer and sell, from time to time, ADSs through our ATM program, with Wainwright acting as our agent. Under the prospectus supplement relating to the ATM program and the accompanying base prospectus, we are permitted to sell ADSs having an aggregate offering price of up to $3,464,000 from time to time through Wainwright, acting as our agent, in accordance with the Wainwright Sales Agreement. To date, we have sold 453,345 ADSs at a weighted average offering price of $4.96 per ADS for aggregate net proceeds of approximately $2.2 million pursuant to the Wainwright Sales Agreement and related prospectus supplement and accompanying base prospectus.

Additional Cash Requirements

We are obligated to make various payments upon the achievement of agreed-upon milestones or make certain royalty payments under our in-license agreements with Apogee with respect to opaganib and with Heidelberg with respect to RHB-107, under our asset purchase agreement with Giaconda Limited with respect to Talicia®, RHB-104, and RHB-106 and under our agreement with UCF or the University of Minnesota, pursuant to which we are obligated to make various payments upon the achievement of agreed-upon milestones or make certain royalty payments. See " - Company Overview – Therapeutic Candidates" above. All of our in-licensing agreements are terminable at-will by us upon prior written notice.

In addition, we have future obligations to purchase API, bulk tables and finished goods with respect to Talicia® for an aggregate purchase price of approximately $6.2 million until the end of 2026 in the ordinary course of business. We expect to purchase the inventory in the regular course of business as part of our ongoing commercialization of Talicia®. We continue to have negative cash flows from operations, and our ability to generate sufficient revenues for our operations is significantly limited after the sale of the rights to Movantik®. We estimate that, absent sufficient revenues from Talicia® and other sources to fund our operations and meet our obligations- including the remaining pre-closing liabilities related to Movantik® and the additional liabilities assumed under the Global Termination Agreement, as described above- we will need to raise significant additional capital in order to continue as a going concern. Our current cash and cash equivalents are not sufficient to continuously fund our operations and satisfy our payment obligations for a period exceeding one year from the date of this Annual Report. If we are unable to secure additional financing, we may be required to reduce our operations, divest certain assets, or take other measures that could materially adversely affect our reputation, business, financial condition or results of operations.

However, additional financing may not be available on acceptable terms, if at all, including due to the difficult conditions in the capital markets, particularly with respect to securities of biopharmaceutical companies on the U.S. stock exchanges, including the ADSs, and due to the very low market capitalization which makes it more difficult to raise significant amounts of capital. If we are not able to maintain compliance with Nasdaq's continued listing requirements this would also adversely affect our ability to raise capital.

Our future capital requirements will depend on many factors including but not limited to:

- our ability to close a strategic business development transaction, including a potential divestiture of certain of our assets;
- our ability to successfully commercialize commercial products and our therapeutic candidates, upon approval, if any, including securing commercialization agreements with third parties and favorable pricing and market share;
- we may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated; the regulatory path of each of our therapeutic candidates;
- the progress, success, and cost of our clinical trials and research and development programs;
- the costs, timing, and outcome of regulatory review and obtaining regulatory approval of our therapeutic candidates and addressing regulatory and other issues that may arise post-approval; the costs of enforcing our issued patents and defending intellectual property-related claims;
- the costs of developing sales, marketing, and distribution channels; and
- consumption of available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated.

Cash Flow

Net Cash Used in Operating Activities

Net Cash Used in Operating Activities for the year ended December 31, 2024, was $9.4 million, compared to $35.8 million for the year ended December 31, 2023. The cash used in operating activities was primarily directed towards settling pre-closing liabilities related to Movantik® and other operational activities. This was partially offset by proceeds received from the Global Termination Agreement, net of payments made to settle obligations arising from this agreement.

Net Cash Provided by Financing Activities

Net Cash Provided by Financing Activities for the year ended December 31, 2024, was $8.4 million, primarily generated through equity offerings. Net Cash Provided by Financing Activities for the year ended December 31, 2023, was $21.4 million, comprised primarily of proceeds from equity offerings and exercise of certain warrants in transactions consummated in each of April 2023, July 2023, September 2023 and November 2023, and from decrease in restricted cash, partially offset by repayment of payables in respect of intangible asset purchases.

We did not have any material commitments for capital expenditures, including any anticipated material acquisition of plant and equipment or interests in other companies, as of December 31, 2024.

C. Research and Development, Patents and Licenses

Our research and development expenses consist primarily of costs of clinical trials, professional services, share-based payments and payroll, and related expenses. The clinical trial costs are mainly related to payments to third parties to manufacture our therapeutic candidates, to perform clinical trials with our therapeutic candidates and to provide us with regulatory services. We charge all research and development expenses to operations as they are incurred. The research and development of certain of our product candidates, including RHB-107, have been supported by government-funded programs.

Due to the inherently unpredictable nature of clinical development processes, we are unable to estimate with any certainty the costs we will incur in the continued development of the therapeutic candidates in our pipeline for potential commercialization. In addition, the government is under no obligation to continue to support research and development of our products and can cease such support at any time. For example, on January 30, 2025, we were notified that funding from the U.S. Government Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) for the ongoing 300-patient Phase 2 RHB-107 arm of the ACESO PROTECT platform trial for early COVID-19 outpatient treatment is subject to termination, requiring the study to cease enrollment on March 5, 2025, prior to completion. It is estimated that approximately 100 patients have been enrolled out of a fully enrolled target patient population of 300. Due to the reduced number of patients enrolled in this study, the study result may not lead to conclusions regarding the efficacy of RHB-107 in this trial.

Our future research and development expenses will depend on the clinical success of each therapeutic candidate, the rate of patient recruitment and the ongoing assessments of each therapeutic candidate’s commercial potential. In addition, we cannot forecast with any degree of certainty which therapeutic candidates may be subject to future commercialization arrangements, when such commercialization arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. See “Item 3. Key Information – D. Risk Factors – Risks Related to Regulatory Matters - Talicia® or any product for which we may obtain regulatory approval or acquire commercialization rights may not become or continue to be commercially viable products.”

As we obtain results from clinical trials, we may elect to discontinue or delay the development and clinical trials for certain therapeutic candidates in order to focus our resources on more promising therapeutic candidates or projects. Completion of clinical trials by us or our licensees may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a therapeutic candidate. See “Item 3. Key Information – D. Risk Factors – Risks Related to Regulatory Matters.”

We expect our research and development expenses to stay material as we continue the advancement of our clinical trials and therapeutic candidates’ development. The lengthy process of completing clinical trials and seeking regulatory approvals for our therapeutic candidates requires substantial expenditures or government support. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Due to the factors set forth above, we are not able to estimate with any high certainty if and when we would recognize any substantial revenues from our projects.

D. Trend Information

Other than as disclosed elsewhere in this Annual Report, we are not aware of any trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on our net revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause reported financial information not necessarily to be indicative of future operating results or financial condition.

E. Critical Accounting Estimates

The preparation of financial statements requires management to make estimates which, by definition, will seldom equal the actual results and will affect the reported amounts in our consolidated financial statements and the accompanying notes. Some of the policies described in Note 2 of our consolidated financial statements involve a high degree of judgment or complexity. We believe that the most critical accounting policies and significant areas of judgment and estimation are in:

- Recognition and measurement of allowance for rebates and patient discount programs.
- Impairment reviews of intangible research and development assets.

Recognition and Measurement of Allowance for Rebates and Patient Discount Programs

We offer various rebate and patient discount programs, which result in discounted prescriptions to qualified patients. Rebates and discounts provided to the wholesalers and to the patients under these arrangements are accounted for as variable consideration, and recognized as a reduction in revenue, for which unsettled amounts are accrued. The allowance for these rebates is calculated based on historical and estimated utilization of the rebate and discount programs at the time the revenues are recognized. The main estimates used in recognizing and measuring this allowance relate to the amount of products sold to customers not yet prescribed to patients (units “in the channel”) and projected duration of the Company to sell the units in the channel. We periodically evaluate our estimates against actual results and, if necessary, updates the estimates accordingly.

Impairment Reviews of Intangible Research and Development Assets

We review annually or when events or changes in circumstances indicate the carrying value of the research and development assets may not be recoverable.

When and if necessary, an impairment loss is recognized for the amount by which the asset’s carrying amount exceeds its recoverable amount. The recoverable amount is determined using discounted cash flow calculations where the asset’s expected post-tax cash flows are risk-adjusted over their estimated remaining useful economic life. The risk-adjusted cash flows are discounted using our estimated post-tax weighted average cost of capital which was 18.1% as of December 31, 2024.

The main estimates used in calculating the recoverable amount include: outcome of the therapeutic candidates research and development activities; probability of success in gaining regulatory approval, size of the potential market and our asset’s specific share in it and amount and timing of projected future cash flows.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth the name, age and position of each of our executive officers and directors as of the date of this Annual Report. Senior management of the Company includes members of the Company's administrative, supervisory or management bodies, or nominees for such positions.

Name	Age	Position(s)
Executive Officers		
Dror Ben-Asher	59	Chief Executive Officer and Chairman of the Board of Directors
Razi Ingber	41	Chief Financial Officer
Reza Fathi, Ph.D.	70	Senior Vice President Research and Development
Gilead Raday	50	Chief Operating Officer
Adi Frish	55	Chief Corporate and Business Development Officer
Guy Goldberg	49	Chief Business Officer
Rick D. Scruggs	65	Chief Commercial Officer and Director
Non-Employee Directors		
Dr. Shmuel Cabilly (2), (3)	75	Director
Dr. Kenneth Reed (1), (2), (3)	71	Director
Ofer Tsimchi (1), (2), (3)	65	Director
Dr. Roni Mamluk (1), (2), (3)	58	Director

(1) Member of our audit committee, which such committee also serves as our financial statements committee.
(2) Member of our compensation committee.
(3) Independent director under the listing rules of Nasdaq.

Executive officers

Dror Ben-Asher has served as our Chief Executive Officer and as a director since August 2009. Since May 2011, Mr. Ben-Asher has also served as Chairman of our board of directors. From January 2002 to November 2010, Mr. Ben-Asher served as a manager at P.C.M.I. Ltd., an affiliate of ProSeed Capital Holdings CVA. Mr. Ben-Asher holds an LLB from the University of Leicester, U.K., an MJur from Oxford University, U.K. and completed LLM studies at Harvard University.

Razi Ingber has served as our Chief Financial Officer since May 1, 2023, and between February 2018 and May 2023, prior to his appointment as Chief Financial Officer of the Company, served in various financial positions at the Company. Mr. Ingber has extensive financial experience, specializing in financial reporting and accounting, financial planning, transactions and business analytics. Between 2011 and 2018, Mr. Ingber held several positions at PwC Israel, ultimately serving as an audit manager responsible for leading audit teams of several public and private companies. Mr. Ingber holds an M.A. and a B.A. from Tel-Aviv University and is a Certified Public Accountant.

Reza Fathi, Ph.D., has served as our Senior Vice President Research and Development since May 2010. From 2005 to 2009, Dr. Fathi served as a Director of Research in XTL Biopharmaceuticals Inc., a biotechnology company engaged in developing small molecule clinical candidates for infectious diseases. Prior to that, from 2000-2005, Dr. Fathi served as Director of Research at Vivoquest, Inc. where he was responsible for developing a number of novel natural product-based combinatorial technologies for infectious diseases such as HCV and HIV. Between 1998-2000, he served as a Manager of Chemical Biology Research at the Institute of Chemistry and Chemical Biology (ICCB) at Harvard Medical School, pioneering chemical genetics to identify small molecules in cancer biology, and from 1991-1998 headed the Discovery Group at PharmaGenics, Inc. Dr. Fathi holds a Postdoctoral and Ph.D. in Chemistry from Rutgers University.

Gilead Raday has served as our Chief Operating Officer since April 2016. From December 2012 until March 2016, Mr. Raday served as Senior Vice President Corporate and Product Development. From November 2010 to December 2012, Mr. Raday served as our Vice President Corporate and Product Development. From January 2010 until October 2010, Mr. Raday served as Interim Chief Executive Officer of Sepal Pharma Plc., an oncology drug development company, and from January 2009 to December 2009, he was an independent consultant, specializing in business development and project management in the field of life sciences. From 2004 to 2008, Mr. Raday was a partner in Charles Street Securities Europe, LLP, an investment banking firm, where he was responsible for the field of life sciences. Mr. Raday previously served on the boards of Sepal Pharma Plc., ViDAC Limited, Morria Biopharmaceuticals Plc., Vaccine Research International Plc., Tksignal Plc., and Miras Medical Imaging Plc. He received his M.Sc. in Neurobiology from the Hebrew University of Jerusalem, Israel, and an M.Phil. in Bioscience Enterprise from Cambridge University, U.K.

Adi Frish has served as our Chief Corporate and Business Development Officer since October 2020. From December 2012 to October 2020 Mr. Frish served as our Senior Vice President Business Development and Licensing. From October 2010 to December 2012, Mr. Frish served as our Vice President Business Development and Licensing. From 2006 to 2010, Mr. Frish served as the Chief Business Development at Medigus Ltd., a medical device company in the endoscopic field, and from 1998 to 2006, Mr. Frish was an associate and a partner at the law firm of Y. Ben Dror & Co. Mr. Frish holds an LLB from Essex University, U.K. and an LLM in Business Law from the Bar-Ilan University, Israel.

Guy Goldberg has served as our Chief Business Officer since 2012. From 2007 to 2012, Mr. Goldberg served as Vice President and then as Senior Vice President of Business Operations at Eagle Pharmaceuticals, a specialty injectable drug development company, based in New Jersey. From 2004 to 2007, Mr. Goldberg was an associate at ProQuest Investments, a healthcare-focused venture capital firm, and from 2002 to 2004, Mr. Goldberg was a consultant at McKinsey & Company. Mr. Goldberg holds a B.A. in Economics and Philosophy from Yale University and a J.D. from Harvard Law School.

Rick D. Scruggs has served as our Chief Commercial Officer since February 2020 and served as our Chief Operations Officer, U.S. Operations since January 1, 2019, and as a member of our board of directors since January 1, 2016. Mr. Scruggs most recently served as Executive Vice President of Business Development at Salix until its acquisition by Valeant (now Bausch Health) in March 2015. Mr. Scruggs joined Salix in 2000, after working at Oclassen Pharmaceuticals Inc. and Watson Pharmaceuticals, and helped build Salix's commercial organization, serving in various sales and commercial trade-related positions. Mr. Scruggs was appointed as Executive Vice President in 2011 and was responsible for all business development activities as well as the worldwide distribution of Salix's innovative products and intellectual property. Mr. Scruggs also served as the head of the board of directors of Oceana Therapeutics, Salix's European subsidiary. Mr. Scruggs holds a B.S. in Criminal Justice from the Appalachian State University in North Carolina.

Non-Employee Directors

Dr. Shmuel Cabilly has served as a member of our board of directors since August 2010. Dr. Cabilly is a scientist and inventor in the field of immunology. In the Backman Research Institute of the City of Hope, Dr. Cabilly initiated the development of a new breakthrough technology for recombinant antibody production, which was patented and known as the "Cabilly Patent." Dr. Cabilly was also a co-founder and a Chief Scientist of Ethrog Biotechnology, where he invented dry buffer technologies enabling the production of a liquid-free disposable apparatus for gel electrophoresis and a technology that enables the condensation of molecular separation zones to a small gel area. This technology was sold to Invitrogen in 2001. Dr. Cabilly serves as a board member at several companies, including BioKine Therapeutics Ltd., Minovia Ltd., Alonbio Ltd. and Raziel Therapeutics Ltd. Dr. Cabilly holds a B.Sc. in Biology from the Ben Gurion University of Beer Sheva, Israel, an M.Sc. in Immunology and Microbiology from the Hebrew University of Jerusalem, Israel, and a Ph.D. in Immunology and Microbiology from the Hebrew University of Jerusalem, Israel.

Dr. Kenneth Reed has served as a member of our board of directors since December 2009. Dr. Reed is a board certified dermatologist and Mohs surgeon. Dr. Reed currently serves on the board of directors of Minerva Biotechnologies Corporation. Dr. Reed received his B.A. from Brown University in the U.S. and an M.D from the University of Medicine and Dentistry of New Jersey in the U.S. Dr. Reed is a board-certified dermatologist with over 25 years of clinical experience since completing the Harvard Medical School Residency Program in Dermatology. Dr. Reed is also a co-founder of Early Cell, a prenatal diagnostics company, Prescient Pharma and Lispiro.

Ofer Tsimchi has served as a director on our board of directors, as Chairman of our compensation committee and as a member in our audit committee since May 2011. Since June 2024, Mr. Tsimchi has also served as Chairman of our audit committee. From 2008 to 2012, Mr. Tsimchi served as the Chairman of the board of directors of Polysack Plastic Industries Ltd. and Polysack-Agriculture Products, served as a board member of Caesarstone Ltd. and Danbar Group Ltd and since 2006, he has served as a Partner in the Danbar Group Ltd., a holding company. Mr. Tsimchi currently serves on the board of directors of Maabarot Products Ltd. Mr. Tsimchi received his BA in Economics and Agriculture from the Hebrew University of Jerusalem, Israel. The board of directors has determined that Mr. Tsimchi is a financial and accounting expert under Israeli law.

Dr. Roni Mamluk currently serves as the Chairperson of OffRa Health, a healthcare AI company, and as a consultant to the Israeli government for Ag-tech in the Gaza Envelop region. Dr. Mamluk served as a board member at Amryt Pharma plc (previously Nasdaq-listed) between 2021-2023 and as a board member at Chiasma between 2013-2021. From 2017 to 2023, Dr. Mamluk was a co-founder and served as President and Chief Executive Officer of Ayala Pharmaceuticals, a Nasdaq-listed clinical-stage precision oncology company. From 2006 to 2017, Dr. Mamluk served in various management roles at Chiasma, a biopharmaceutical company, including as Chief Development Officer and Chief Executive Officer. Dr. Mamluk received a Ph.D., Summa Cum Laude, from The Hebrew University in Jerusalem, the Department of Animal Sciences.

End of Service

Ms. Alla Felder served as a member of our board of directors until June 4, 2024. Ms. Felder resigned due to personal reasons and not as a result of any disagreement with the Company on any matter relating to the Company's operations, policies or practice.

Mr. Eric Swenden served as a member of our board of directors until April 8, 2025. His resignation was due to personal reasons and was not related to any disagreement with the Company's operations, policies, or practices.

B. Compensation

The aggregate compensation paid, and benefits-in-kind granted to or accrued on behalf of all of our directors and executive officers for their services, in all capacities, to us during the year ended December 31, 2024, was approximately $2.2 million. Out of that amount, approximately $1.7 million was paid as salary, approximately $0.2 million was attributed to the value of the RSUs granted to senior management and the directors during the year ended December 31, 2024, approximately $0.3 million was attributed to retirement plans and approximately $0.05 million was attributed to other long-term benefits. No additional amounts have been set aside or accrued by us to provide pension, retirement or similar benefits.

The compensation terms for our directors and officers are derived from their employment agreements and directors' compensation arrangements and comply with our Compensation Policy for Executive Officers and Directors as approved by our shareholders (the "Compensation Policy"). On November 16, 2023, our board of directors adopted the Policy for Recovery of Erroneously Awarded Compensation (the "Compensation Recovery Policy"), effective as of December 1, 2023, which provides for certain incentive-based compensation (including cash bonuses and equity-based compensation) awarded to our officers to be recovered in the event that we are required to prepare an accounting restatement to correct material noncompliance with any financial reporting requirement to which we are subject. This description of the Compensation Recovery Policy is qualified by reference to the full text of such policy, which is filed as an exhibit to this Annual Report. On March 23, 2025, our board of directors approved an amendment to our Compensation Policy to align it with the Compensation Recovery Policy. These changes are subject to approval by the annual general meeting of shareholders scheduled for May 5, 2025. In the event of any inconsistency between our Compensation Policy and the Compensation Recovery Policy, in respect to the recovery of any portion of Incentive-Based Compensation that is Erroneously Awarded Compensation (both as defined in the Compensation Recovery Policy) that would not be recoverable under the Compensation Policy, the terms of the Compensation Recovery Policy shall prevail.

The table and summary below outline the compensation granted to our five highest compensated directors and officers during the year ended December 31, 2024. The compensation detailed in the table below refers to the actual compensation granted or paid to the director or officer during the year ended December 31, 2024.

Name and Position of Director or Officer	Base Salary or Other Payment (1)	Value of Social Benefits (2)	Value of Equity-Based Compensation Granted (3)	All Other Compensation (4)	Total
Dror Ben-Asher, Chief Executive Officer, and Chairman of the Board of Directors (5)	$ 410,832	$ 91,133	$ 47,549	$ 16,951	$ 566,465
Rick Scruggs, Chief Commercial Officer (6)	$ 385,140	$ 21,156	$ 37,440	—	$ 443,736
Razi Ingber, Chief Financial Officer	$ 236,591	$ 64,142	$ 31,824	$ 16,951	$ 349,508
Gilead Raday, Chief Operating Officer	$ 264,483	$ 66,026	$ 31,824	$ 3,998	$ 366,331
Adi Frish, Chief Corporate and Business Development Officer	$ 218,512	$ 61,384	$ 26,208	$ 16,488	$ 322,592

(1) "Base Salary or Other Payment" means the aggregate yearly gross monthly salaries or other payments with respect to the Company's Executive Officers and members of the board of directors for the year ended December 31, 2024. Messrs. Ben-Asher and Scruggs do not receive extra compensation for their service as members of the board of directors.

(2) "Social Benefits" include payments to the National Insurance Institute, advanced education funds, managers' insurance and pension funds; vacation pay; and recuperation pay as mandated by Israeli and U.S. laws.

(3) Consists of the fair value of the equity-based compensation granted during the year ended December 31, 2024, in exchange for the directors and officers services recognized as an expense in profit or loss and is carried to the accumulated deficit under equity. The total amount is recognized as an expense over the vesting period of the RSUs. See "Management - Share Ownership" for further information regarding the RSUs.

(4) "All Other Compensation" includes, among other things, car-related expenses (including tax gross-up), communication expenses, and basic health insurance.

(5) Mr. Ben-Asher's employment terms as the Company's Chief Executive Officer provide that Mr. Ben-Asher is currently entitled to a monthly base gross salary of NIS 124,740 (approximately $34,203). Mr. Ben-Asher is further entitled to vacation days, sick days and convalescence pay in accordance with the market practice and applicable law, monthly remuneration for a study fund, contribution by the Company to an insurance policy and pension fund, and additional benefits, including communication expenses reimbursement of up to NIS 3,500 per year for private medical insurance, and coverage of one annual comprehensive medical check-up. In addition, Mr. Ben-Asher is entitled to reimbursement of car-related expenses from the Company. Mr. Ben-Asher's employment terms include an advance notice period of 12 months by the Company and 90 days by Mr. Ben-Asher. During such an advance notice period, Mr. Ben-Asher will be entitled to all of the compensation elements, and to the continuation of vesting of any options or restricted shares granted to him. Additionally, in the event Mr. Ben-Asher's employment is terminated in connection with a "change in control" he will be entitled to a special one-time payment equal to his then-current monthly salary multiplied by 18. A "change in control" is defined under the change in control employee retention plan (the "CIC Plan") as follows: (1) the consummation of any merger, consolidation, reorganization, or similar transaction or series of related transactions of the Company with another entity, other than a merger, consolidation, reorganization, or similar transaction or series of related transactions which would result in the shareholders of the Company immediately preceding the transaction beneficially owning, immediately after the transaction, at least 50% of the combined voting power of the outstanding securities of the surviving or resulting entity (or its parent); (2) any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act or "group" (two or more persons acting as a partnership, limited partnership, syndicate or other group for the purpose of acquiring, holding, or disposing of the applicable securities referred to herein) becomes the "beneficial owner" (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of securities of the Company representing fifty percent (50%) or more of the total voting power represented by the Company's then-outstanding voting securities; (3) the election of a board of directors over a three-year period or less, the majority of which is not supported by at least a majority of the then existing board of directors of the Company; or (4) any sale, lease, exchange, or other transfer (in one transaction or a series of related transactions) of all or substantially all of the assets of the Company (other than to an entity controlled by the Company).

(6) Mr. Rick Scruggs' employment term as the Company's Chief Commercial Officer provides that Mr. Scruggs is currently entitled to a monthly base gross salary of approximately $33,858. Mr. Scruggs is further entitled to vacation days and sick days in accordance with the market practice and applicable law, contribution by the Company to welfare benefits insurance policies, and additional benefits, including communication expenses. Mr. Scruggs will be entitled to payment of severance in the amount of 12 months' base salary at the time of termination in the event Mr. Scruggs' employment is terminated without cause by the Company. Mr. Scruggs's employment terms also include an advance notice period of 60 days by either party. During such an advance notice period, Mr. Scruggs will be entitled to all of the compensation elements, and to the continuation of vesting of any options or restricted shares granted to him. Additionally, in the event Mr. Scruggs's employment is terminated in connection with a "change in control" he will be entitled to a special one-time payment equal to his then-current monthly salary and retirement benefits, including payments to an advanced study fund and pension arrangement, multiplied by 12. A "change in control" is defined in the same manner as defined for Mr. Ben-Asher as described in footnote (5) above.

Employment Agreements

We have entered into employment or consultant agreements with each of our executive officers. All of these agreements contain customary provisions regarding non-competition, confidentiality of information and assignment of inventions. However, the enforceability of the non-competition provisions may be limited under applicable laws.

For information on exemption and indemnification letters granted to our directors and officers, please see "Item 6 – C. Board Practices – Exemption, Insurance and Indemnification of Directors and Officers."

Director Compensation

We currently pay our non-executive directors (i) an annual cash fee retainer of $26,000, (ii) a committee membership annual cash fee retainer of (a) $6,500 to each Audit Committee member and (b) $6,000 to each Compensation Committee member and (iii) a committee chairperson annual cash fee retainer in an amount that is higher than the annual cash fee payable to other members of that committee (as described in clause (ii) above) by 50% to each of the Audit Committee and Compensation Committee chairs (without duplication of the fees paid under clause (ii)). These amounts reflect the voluntary deferral by our directors of a portion of their director fees, as described below.

Change in Control Retention Plan and Agreements; Severance Arrangements

We have adopted a change in control employee retention plan and entered into employment agreements providing for compensation to Company employees, in the event of a change in control (as defined by the plan and the employment agreements), subject to the satisfaction of various conditions. Compensation to employees would be up to 12 months' salary depending on employee seniority and years with the Company.

Compensation Policy

On May 13, 2022, our shareholders approved the Compensation Policy for our directors and officers in accordance with the Israeli Companies Law, pursuant to which we are required to determine the compensation of our directors and officers, and which must be approved by our shareholders every three years. The policy was previously approved by our board of directors, upon the recommendation of our compensation committee and includes certain amendments to comply with applicable regulatory requirements.

The Compensation Policy is in effect for three years from the 2022 annual general meeting. Our Compensation Policy principles were designed to grant proper, fair and well-considered remuneration to our officers, in alignment with our long-term best interests and overall organizational strategy. Part of the rationale is that our Compensation Policy should encourage our officers to identify with our objectives, and an increase in officer satisfaction and motivation should retain the employment of high-quality officers in our service over the long term.

On March 23, 2025, our board of directors approved certain amendments to the Compensation Policy to align it with the Compensation Recovery Policy adopted in 2023. We have scheduled an annual general meeting of shareholders for May 5, 2025 to, among other things, vote on the approval of an amended version of our compensation policy for an additional period of three years.

C. Board Practices

Appointment of Directors and Terms of Officers

Pursuant to our articles of association, the size of our board of directors shall be no less than five persons and no more than eleven persons, including any external directors whose appointment is required by law. The directors who are not external directors are divided into three classes, as nearly equal in number as possible. At each annual general meeting, which is required to be held annually, but not more than fifteen months after the prior annual general meeting, the term of one class of directors expires, and the directors of such class are re-nominated to serve an additional three-year term that expires at the annual general meeting held in the third year following such election. This process continues indefinitely. A simple majority shareholder vote may elect directors for a term of less than three years in order to ensure that the three groups of directors have as equal a number of directors as possible as provided above. The directors of the first class, currently consisting of Mr. Ofer Tsimchi and Dr. Roni Mamluk will hold office until our annual general meeting to be held in the year 2027. The directors of the second class, currently consisting of Mr. Dror Ben-Asher and Dr. Kenneth Reed, will hold office until our annual general meeting to be held in the year 2025. The directors of the third class, currently consisting of Dr. Shmuel Cabilly and Mr. Rick Scruggs, will hold office until our annual general meeting to be held in the year 2026. Until the next annual general meeting, the board of directors may elect new directors to fill vacancies or increase the number of members of the board of directors up to the maximum number provided in our articles of association. Any director so appointed may hold office until the first general shareholders' meeting convened after the appointment. See "Management - Board Practices – Independent and External Directors – Israeli Companies Law Requirements" below for a description of the adoption by the Company of the corporate governance exemptions set forth in Regulation 5D of the Israeli Companies Regulations (Relief for Public Companies with Shares Listed for Trading on a Stock Market Outside of Israel), 5760-2000, including with respect to external directors.

Pursuant to the Israeli Companies Law, one may not be elected and may not serve as a director in a public company if he or she does not have the required qualifications and the ability to dedicate an appropriate amount of time for the performance of his duties as a director in the company, taking into consideration, among other things, the special needs and size of the company. In addition, a public company may convene an annual general meeting of shareholders to elect a director, and may elect such director, only if prior to such shareholders meeting, the nominee declares, among other things, that he or she possesses all of the required qualifications to serve as a director (and lists such qualifications in such declaration) and has the ability to dedicate an appropriate amount of time for the performance of his duties as a director of the company.

Under the Israeli Companies Law, entry by a public company into a contract with a non-controlling director as to the terms of his office, including exculpation, indemnification or insurance, requires the approval of the compensation committee, the board of directors and the shareholders of the company.

The Israeli Companies Law requires that the terms of service and engagement of the chief executive officer, directors or controlling shareholders (or a relative thereof) receive the approval of the compensation committee, board of directors, and shareholders, subject to limited exceptions. The appointment and terms of office of a company's officers, other than directors and the general manager (i.e., chief executive officer) are subject to the approval by first, the company's compensation committee; second, the company's board of directors, in each case subject to the company's compensation policy, and then approved by its shareholders. However, in special circumstances, they may approve the appointment and terms of office of officers inconsistent with such policy, provided that (i) they have considered those provisions that must be included in the compensation policy according to the Israeli Companies Law and (ii) shareholder approval is obtained (by a majority of shareholders that does not include the controlling shareholders of the company and any shareholders interested in the approval of the compensation). However, if the shareholders of the company do not approve a compensation arrangement with an officer inconsistent with the company's compensation policy, in special situations the compensation committee and the board of directors may override the shareholders' decision if each of the compensation committee and the board of directors provide detailed reasons for their decision. In addition, non-material amendments to the compensation of a public company's officers (other than the chief executive officer and the directors) may be approved by the chief executive officer of the company if the company's compensation policy establishes that non-material amendments within the parameters established in the compensation policy may be approved by the chief executive officer, so long as the compensation is consistent with the company's compensation policy. An amendment to the Israeli Companies Law requires that the board and shareholders (with approval by a "special majority" as further discussed below) adopt a compensation policy applicable to the company's directors and officers which must take into account, among other things, providing proper incentives to directors and officers, the risk management of the company, the officer's contribution to achieving corporate objectives and increasing profits, and the function of the officer or director. Under the Israeli Companies Law, a "special majority" requires (i) the vote of at least a majority of the shares held by shareholders who are not controlling shareholders or have a personal interest in the proposal (shares held by abstaining shareholders are not taken into account); or (ii) that the aggregate number of shares voting against the proposal held by such shareholders does not exceed 2% of the company's voting shareholders.

The compensation paid to a public company's chief executive officer is required to be approved by, first, the company's compensation committee; second, the company's board of directors; and third, unless exempted under the regulations promulgated under the Israeli Companies Law, by the company's shareholders (by a special majority vote as discussed above with respect to the approval of director compensation). However, if the shareholders of the company do not approve the compensation arrangement with the chief executive officer, the compensation committee and board of directors may override the shareholders' decision if each of the compensation committee and the board of directors provide a detailed report for their decision. The renewal or extension of the engagement with a public company's chief executive officer need not be approved by the shareholders of the company if the terms and conditions of such renewal or extension are no more beneficial than the previous engagement or there is no substantial difference in the terms and conditions under the circumstances, and the terms and conditions of such renewal or extension are in accordance with the company's compensation policy. The compensation committee and board of directors approval should be in accordance with the company's stated compensation policy; however, in special circumstances, they may approve compensation terms of a chief executive officer that are inconsistent with such policy provided that they have considered those provisions that must be included in the compensation policy according to the Israeli Companies Law and that shareholder approval was obtained (by a special majority vote as discussed above with respect to the approval of director compensation). The compensation committee may waive the shareholder approval requirement with regards to the approval of the initial engagement terms of a candidate for the chief executive officer position, if they determine that the compensation arrangement is consistent with the company's stated compensation policy, and that the chief executive officer did not have a prior business relationship with the company or a controlling shareholder of the company and that subjecting the approval of the engagement to a shareholder vote would impede the company's ability to employ the chief executive officer candidate. The engagement with a public company's chief executive officer need not be approved by the shareholders of the company with respect to the period from the commencement of the engagement until the next shareholder meeting convened by the company, if the terms and conditions of such engagement were approved by the compensation committee and the board of directors of the company, the terms and conditions of such engagement are in accordance with the company's compensation policy approved in accordance with the Israeli Companies Law, and if the terms and conditions of such engagement are no more beneficial than the terms and conditions of the person previously serving in such role or there is no substantial difference in the terms and conditions of the previous engagement versus the new one under the circumstances, including the scope of engagement.

We have service contracts with two of our directors, Dror Ben-Asher and Rick Scruggs, that provide for benefits upon termination of their employment. For more information, see "Item 6. Directors, Senior Management and Employees – B. Compensation."

In June 2022, our directors and officers voluntarily deferred 20% of their fees or salary (as the case may be), which amounts may be fully or partially paid at a later date, subject to several conditions. In June 2023 (only the officers) and October 2023, our directors and officers voluntarily deferred an additional sum of the cash compensation due to them under their respective employment agreements or compensation arrangements, as the case may be.

Independent and External Directors – Israeli Companies Law Requirements

We are subject to the provisions of the Israeli Companies Law. The Israeli Minister of Justice has adopted regulations exempting companies like us whose shares are traded outside of Israel from some provisions of the Israeli Companies Law.

Under the Israeli Companies Law, except as provided below, companies incorporated under the laws of Israel whose shares are either (i) listed for trading on a stock exchange or (ii) have been offered to the public in or outside of Israel and are held by the public (Public Company) are required to appoint at least two external directors.

Our board of directors has resolved to adopt the corporate governance exception set forth in Regulation 5D of the Israeli Companies Regulations (the "Regulation"). In accordance with the Regulation, a public company with securities listed on certain foreign exchanges, including the Nasdaq Stock Market, that satisfies the applicable foreign country laws and regulations that apply to companies organized in that country relating to the appointment of independent directors and composition of audit and compensation committees and have no controlling shareholder are exempt from the requirement to appoint external directors or comply with the audit committee and compensation committee composition requirements under the Israeli Companies Law. In accordance with our board of directors' resolution, pursuant to the Regulation, we intend to comply with the Nasdaq Listing Rules in connection with a majority of independent directors on the board of directors and in connection with the composition of each of the audit committee and the compensation committee, in lieu of such requirements of the Israeli Companies Law.

The Israeli Companies Law provides that a person may not be appointed as an external director if the person is a relative of the controlling shareholder or if the person or the person's relative, partner, employer, someone to whom he is subordinated directly or indirectly or any entity under the person's control, has, as of the date of the person's appointment to serve as external director, or had, during the two years preceding that date, any affiliation with us, our controlling shareholder, any relative of our controlling shareholder, as of the date of the person's appointment to serve as external director, or any entity in which, currently or within the two years preceding the appointment date, the controlling shareholder was the company or the company's controlling shareholder; and in a company without a controlling shareholder or without a shareholder holding 25% or more of the voting rights in the company, any affiliation to the chairman of the board of directors, to the general manager (Chief Executive Officer), to a shareholder holding 5% or more of the company's shares or voting rights, or to the chief officer in the financial or economic field as of the date of the person's appointment. The term "affiliation" includes:

- an employment relationship;
- a business or professional relationship maintained on a regular basis;
- control; and
- service as an officer, other than service as a director who was appointed in order to serve as an external director of a company when such company was about to make an initial public offering.

Under the Israeli Companies Law, an "officer" is defined as a general manager, chief business manager, deputy general manager, vice general manager, any person filing any of these positions in a company even if he holds a different title, director or any manager directly subordinate to the general manager.

However, a person may not serve as an external director if the person or the person's relative, partner, employer, someone to whom he is subordinated directly or indirectly or any entity under the person's control has a business or professional relationship with an entity which has an affiliation with is prohibited as detailed above, even if such relationship is not on a regular basis (excluding negligible relationship). In addition, an external director may not receive any compensation other than the compensation permitted by the Israeli Companies Law.

Regulations under the Israeli Companies Law provide for various instances and kinds of relationships in which an external director will not be deemed to have "affiliation" with the public company for which he serves or is a candidate for serving as an external director.

No person can serve as an external director if the person's positions or other businesses create, or may create, a conflict of interests with the person's responsibilities as a director or may impair his ability to serve as a director. In addition, a person who is a director of a company may not be elected as an external director of another company if, at that time, a director of the other company is acting as an external director of the first company.

Except for the cessation of classification of directors as external directors in connection with the adoption by certain companies listed on foreign stock exchanges, including the Nasdaq Stock Market, of the corporate governance exceptions set forth in the Regulation, as described above, until the lapse of two years from termination of office, a company, its controlling shareholder, or a company controlled by him may not engage an external director, his spouse, or child to serve as an officer in the company or in any entity controlled by the controlling shareholder and cannot employ or receive professional services for consideration from that person, and may not grant such person any benefit either directly or indirectly, including through a corporation controlled by that person. The same restrictions apply to relatives other than a spouse or a child, but such limitations may only apply for one year from the date such external director ceased to be engaged in such capacity. In addition, if at the time an external director is appointed all current members of the board of directors who are neither controlling shareholders nor relatives of controlling shareholders are of the same gender, then the external director to be appointed must be of the other gender.

Under the Israeli Companies Law, a public company is required to appoint as an external director, a person who has "professional expertise" or a person who has "financial and accounting expertise," provided that at least one of the external directors must have "financial and accounting expertise." However, if at least one of our other directors (1) meets the independence requirements of the Exchange Act, (2) meets the standards of the Nasdaq Stock Market for membership on the audit committee and (3) has financial and accounting expertise as defined in the Israeli Companies Law and applicable regulations, then neither of our external directors is required to possess financial and accounting expertise as long as both possess other requisite professional qualifications. The determination of whether a director possesses financial and accounting expertise is made by the board of directors.

Under the Israeli Companies Law regulations, a director having financial and accounting expertise is a person who, due to his education, experience and qualifications is highly skilled in respect of, and understands, business-accounting matters and financial reports in a manner that enables him to understand in depth the company's financial statements and to stimulate discussion regarding the manner in which the financial data is presented. Under the Israeli Companies Law regulations, a director having professional expertise is a person who has an academic degree in either economics, business administration, accounting, law or public administration or another academic degree or has completed other higher education studies, all in an area relevant to the main business sector of the company or in a relevant area of the board of directors position, or has at least five years of experience in one of the following or at least five years of aggregate experience in two or more of the following: a senior management position in the business of a corporation with a substantial scope of business, in a senior position in the public service or a senior position in the main field of the company's business.

Under the Israeli Companies Law, each Israeli public company is required to determine the minimum number of directors with "accounting and financial expertise" that such company believes appropriate in light of the company's type, size, the scope and complexity of its activities and other factors. Once a company has made this determination, it must ensure that the necessary appointments to the board of directors are made in accordance with this determination. Our board of directors determined that two directors with "accounting and financial expertise" is appropriate for us. Our board of directors currently has three directors with such "accounting and financial expertise."

External directors are to be elected by a majority vote at a shareholders' meeting, provided that either (1) the majority of shares voted at the meeting, including at least a majority of the votes of the shareholders who are not controlling shareholders (as defined in the Israeli Companies Law), do not have a personal interest in the appointment (excluding a personal interest which did not result from the shareholder's relationship with the controlling shareholder), vote in favor of the election of the director without taking abstentions into account; or (2) the total number of shares of the above-mentioned shareholders who voted against the election of the external director does not exceed two percent of the aggregate voting rights in the company.

The initial term of an external director is three years and may be extended for two additional three-year terms under certain circumstances and conditions. Nevertheless, regulations under the Israeli Companies Law provide that companies, whose shares are listed for trading the Nasdaq Stock Market, may appoint an external director for additional three-year terms, under certain circumstances and conditions. External directors may be removed only in a general meeting, by the same percentage of shareholders as is required for their election, or by a court, and in both cases only if the external directors cease to meet the statutory qualifications for their appointment or if they violate their duty of loyalty to us. Each committee authorized to exercise any of the powers of the board of directors is required to include at least one external director and the audit committee is required to include all of the external directors.

An external director is entitled to compensation and reimbursement of expenses in accordance with regulations promulgated under the Israeli Companies Law and is otherwise prohibited from receiving any other compensation, directly or indirectly, in connection with serving as a director except for certain exculpation, indemnification and insurance provided by the company.

Committees

Israeli Companies Law Requirements

Our board of directors has established two standing committees, the audit committee and the compensation committee. To streamline oversight functions, the responsibilities of the investment committee were assigned in December 2024 to the audit committee.

Audit Committee

Under the Israeli Companies Law, the board of directors of a public company must appoint an audit committee. Except in the case of companies listed on foreign stock exchanges, including the Nasdaq Stock Market, which have adopted the corporate governance exceptions set forth in the Regulation, such as us, as described under "- Independent and External Directors – Israeli Companies Law Requirements", who are exempt from the audit committee composition requirements under the Companies Law, an audit committee of a public company under the Israeli Companies Law must be comprised of at least three directors including all of the external directors.

In addition, the Israeli Companies Law provides that the majority of the members of the audit committee, as well as the majority of members present at audit committee meetings, must be "independent" (as such term is defined below) and the chairman of the audit committee must be an external director. In addition, the following are disqualified from serving as members of the audit committee: the chairman of the board of directors, the controlling shareholder and her or his relatives, any director employed by the company or by its controlling shareholder or by an entity controlled by the controlling shareholder, a director who regularly provides services to the company or to its controlling shareholder or to an entity controlled by the controlling shareholder, and any director who derives most of its income from the controlling shareholder. Any persons not qualified from serving as a member of the audit committee may not be present at the audit committee meetings during the discussion and at the time decisions are made, unless the chairman of the audit committee determines that the presence of such person is required to present a matter to the meeting or if such person qualifies under an available exemption in the Israeli Companies Law.

An "independent director" is defined as an external director or a director who meets the following conditions: (i) satisfies certain conditions for appointment as an external director (as described above) and the audit committee has determined that such conditions have been met and (ii) has not served as a director of the company for more than nine consecutive years, with any interruption of up to two years in service not being deemed a disruption in the continuity of such service.

The role of the audit committee under the Israel Companies Law is to examine suspected flaws in our business management, in consultation with the internal auditor or our independent accountants and suggest an appropriate course of action in order to correct such flaws. In addition, the approval of the audit committee is required to effect specified actions and related party transactions.

Additional functions to be performed by the audit committee include, among others, the following:

- the determination whether certain related party actions and transactions are "material" or "extraordinary" for purposes of the requisite approval procedures;
- to determine whether to approve actions and transactions that require audit committee approval under the Israel Companies Law;
- to assess the scope of work and compensation of the company's independent accountant;
- to assess the company's internal audit system and the performance of its internal auditor and if the necessary resources have been made available to the internal auditor considering the company's needs and size; and
- to determine arrangements for handling complaints of employees in relation to suspected flaws in the business management of the company and the protection of the rights of such employees.

Our audit committee also serves as our financial statements committee. The members of our audit committee are Mr. Ofer Tsimchi (Chairman), Dr. Kenneth Reed and Dr. Roni Mamluk.

An amendment to the Israeli Companies Law allows a company whose audit committee's composition meets the requirements set for the composition of a compensation committee (as further detailed below) to have one committee acting as both audit and compensation committees. As of the date of this Annual Report, we have not elected to have one committee acting as both the audit and the compensation committees.

Our audit committee assumed the responsibilities of the investment committee, assisting the board in executing its duties related to our financial and investment strategies and policies. This includes establishing policies and guidelines, as well as monitoring their implementation. The committee is also authorized to approve specific financial transactions, assess risks related to the management of our finances, and evaluate measures for mitigating these risks. Additionally, it reviews our financial controls, reporting processes, and other finance-related matters.

Compensation Committee

According to the Israeli Companies Law, the board of directors of a public company must establish a compensation committee. Except in the case of companies listed on foreign stock exchanges, including the Nasdaq Stock Market, which have adopted the corporate governance exceptions set forth in the Regulation, such as us, as described under "- Independent and External Directors – Israeli Companies Law Requirements", who are exempt from the compensation committee composition requirements under the Companies Law, the Israeli Companies Law requires that the compensation committee must consist of at least three directors and include all of the external directors who must constitute a majority of its members. The remaining members must be qualified to serve on the audit committee pursuant to the Israeli Companies Law requirements described above. The compensation committee chairman must be an external director and any persons not qualified from serving as a member of the compensation committee may not be present at the compensation committee meetings during the discussion and at the time decisions are made, unless the chairman of the compensation committee determines that the presence of such person is required to present a matter to the meeting or if such person qualifies under an available exemption in the Israeli Companies Law.

Our compensation committee, which consists of Ofer Tsimchi (Chairman), Dr. Shmuel Cabilly, Dr. Kenneth Reed and Dr. Roni Mamluk, administers issues relating to our global compensation plan with respect to our employees, directors, and consultants. Our compensation committee is responsible for making recommendations to the board of directors regarding the issuance of share options and compensation terms for our directors and officers and for determining salaries and incentive compensation for our executive officers and incentive compensation for our other employees and consultants. Each of the members of the compensation committee is "independent" as such term is defined in the Nasdaq Listing Rules.

Nasdaq Stock Market Requirements

Under the Nasdaq Listing Rules, we are required to maintain an audit committee consisting of at least three members, all of whom are independent and are financially literate and one of whom has accounting or related financial management expertise.

The independence requirements of Rule 10A-3 of the Exchange Act implement two basic criteria for determining independence:

- audit committee members are barred from accepting directly or indirectly any consulting, advisory or other compensatory fee from the issuer or an affiliate of the issuer, other than in the member's capacity as a member of the board of directors and any board committee; and
- audit committee members may not be an "affiliated person" of the issuer or any subsidiary of the issuer apart from her or his capacity as a member of the board of directors and any board committee.

The SEC has defined "affiliate" for non-investment companies as "a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified." The term "control" is intended to be consistent with the other definitions of this term under the Exchange Act, as "the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." A safe harbor has been adopted by the SEC, under which a person who is not an executive officer or 10% shareholder of the issuer would be deemed not to have control of the issuer.

In accordance with the Sarbanes-Oxley Act of 2002 and the Nasdaq Listing Rules, the audit committee is directly responsible for the appointment, compensation, and performance of our independent auditors. In addition, the audit committee is responsible for assisting the board of directors in reviewing our annual financial statements, the adequacy of our internal control and our compliance with legal and regulatory requirements. The audit committee also oversees our major financial risk exposures and policies for managing such potential risks, discusses with management and our independent auditor significant risks or exposure and assesses the steps management has taken to minimize such risk.

As noted above, the members of our audit committee include Mr. Ofer Tsimchi, Dr. Roni Mamluk and Dr. Kenneth Reed, with Mr. Tsimchi serving as Chairman. All members of our audit committee meet the requirements for financial literacy under the Nasdaq Listing Rules. Our board of directors has determined that each of Mr. Ofer Tsimchi and Dr. Kenneth Reed is an audit committee financial expert as defined by the SEC rules and all members of the audit committee have the requisite financial experience as defined by the Nasdaq Listing Rules. Each of the members of the audit committee is "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act.

Diversity of the Board of Directors

We are committed to diversity among our Board. The ability to incorporate a wide range of viewpoints, backgrounds, skills, and experience is critical to our success. By bringing together individuals with varying backgrounds, expertise, and perspectives into an inclusive and collaborative work environment, we believe we can better achieve our corporate objectives and deliver long-term, sustained value for our shareholders.

We recognize that gender diversity is a significant aspect of diversity and acknowledge the important role that women with appropriate and relevant skills and experience can play in contributing to the diversity of thought on the Board. As such, when reviewing and assessing the qualifications of possible nominees to the Board, our Board is guided by the following considerations:

- the competencies and skills necessary for the Board as a whole should possess;
- the experience and skill each new nominee will bring to the Board;
- the diversity of the Board as a whole and whether the new nominee would enhance such diversity; and
- whether the nominees can devote sufficient time and resources to his or her duties as a Board member.

Due to the size of the Company and Board, our activities, and our current number of employees across two geographies, we have not yet set measurable objectives or adopted a formal policy for achieving gender diversity on the Board. However, our Board and the Company continues to monitor and consider the level of female representation on the Board and, where appropriate, aim to recruit qualified female candidates as part of the selection process to fill vacancies. We will consider establishing measurable objectives as it develops further.

Internal Auditor

Under the Israeli Companies Law, the board of directors must appoint an internal auditor proposed by the audit committee. The role of the internal auditor is, among others, to examine whether our actions comply with the law and orderly business procedure. Under the Israeli Companies Law, the internal auditor may not be an interested party, an officer or a director, a relative of an interested party, or a relative of an officer or a director, nor may the internal auditor be our independent accountant or its representative. In December 2024, Mr. Alon Amit, CEO of Internal Audit at Raveh Ravid & Co., was elected to serve as our internal auditor. Mr. Alon Amit replaced the position of Ms. Tal Yaron of Deloitte Israel.

Duties of Directors and Officers and Approval of Specified Related Party Transactions under the Israeli Companies Law

Fiduciary Duties of Officers

The Israeli Companies Law imposes a duty of care and a duty of loyalty on all directors and officers of a company, including directors and executive officers. The duty of care requires a director or an officer to act with the level of care, according to which a reasonable director or officer in the same position would have acted under the same circumstances.

The duty of care includes a duty to use reasonable means to obtain:

- information on the appropriateness of a given action brought for the directors' or officer's approval or performed by such person by virtue of such person's position; and
- all other important information pertaining to the previous actions.

The duty of loyalty requires a director or an officer to act in good faith and for the benefit of the company and includes a duty to:

- refrain from any action involving a conflict of interest between the performance of the director's or officer's duties in the company and such person's personal affairs;
- refrain from any activity that is competitive with the company's business;
- refrain from usurping any business opportunity of the company to receive a personal gain for the director, officer or others; and
- disclose to the company any information or documents relating to a company's affairs which the director or officer has received due to such person's position as a director or an officer.

Under the Israeli Companies Law, subject to certain exceptions, directors' compensation arrangements require the approval of the compensation committee, the board of directors and the shareholders.

The Israeli Companies Law requires that a director or an officer of a company promptly and, in any event, not later than the first board meeting at which the transaction is discussed, disclose any personal interest that he may have, and all related material facts or document known to such person, in connection with any existing or proposed transaction by the company. A personal interest of a director or an officer (which includes a personal interest of the director's or officer's relative) is in a company in which the director or officer or the director's or officer's relative is: (i) a shareholder which holds 5% or more of a company's share capital or its voting rights, (ii) a director or a general manager, or (iii) in which the director or officer has the right to appoint at least one director or the general manager. A personal interest also includes a personal interest of a person who votes according to a proxy of another person, even if the other person has no personal interest, and a personal interest of a person who gave a proxy to another person to vote on his behalf – in each case, regardless whether discretion with respect to how to vote lies with the person voting or not. In the case of an extraordinary transaction, the director's or the officer's duty to disclose also applies to a personal interest of the director or officer's relative.

Under the Israeli Companies Law, an extraordinary transaction is a transaction:

- other than in the ordinary course of business;
- other than on market terms; or
- that is likely to have a material impact on the company's profitability, assets or liabilities.

Under the Israeli Companies Law, once a director or an officer complies with the above disclosure requirement, the board of directors may approve an ordinary transaction between the company and a director or an officer, or a third party in which a director or an officer has a personal interest, unless the articles of association provide otherwise. A transaction that does not benefit the company's interest cannot be approved. Subject to certain exceptions, the compensation committee and the board of directors must approve the conditions and term of office of an officer (who is not a director).

If the transaction is an extraordinary transaction, both the audit committee and the board of directors, in that order, must approve the transaction. Under specific circumstances, shareholder approval may also be required. Whoever has a personal interest in a matter, which is considered at a meeting of the board of directors or the audit committee, may not be present at this meeting or vote on this matter. However, if the chairman of the board of directors or the chairman of the audit committee has determined that the presence of such person is required to present a matter at the meeting; such officer holder may be present at the meeting. Notwithstanding the foregoing, if the majority of the directors have a personal interest in a matter, a director who has the personal interest in this matter may be present at this meeting or vote on this matter, but the board of directors' decision requires the shareholder approval.

Controlling Shareholder Transactions and Actions

Under the Israeli Companies Law, the disclosure requirements which apply to a director or an officer also apply to a controlling shareholder of a public company and to a person who would become a controlling shareholder as a result of a private placement. A controlling shareholder includes a person who has the ability to direct the activities of a company, other than if this power derives solely from his/her position on the board of directors or any other position with the company. In addition, for such purposes, a controlling shareholder includes a shareholder that holds 25% or more of the voting rights in a public company if no other shareholder owns more than 50% of the voting rights in the company. Extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, including a private placement in which a controlling shareholder has a personal interest; and the terms of engagement of the company, directly or indirectly, with a controlling shareholder or his or her relative (including through a corporation controlled by a controlling shareholder), regarding the company's receipt of services from the controlling shareholder, and if such controlling shareholder is also a director or an officer of the company or an employee, regarding his or her terms of office and employment, require the approval of the audit committee, the board of directors and the shareholders of the company, in that order. The shareholders' approval must include either:

- a majority of the shareholders who have no personal interest in the transaction and who are participating in the voting, in person, by proxy or by written ballot, at the meeting (votes abstaining not being taken into account); or
- the total number of shares voted against the proposal by shareholders without a personal interest does not exceed 2% of the aggregate voting rights in the Company.

In addition, any such transaction whose term is more than three years requires the above-mentioned approval every three years, unless, with respect to transactions not involving the receipt of services or compensation, the audit committee approves a longer term as reasonable under the circumstances.

However, under regulations, promulgated pursuant to the Israeli Companies Law, certain transactions between a company and its controlling shareholders, or the controlling shareholder's relative, do not require shareholder approval.

For information concerning the direct and indirect personal interests of certain of our directors or officers and principal shareholders in certain transactions with us, see "Item 7. Major Shareholders – B. Related Party Transactions."

The Israeli Companies Law requires that every shareholder that participates, either by proxy or in person, in a vote regarding a transaction with a controlling shareholder indicate whether or not that shareholder has a personal interest in the vote in question, the failure of which results in the invalidation of that shareholder's vote.

The Israeli Companies Law further provides that an acquisition of shares or voting rights in a public company must be made by means of a tender offer if as a result of the acquisition the purchaser would become a holder of 45% of the voting rights of the company, unless there is a holder of more than 45% of the voting rights of the company or would become a holder of 25% of the voting rights unless there is another person holding 25% of the voting rights. This restriction does not apply to:

- an acquisition of shares in a private placement, if the acquisition had been approved in a shareholders meeting under certain circumstances;
- an acquisition of shares from a holder of at least 25% of the voting rights, as a result of which a person would become a holder of at least 25% of the voting rights; and
- an acquisition of shares from a holder of more than 45% of the voting rights, as a result of which the acquirer would become a holder of more than 45% of the voting rights in the company.

The Israeli Companies Law further provides that a shareholder has a duty to act in good faith toward the company and other shareholders when exercising his rights and duties and must refrain from oppressing other shareholders, including in connection with the voting at a shareholders' meeting on:

- any amendment to the articles of association;
- an increase in the company's authorized share capital;
- a merger; or
- approval of certain transactions with control persons and other related parties, which require shareholder approval.

In addition, any controlling shareholder, any shareholder who knows that it possesses power to determine the outcome of a shareholder vote and any shareholder who, pursuant to the provisions of a company's articles of association, has the power to appoint or prevent the appointment of a director or an officer in the company, or has any other power over the company, is under a duty to act with fairness toward the company. Under the Israeli Companies Law, the laws that apply to a breach of a contract will generally also apply to a breach of the duty of fairness.

Exemption, Insurance, and Indemnification of Directors and Officers

Exemption of Officers and Directors

Under the Israeli Companies Law, a company may not exempt an officer or director from liability with respect to a breach of his duty of loyalty, but may exempt in advance an officer or director from liability to the company, in whole or in part, with respect to a breach of his duty of care, except in connection with a prohibited distribution made by the company, if so provided in its articles of association. Our articles of association provide for this exemption from liability for our directors and officers.

Directors' and Officers' Insurance

The Israeli Companies Law and our articles of association provide that, subject to the provisions of the Israeli Companies Law, we may obtain insurance for our directors and officers for any liability stemming from any act performed by an officer or director in his capacity as an officer or director, as the case may be with respect to any of the following:

- a breach of such officer's or director's duty of care to us or to another person;
- a breach of such officer's or director's duty of loyalty to us, provided that such officer or director acted in good faith and had reasonable cause to assume that his act would not prejudice our interests;
- a financial liability imposed upon such officer or director in favor of another person;
- financial liability imposed on the officer or director for payment to persons or entities harmed as a result of violations in administrative proceedings as described in Section 52(54)(a)(1)(a) of the Israeli Securities Law ("Party Harmed by the Breach");
- expenses incurred by such officer or director in connection with an administrative proceeding conducted in this matter, including reasonable litigation expenses, including legal fees; or
- a breach of any duty or any other obligation, to the extent insurance may be permitted by law.

Pursuant to the Compensation Policy, we may obtain a directors' and officers' liability insurance policy, which would apply to our or our subsidiaries' directors and officers, as they may be, from time to time, subject to the following terms and conditions: (a) the total insurance coverage under the insurance policy may not exceed $100 million; and (b) the purchase of such policy must be approved by the Compensation Committee (and, if required by law, by the board of directors) which shall determine that such policy reflects the current market conditions and that it does not materially affect the Company's profitability, assets or liabilities. In addition, pursuant to our Compensation Policy, should we sell our operations (in whole or in part) or in case of a merger, spin-off or any other significant business combination involving us or part or all of our assets, we may obtain a director's and officers' liability insurance policy (run-off) for our directors and officers in office with regard to the relevant operations, subject to the following terms and conditions: (a) the insurance term may not exceed seven years; (b) the coverage amount may not exceed $100 million; and (c) the purchase of such policy must be approved by the Compensation Committee (and, if required by law, by the board of directors) which shall determine that such policy reflects the current market conditions and that it does not materially affect the Company's profitability, assets or liabilities. The Compensation Policy is in effect for three years from the 2022 annual general meeting. We have scheduled an annual general meeting of shareholders for May 5, 2025 to, among other things, vote on the approval of an amended version of our compensation policy for an additional period of three years.

Pursuant to the foregoing approvals, we carry directors' and officers' liability insurance. This insurance is renewed on an annual basis.

Indemnification of Officers and Directors

The Israeli Companies Law provides that a company may indemnify an officer or director for payments or expenses associated with acts performed in his capacity as an officer or director of the company, provided the company's articles of association include the following provisions with respect to indemnification:

- a provision authorizing the company to indemnify an officer or director for future events with respect to a monetary liability imposed on him in favor of another person pursuant to a judgment (including a judgment given in a settlement or an arbitrator's award approved by the court), so long as such indemnification is limited to types of events which, in the board of directors' opinion, are foreseeable at the time of granting the indemnity undertaking given the company's actual business, and in such amount or standard as the board of directors deems reasonable under the circumstances. Such undertaking must specify the events that, in the board of directors' opinion, are foreseeable in view of the company's actual business at the time of the undertaking and the amount or the standards that the board of directors deemed reasonable at the time;

- a provision authorizing the company to indemnify an officer or director for future events with respect to reasonable litigation expenses, including counsel fees, incurred by an officer or director in which he is ordered to pay by a court, in proceedings that the company institutes against him or instituted on behalf of the company or by another person, or in a criminal charge of which he was acquitted, or a criminal charge in which he was convicted of a criminal offense that does not require proof of criminal intent;
- a provision authorizing the company to indemnify an officer or director for future events with respect to reasonable litigation fees, including attorney's fees, incurred by an officer or director due to an investigation or proceeding filed against him by an authority that is authorized to conduct such investigation or proceeding, and that resulted without filing an indictment against him and without imposing on him financial obligation in lieu of a criminal proceeding, or that resulted without filing an indictment against him but with imposing on him a financial obligation as an alternative to a criminal proceeding in respect of an offense that does not require the proof of criminal intent or in connection with a monetary sanction;
- a provision authorizing the company to indemnify an officer or director for future events with respect to a Party Harmed by the Breach;
- a provision authorizing the company to indemnify an officer or director for future events with respect to expenses incurred by such officer or director in connection with an administrative proceeding, including reasonable litigation expenses, including legal fees; and
- a provision authorizing the company to indemnify an officer or director retroactively.

Limitations on Insurance, Exemption and Indemnification

The Israeli Companies Law and our articles of association provide that a company may not exempt or indemnify a director or an officer nor enter into an insurance contract, which would provide coverage for any monetary liability incurred as a result of any of the following:

- a breach by the officer or director of his duty of loyalty, except for insurance and indemnification where the officer or director acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach by the officer or director of his duty of care if the breach was done intentionally or recklessly, except if the breach was solely as a result of negligence;
- any act or omission done with the intent to derive an illegal personal benefit; or
- any fine, civil fine, monetary sanctions, or forfeit imposed on the officer or director.

In addition, under the Israeli Companies Law, exemption of, indemnification of, and procurement of insurance coverage for, our directors and officers must be approved by our audit committee and board of directors and, in specified circumstances, by our shareholders.

Letters of Indemnification

We may provide a commitment to indemnify in advance any director or officer of ours in the course of such person's position as our director or officer, all subject to the letter of indemnification, as approved by our shareholders from time to time and in accordance with our articles of association. We may provide retroactive indemnification to any officer to the extent allowed by the Israeli Companies Law. As approved by our shareholders on May 13, 2022, the amount of the advance indemnity is limited to the higher of 25% of our then shareholders' equity, per our most recent annual financial statements, or $10 million.

As part of the indemnification letters, we exempted our directors and officers, in advance, to the extent permitted by law, from any liability for any damage incurred by them, either directly or indirectly, due to the breach of an officer's or director's duty of care *vis-à-vis* us, within his acts in his capacity as an officer or director. The letter provides that so long as not permitted by law, we do not exempt an officer or director in advance from his liability to us for a breach of the duty of care upon distribution, to the extent applicable to the officer or director, if any. The letter also exempts an officer or director from any liability for any damage incurred by him, either directly or indirectly, due to the breach of the officer or director's duty of care *vis-à-vis* us, by his acts in his capacity as an officer or director prior to the letter of exemption and indemnification becoming effective.

D. Employees

As of December 31, 2024, we had 35 employees, of which 13 provide services in Israel and 11 provide services in the U.S. In addition, we also receive services from 10 consultants, of which three are in the U.S., four are in Canada and four are in Israel.

	As of December 31,					
	2024		2023		2022	
	Company Employees	Consultants	Company Employees	Consultants	Company Employees	Consultants
Management and administration	12	—	14	—	15	—
Research and development	1	10	1	8	2	10
Commercial operations	11	—	38	—	96	—

While none of our employees are party to a collective bargaining agreement, certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Associations) are applicable to our employees by order of the Israel Ministry of Labor. These provisions primarily concern the length of the workday, minimum daily wages for professional workers, pension fund benefits for all employees, insurance for work-related accidents, procedures for dismissing employees, determination of severance pay and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimums.

We have never experienced any employment-related work stoppages and believe our relationship with our employees is good.

E. Share Ownership

The following table sets forth information regarding the beneficial ownership of our outstanding Ordinary Shares as of April 6, 2025, of each of our directors and executive officers individually and as a group based on information provided to us by our directors and executive officers. As of the date of this Annual Report, there is no executive officer or director that beneficially own 5.0% or more of our outstanding Ordinary Shares. The information in this table is based on 17,691,201,000 Ordinary Shares outstanding as of such date. The number of Ordinary Shares beneficially owned by a person includes Ordinary Shares subject to RSUs that are due to vest within 60 days of April 6, 2025, and to options held by that person that were currently exercisable at, or exercisable within 60 days of April 6, 2025. The Ordinary Shares issuable under these options are treated as if they were outstanding for purposes of computing the percentage ownership of the person holding these options but not the percentage ownership of any other person. The beneficial ownership of our ordinary shares is determined in accordance with the rules of the SEC. Under these rules, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. None of the holders of the Ordinary Shares listed in this table have voting rights different from other holders of the Ordinary Shares.

	Number of Ordinary Shares Beneficially Held	Percent of Class
Non-Employee Directors		
Dr. Kenneth Reed (1)	7,690,000	*
Dr. Shmuel Cabilly (2)	12,293,270	*
Ofer Tsimchi (3)	10,600,000	*
Dr. Roni Mamluk	—	*
Executive officers		
Dror Ben-Asher (4)	32,560,620	*
Reza Fathi, Ph.D. (5)	16,580,000	*
Adi Frish (6)	28,921,120	*
Gilead Raday (7)	26,990,000	*
Guy Goldberg (8)	23,870,000	*
Razi Ingber (9)	28,990,000	*
Rick D. Scruggs (10)	23,200,000	*
All directors and executive officers as a group (11 persons)	211,695,010	1.20%

* Less than 1.0%

(1) Includes options to purchase 470,000 Ordinary Shares exercisable within 60 days of April 6, 2025. The exercise price of these options ranges between $4,870 and $7,000 per share and the options expire between 2029 and 2031.

(2) Includes options to purchase 270,000 Ordinary Shares exercisable within 60 days of April 6, 2025. The exercise price of these options ranges between $4,870 and $7,080 per share and the options expire between 2030 and 2031.

(3) Includes options to purchase 420,000 Ordinary Shares exercisable within 60 days of April 6, 2025. The exercise price of these options ranges between $4,870 and $7,080 per share and the options expire between 2029 and 2031.

(4) Includes options to purchase 3,250,000 Ordinary Shares exercisable within 60 days of April 6, 2025. The exercise price of these options ranges between $4,870 and $7,080 per share and the options expire between 2028 and 2031.

(5) Includes options to purchase 2,470,000 Ordinary Shares exercisable within 60 days of April 6, 2025. The exercise price of these options ranges between $4,870 and $7,080 per share, and the options expire between 2025 and 2031.

(6) Includes options to purchase 2,220,000 Ordinary Shares exercisable within 60 days of April 6, 2025. The exercise price of these options ranges between $4,870 and $7,080 per share and the options expire between 2025 and 2031.

(7) Includes options to purchase 2,260,000 Ordinary Shares exercisable within 60 days of April 6, 2025. The exercise price of these options ranges between $4,870 and $7,080 per share and the options expire between 2025 and 2031.

(8) Includes options to purchase 1,920,000 Ordinary Shares exercisable within 60 days of April 6, 2025. The exercise price of these options ranges between $4,870 and $7,080 per share and the options expire between 2025 and 2031.
(9) Includes options to purchase 450,000 Ordinary Shares exercisable within 60 days of April 6, 2025. The exercise price of these options ranges between $5,000 and $7,080 per share and the options expire between 2028 and 2031.
(10) Includes options to purchase 1,910,000 Ordinary Shares exercisable within 60 days of April 6, 2025. The exercise price of these options ranges between $6,620 and $7,000 per share and the options expire between 2029 and 2031.

Award Plans

Amended and Restated Award Plan

Our Award Plan provides for the granting of Ordinary Shares, ADSs, stock options under various tax regimes in Israel and the U.S., RSUs, restricted shares, and other share-based awards to our directors, officers, employees, consultants and service providers and individuals who are their employees, and to the directors, officers, employees, consultants and service providers of our subsidiaries and affiliates. The Award Plan provides for awards to be issued at the determination of our board of directors in accordance with applicable laws. As of April 6, 2025, there were 1,010,200,000 Ordinary Shares issuable upon the exercise or vesting of outstanding awards under the Award Plan and 3,001,613,300 Ordinary Shares available for future issuance under the Award Plan. Our Award Plan provides that the maximum number of Ordinary Shares that may be issued under the Award Plan will automatically be increased on January 1, April 1, July 1 and October 1 of each calendar year such that immediately following such increase the maximum number of Ordinary Shares that may be issued under the Award Plan will be equal to sixteen and a half percent (16.5%) of the number of outstanding Ordinary Shares on a fully-diluted basis on the last day of immediately preceding fiscal quarter.

Administration of Our Amended and Restated Award Plan

Our Award Plan is administered by our compensation committee regarding the granting of awards and the terms of awards grants, including the exercise price, method of payment, vesting schedule, acceleration of vesting and the other matters necessary in the administration of these plans. Options and other awards granted under the Award Plan to eligible Israeli employees, directors and officers are granted under Section 102 of the Israel Income Tax Ordinance pursuant to which the options or the Ordinary Shares issued upon their exercise must be allocated or issued to a trustee and be held in trust for two years from the date upon which such options were granted in order to benefit from the provisions of Section 102. Under Section 102, any tax payable by an employee from the grant or exercise of the options is deferred until the transfer of the options or Ordinary Shares by the trustee to the employee or upon the sale of the options or Ordinary Shares, and gains may qualify to be taxed as capital gains at a rate equal to 25%, subject to compliance with specified conditions. See “Item 10. Additional Information – E. Taxation – Israeli Tax Considerations.”

Options granted under the Award Plan, as amended, generally vest over a period of 4 years and expire ten (10) years after the grant date. The Award Plan, however, permits options to have a term of up to 10 years. In addition, RSUs granted under the Award Plan, as amended, generally vest over a period of two to three years. If we terminate a grantee for cause (as such term is defined in the Award Plan) the right to exercise all the options granted to the grantee, the grantee’s vested and unvested options will expire immediately, on the earlier of:

- termination of the engagement; or
- the date of the notice of the termination of the engagement.

Upon termination of employment for any other reason, other than in the event of death, disability, retirement after the age of 60, a merger or other change in control approved by the board of directors, or for cause, all unvested options will expire and all vested options will generally be exercisable for 90 days following termination, or such other period as determined by the plan administrator, subject to the terms of the Award Plan and the governing option agreement.

Upon termination in the event of a merger or other change in control approved by the board of directors, the grantee will be entitled at the time of termination to full acceleration of all the options granted prior to the event.

Under our Award Plan, as amended, in the event any person, entity or group that was not an interested party at the time of our initial public offering on the TASE becoming a controlling shareholder, all options granted by us under the plan will be accelerated, so that the grantee will be entitled to exercise all of those options. A "controlling shareholder" in this paragraph is a controlling shareholder, as defined in the Israel Securities Law, 1968. An "interested party" is defined in the Securities Law and includes, among others:

- a holder of 5% or more of the outstanding shares or voting rights of an entity;
- a person entitled to appoint one or more of the directors or chief executive officer of an entity;
- a director of an entity or its chief executive officer;
- an entity, in which an individual referred to above holds 25% or more of its outstanding shares or voting rights, or is entitled to appoint 25% or more of its directors; or
- a person who initiated the establishment of the entity.

Upon termination of employment due to death or disability, or retirement after the age of 60, subject to the board of directors' approval, all the vested options at the time of termination will be exercisable for 24 months, or such other period as determined by the plan administrator, subject to the terms of the Award Plan and the governing option agreement.

F. Disclosure of a Registrant's Action to Recover Erroneously Awarded Compensation

Not applicable

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares by each person or entity known to us to beneficially own 5% or more of our outstanding ordinary shares.

The beneficial ownership of our ordinary shares is determined in accordance with the rules of the SEC. Under these rules, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. We deem ordinary shares issuable pursuant to options or warrants that are currently exercisable or exercisable within 60 days of April 6, 2025, and ordinary shares underlying RSUs that vest within 60 days of April 6, 2025, if any, to be outstanding and to be beneficially owned by the person holding the options, warrants or RSUs for the purposes of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. The calculation of beneficial ownership is based on 17,691,201,000 ordinary shares outstanding as of April 6, 2025. None of the holders of the ordinary shares listed in this table have voting rights different from other holders of ordinary shares.

Name	Number of Ordinary Shares Beneficially Held	Percent of Class
R&S United Services Inc. (1)	3,029,016,000	16.48 %

(1) To the best of our knowledge, R&S United Services Inc. is the direct holder of the ordinary shares in the table above, exercises voting and investment power over the ordinary shares, and thus may be deemed to beneficially own the ordinary shares. Avi Polischuk, as the President of R&S United Services, may be deemed to beneficially own the ordinary shares held by the R&S United Services. The number of ordinary shares beneficially owned in the table above includes 686,236,000 ordinary shares (represented by 68,623 ADSs) issuable upon the exercise of a certain warrant issued to R&S United Services on April 3, 2024. The address of R&S United Services is 15 Ranick Drive West, Amityville, NY 11701.

To the best of our knowledge, we are not owned or controlled, directly or indirectly, by another corporation or by any foreign government. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

Record Holders

On April 6, 2025, 407 ADSs (equivalent to 4,078,800 Ordinary Shares, or approximately 0.02% of our total issued and outstanding Ordinary Shares) were held of record by four record holders, of which two holders have a U.S. address. All other ADSs are held by Cede & Co., the nominee of the Depositary Trust Company, which is a United States registered holder. The number of record holders is not at all representative of the number of beneficial holders of the ADSs because many of the ADSs are held by brokers or other nominees. As of April 6, 2025, there was one shareholder of record of our Ordinary Shares.

B. Related Party Transactions

The Company is party to ordinary course employment arrangements with its officers. See “Management - Compensation - Employment Agreements” and See “Management - Compensation - Change in Control Retention Plan and Agreements; Severance Arrangements.”

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Financial Statements and Other Financial Information

The financial statements required by this item are found at the end of this Annual Report, beginning on page F-1.

Legal Proceedings

From time to time, we may become a party to legal proceedings and claims in the ordinary course of business. On February 22, 2021, Aether filed a complaint against RedHill U.S. in the United States District Court for the District of Delaware. We refer to this matter as the Aether Litigation. The complaint asserts that our marketing of the Movantik® product infringes certain U.S. Patents held by Aether (the "Aether Patents"). Aether has asserted the Aether Patents against other entities previously involved in the marketing of Movantik®. The complaint requests customary remedies for patent infringement. In November 2022, the Company and AstraZeneca signed a settlement agreement, according to which AstraZeneca will be solely responsible for any costs incurred in the defense of this litigation, including any settlement amounts, damages awarded, and legal fees.

On September 2, 2022, the Company filed a lawsuit against Kukbo in the Supreme Court of the State of New York, County of New York, Commercial Division, as a result of Kukbo’s default in delivering to us $5.0 million under the Subscription Agreement, dated October 25, 2021, in exchange for ADSs we were to issue to Kukbo, and in delivering to us the $1.5 million due under the Exclusive License Agreement. Kukbo thereafter filed counterclaims with various allegation, such as breach of contract, misrepresentation and the breach of the duty of good faith and fair dealing. On November 20, 2023, we entered into a contingency fee agreement with our legal firm, H&B, under which certain legal costs related to the Kukbo litigation will be assumed by H&B. On December 2, 2024, we were awarded a judgment of approximately $6.5 million in principal and approximately $1.5 million in accrued interest, as of the date of the judgment, which interest continues to accrue at a rate of 9% per annum, in a summary judgment by the Supreme Court of the State of New York, New York County. In accordance with the court’s ruling that we are entitled to recover attorneys’ fees, we filed a motion seeking recovery of approximately $1.8 million in legal fees as of December 31, 2024. The court dismissed the entirety of Kukbo’s counterclaims in the case. Kukbo filed a notice of appeal and retains the right to seek an appeal. We intend to vigorously pursue the recovery of attorneys’ fees and the collection of the judgment.

Dividend Policy

We have never declared or paid cash dividends to our shareholders. Currently, we do not intend to pay cash dividends. We currently intend to reinvest any future earnings, if any, in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our board of directors and will depend on a number of factors, including future earnings, if any, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, applicable Israeli law and other factors our board of directors may deem relevant.

B. Significant Changes

Except as otherwise disclosed in this Annual Report, no significant change has occurred since December 31, 2024.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our Ordinary Shares were traded on the TASE under the symbol "RDHL" from February 2011 to February 2020 and were voluntarily delisted from trading on the TASE, effective February 13, 2020. They are listed but are not traded on Nasdaq in connection with the ADSs. The ADSs were traded on Nasdaq under the symbol "RDHL" from December 27, 2012, were listed on the Nasdaq Global Market under the same symbol from July 20, 2018, to November 14, 2023, and have been re-listed on Nasdaq Capital Market under the same symbol since November 15, 2023.

B. Plan of Distribution

Not applicable.

C. Markets

The ADSs, each representing 10,000 Ordinary Shares and evidenced by an American depositary receipt ("ADRs"), are traded on Nasdaq under the symbol "RDHL." The ADRs are issued pursuant to a Depositary Agreement entered into with The Bank of New York Mellon.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Securities Registrar

The transfer agent and registrar for the ADSs is The Bank of New York Mellon, and its address is 240 Greenwich Street, New York, NY 10286.

Objects and Purposes

According to Section 4 of our articles of association, we shall engage in any legal business. Our number with the Israeli Registrar of Companies is 514304005.

Private Placements

Under the Israeli Companies Law, if (i) as a result of a private placement a person would become a controlling shareholder or (ii) a private placement will entitle investors to receive 20% or more of the voting rights of a company as calculated before the private placement, and all or part of the private placement consideration is not in cash or in public traded securities or is not in market terms and if as a result of the private placement the holdings of a substantial shareholder will increase or as a result of it a person will become a substantial shareholder, then, in either case, the allotment must be approved by the board of directors and by the shareholders of the company. A "substantial shareholder" is defined as a shareholder who holds five percent or more of the company's outstanding share capital, assuming the exercise of all of the securities convertible into shares held by that person. In order for the private placement to be on "market terms" the board of directors has to determine, on the basis of detailed explanation, that the private placement is on market terms, unless proven otherwise.

Board of Directors

Under our articles of association, resolutions by the board of directors are decided by a majority of votes of the directors present, or participating, in the case of voting by media, and voting, each director having one vote.

In addition, the Israeli Companies Law requires that certain transactions, actions, and arrangements be approved as provided for in a company's articles of association and in certain circumstances by the compensation or audit committee and by the board of directors itself. Those transactions that require such approval pursuant to a company's articles of association must be approved by its board of directors. In certain circumstances, compensation or audit committee and shareholder approval are also required. See "Item 6. Directors, Senior Management and Employees – C. Board Practices."

The Israeli Companies Law requires that a member of the board of directors or senior management of the company promptly and, in any event, not later than the first board meeting at which the transaction is discussed, disclose any personal interest that he or she may have, either directly or by way of any corporation in which he or she is, directly or indirectly, a 5% or greater shareholder, director or general manager or in which he or she has the right to appoint at least one director or the general manager, as well as all related material information known to him or her, in connection with any existing or proposed transaction by the company. In addition, if the transaction is an extraordinary transaction, (that is, a transaction other than in the ordinary course of business, otherwise than on market terms, or is likely to have a material impact on the company's profitability, assets or liabilities), the member of the board of directors or senior management must also disclose any personal interest held by his or her spouse, siblings, parents, grandparents, descendants, spouse's descendants, siblings and parents, and the spouses of any of the foregoing.

Once the member of the board of directors or senior management complies with the above disclosure requirement, a company may approve the transaction in accordance with the provisions of its articles of association. Under the provisions of the Israeli Companies Law, whoever has a personal interest in a matter, which is considered at a meeting of the board of directors or the audit committee, may not be present at this meeting or vote on this matter, unless it is not an extraordinary transaction as defined in the Israeli Companies Law. However, if the chairman of the board of directors or the chairman of the audit committee has determined that the presence of a director or an officer with a personal interest is required for the presentation of a matter, such officer holder may be present at the meeting. Notwithstanding the foregoing, if the majority of the directors have a personal interest in a matter, they will be allowed to participate and vote on this matter, but an approval of the transaction by the shareholders in the general meeting will be required.

Our articles of association provide that, subject to the Israeli Companies Law, all actions executed in good faith by the board of directors or by a committee thereof or by any person acting as a director or a member of a committee of the board of directors, will be deemed to be valid even if, after their execution, it is discovered that there was a flaw in the appointment of these persons or that any one of these persons was disqualified from serving in his or her office.

Our articles of association provide that, subject to the provisions of the Israeli Companies Law, the board of directors may appoint board of directors' committees. The committees of the board of directors report to the board of directors their resolutions or recommendations on a regular basis, as prescribed by the board of directors. The board of directors may cancel the resolution of a committee that has been appointed by it; however, such cancellation will not affect the validity of any resolution of a committee, pursuant to which we acted, vis-à-vis another person, who was not aware of the cancellation thereof. Decisions or recommendations of the committee of the board which require the approval of the board of directors will be brought to the directors' attention at a reasonable time prior to the discussion at the board of directors.

According to the Israeli Companies Law, a contract of a company with its directors, regarding their conditions of service, including the grant to them of exemption from liability from certain actions, insurance, and indemnification as well as the company's contract with its directors on conditions of their employment, in other capacities, require the approval of the compensation committee, the board of directors, and the shareholders by a Special Majority.

Description of Securities

Ordinary Shares

At our extraordinary general meeting of the shareholders held on March 21, 2024, our shareholders approved the increase of our authorized share capital to NIS 400,000,000 from NIS 200,000,000, divided into (i) 39,994,000,000 registered Ordinary Shares of NIS 0.01 par value each, and (ii) 6,000,000 preferred shares of NIS 0.01 par value each. Our board of directors has approved an increase in our authorized share capital to NIS 1,600,000,000, divided into (i) 159,994,000,000 registered ordinary shares of NIS 0.01 par value each and (ii) 6,000,000 preferred shares of NIS 0.01 par value each. This proposal is on the agenda for the annual general shareholder meeting scheduled for May 5, 2025.

The Ordinary Shares do not have preemptive rights, preferred rights or any other right to purchase our securities. Neither our articles of association nor the laws of the State of Israel restrict the ownership or voting of Ordinary Shares by non-residents of Israel, except for subjects of countries that are enemies of Israel.

Transfer of Shares. Fully paid Ordinary Shares are issued in registered form and may be freely transferred pursuant to our articles of association unless that transfer is restricted or prohibited by another instrument.

Notices. Under the Israeli Companies Law and our articles of association, we are required to publish notices in two Hebrew-language daily newspapers or our website at least 21 calendar days prior notice of a shareholders' meeting. However, under regulations promulgated under the Israeli Companies Law, we are required to publish a notice in two daily newspapers at least 35 calendar days prior any shareholders' meeting in which the agenda includes matters which may be voted on by voting instruments. Regulations under the Israeli Companies Law exempt companies whose shares are listed for trading both on a stock exchange in and outside of Israel, from some provisions of the Israeli Companies Law. An amendment to these regulations exempts us from the requirements of the Israeli proxy regulation, under certain circumstances.

According to the Israeli Companies Law and the regulations promulgated thereunder, for purposes of determining the shareholders entitled to notice and to vote at such meeting, the board of directors may fix the record date not more than 40 nor less than four calendar days prior to the date of the meeting, provided that an announcement regarding the general meeting be given prior to the record date. Under the regulations promulgated thereunder and as a company listed on an exchange outside Israel, our board of directors may fix the record date not more than 40 nor less than four calendar days prior to the date of the meeting.

Election of Directors. The number of directors on the board of directors shall be no less than five and no more than eleven, including any external directors whose appointment is required by law. The general meeting is entitled, at any time and from time to time, in a resolution approved by a majority of 75% or more of the votes cast by those shareholders present and voting at the meeting in person, by proxy or by a voting instrument, not taking into consideration abstaining votes, to change the minimum or maximum number of directors as stated above as well as to amend the board classification under our Articles. A simple majority shareholder vote is required to elect a director for a term of less than three years. For more information, please see "Item 6. Directors, Senior Management and Employees – C. Board Practices – Appointment of Directors and Terms of Office."

Dividend and Liquidation Rights. Our profits, in respect of which a resolution was passed to distribute them as a dividend or bonus shares, are to be paid pro rata to the amount paid or credited as paid on account of the nominal value of shares held by the shareholders. In the event of our liquidation, the liquidator may, with the general meeting's approval, distribute parts of our property in specie among the shareholders and he may, with similar approval, deposit any part of our property with trustees in favor of the shareholders as the liquidator, with the approval mentioned above deems fit. The terms of our term loan facility prohibit us from paying dividends.

Voting, Shareholders' Meetings and Resolutions. Holders of Ordinary Shares are entitled to one vote for each Ordinary Share held on all matters submitted to a vote of shareholders. The quorum required for an ordinary meeting of shareholders consists of at least two shareholders present, in person or by proxy, or who has sent us a voting instrument indicating the way in which he is voting, who hold or represent, in the aggregate, at least 25% of the voting rights of our outstanding share capital. A meeting adjourned for lack of a quorum is adjourned to the following day at the same time and place or any time and place as prescribed by the board of directors in the notice to the shareholders. At the reconvened meeting one shareholder at least, present in person or by proxy constitutes a quorum except where such meeting was called at the demand of shareholders. With the agreement of a meeting at which a quorum is present, the chairman may, and on the demand of the meeting he must, adjourn the meeting from time to time and from place to place, as the meeting resolves. Annual general meetings of shareholders are held once every year within a period of not more than 15 months after the last preceding annual general shareholders' meeting. The board of directors may call special general meetings of shareholders. Additionally, the Israeli Companies Law provides that the Company's board of directors is required to convene a special general meeting of its shareholders upon the written request of (i) any two or more of its directors, (ii) one-quarter (25%) or more of the serving members of its board of directors or (iii) as a company listed on an exchange in the U.S., one or more shareholders holding, in the aggregate, either (a) 10% or more of our issued and outstanding shares and 1% or more of our outstanding voting power or (b) 10% or more of our outstanding voting power.

In addition, under Israeli law, one or more shareholders holding at least 1% of the voting rights at a general meeting of shareholders may request that the Company's board of directors include a matter in the agenda of a general meeting of shareholders to be convened in the future, provided that it is appropriate to discuss such a matter at the general meeting. Notwithstanding the foregoing, as a company listed on an exchange outside of Israel, a matter relating to the appointment or removal of a director may only be requested by one or more shareholders holding at least 5% of the voting rights at the general meeting of the shareholders.

An ordinary resolution requires approval by the holders of a majority of the voting rights present, in person or by proxy, at the meeting and voting on the resolution.

Allotment of Shares. Our board of directors has the power to allot or to issue shares to any person, with restrictions and conditions as it deems fit.

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Israeli Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company.

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the same class for the purchase of all of the issued and outstanding shares of the same class.

If the shareholders who do not respond to or accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class of the shares, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will be accepted if the shareholders who do not accept it hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of the shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition the Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may determine in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class, the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

The description above regarding a full tender offer will also apply, with necessary changes, when a full tender offer is accepted, and the offeror has also offered to acquire all of the company's securities.

Special Tender Offer

The Israeli Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of at least 25% of the voting rights in the company. This rule does not apply if there is already another holder of at least 25% of the voting rights in the company.

Similarly, the Israeli Companies Law provides that an acquisition of shares of a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company.

These requirements do not apply if the acquisition (i) occurs in the context of a private offering, on the condition that the shareholders meeting approved the acquisition as a private offering whose purpose is to give the acquirer at least 25% of the voting rights in the company if there is no person who holds at least 25% of the voting rights in the company, or as a private offering whose purpose is to give the acquirer 45% of the voting rights in the company, if there is no person who holds 45% of the voting rights in the company; (ii) was from a shareholder holding at least 25% of the voting rights in the company and resulted in the acquirer becoming a holder of at least 25% of the voting rights in the company; or (iii) was from a holder of more than 45% of the voting rights in the company and resulted in the acquirer becoming a holder of more than 45% of the voting rights in the company.

The special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the special tender offer is accepted by a majority of the votes of those offerees who gave notice of their position in respect of the offer; in counting the votes of offerees, the votes of a holder in control of the offeror, a person who has personal interest in acceptance of the special tender offer, a holder of at least 25% of the voting rights in the company, or any person acting on their or on the offeror's behalf, including their relatives or companies under their control, are not taken into account.

In the event that a special tender offer is made, a company's board of directors is required to express its opinion on the advisability of the offer or must abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention.

An officer in a target company who, in his or her capacity as an officer, performs an action the purpose of which is to cause the failure of an existing or foreseeable special tender offer or is to impair the chances of its acceptance, is liable to the potential purchaser and shareholders for damages resulting from his acts, unless such officer acted in good faith and had reasonable grounds to believe he or she was acting for the benefit of the company. However, officers of the target company may negotiate with the potential purchaser in order to improve the terms of the special tender offer and may further negotiate with third parties in order to obtain a competing offer.

If a special tender offer was accepted by a majority of the shareholders who announced their stand on such offer, then shareholders who did not respond to the special offer or had objected to the special tender offer may accept the offer within four days of the last day set for the acceptance of the offer. In the event that a special tender offer is accepted, then the purchaser or any person or entity controlling it and any corporation controlled by them must refrain from making a subsequent tender offer for the purchase of shares of the target company and may not execute a merger with the target company for a period of one year from the date of the offer unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Merger

The Israeli Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Israeli Companies Law are met, a majority of each party's shareholders, by a majority of each party's shares that are voted on the proposed merger at a shareholders' meeting.

The board of directors of a merging company is required pursuant to the Israeli Companies Law to discuss and determine whether in its opinion there exists a reasonable concern that, as a result of a proposed merger, the surviving company will not be able to satisfy its obligations toward its creditors, taking into account the financial condition of the merging companies. If the board of directors has determined that such a concern exists, it may not approve a proposed merger. Following the approval of the board of directors of each of the merging companies, the boards of directors must jointly prepare a merger proposal for submission to the Israeli Registrar of Companies.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares voting at the shareholders meeting (excluding abstentions) that are held by parties other than the other party to the merger, any person who holds 25% or more of the means of control (see "Management – Audit Committee – Approval of Transactions with Related Parties" for a definition of means of control) of the other party to the merger or anyone on their behalf including their relatives (see "Management – External Directors – Qualifications of External Directors" for a definition of relatives) or corporations controlled by any of them, vote against the merger.

In addition, if the non-surviving entity of the merger has more than one class of shares, the merger must be approved by each class of shareholders. If the transaction would have been approved but for the separate approval of each class of shares or the exclusion of the votes of certain shareholders as provided above, a court may still rule that the company has approved the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the appraisal of the merging companies' value and the consideration offered to the shareholders.

Under the Israeli Companies Law, each merging company must send a copy of the proposed merger plan to its secured creditors. Unsecured creditors are entitled to receive notice of the merger, as provided by the regulations promulgated under the Israeli Companies Law. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the target company. The court may also give instructions in order to secure the rights of creditors.

In addition, a merger may not be completed unless at least 50 days have passed from the date that a proposal for approval of the merger was filed with the Israeli Registrar of Companies and 30 days from the date that shareholder approval of both merging companies was obtained.

Anti-takeover Measures

The Israeli Companies Law allows us to create and issue shares having rights different from those attached to our Ordinary Shares, including shares providing certain preferred or additional rights to voting, distributions or other matters and shares having preemptive rights. We have 6,000,000 authorized unissued preferred shares. Our authorized preferred shares, and any other class of shares other than Ordinary Shares that we may create and issue in the future, depending on the specific rights that may be attached to them, may delay or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their Ordinary Shares. The authorization of a new class of shares will require an amendment to our articles of association which requires the prior approval of a majority of our shares represented and voting at a general meeting. Shareholders voting at such a meeting will be subject to the restrictions under the Israeli Companies Law described in "– Voting." In addition, provisions of our articles of our association relating to the election of our directors for terms of three years make it more difficult for a third party to effect a change in control or takeover attempt that our management and board of directors oppose. See "Item 6. Directors, Senior Management and Employees – C. Board Practices – Appointment of Directors and Terms of Officers."

History of Share Capital

For information regarding the history of changes to our share capital since January 1, 2022, please see "Item 5. Operating and Financial Review and Prospects - Liquidity and Capital Resources - Financing Activities".

C. Material Contracts

For a description of other material agreements, please see "Item 4. Information on the Company – B. Business Overview."

D. Exchange Controls

Israeli law and regulations do not impose any material foreign exchange restrictions on non-Israeli holders of our Ordinary Shares. Dividends, if any, paid to holders of our Ordinary Shares, and any amounts payable upon our dissolution, liquidation or winding up, as well as the proceeds of any sale in Israel of our Ordinary Shares to an Israeli resident, may be paid in non-Israeli currency or, if paid in Israeli currency, may be converted into U.S. dollars at the rate of exchange prevailing at the time of conversion.

E. Taxation

Israeli Tax Considerations

General

The following is a brief summary of the material tax consequences under Israeli law concerning the purchase, ownership and disposition of American Depositary Shares representing Ordinary Shares (collectively, the "Shares").

This discussion does not purport to constitute a complete analysis of all potential tax consequences applicable to investors upon purchasing, owning or disposing of our Shares. In particular, this discussion does not take into account the specific circumstances of any particular investor (such as tax-exempt entities, financial institutions, certain financial companies, broker-dealers, investors that own, directly or indirectly, 10% or more of our outstanding voting rights, all of whom are subject to special tax regimes not covered under this discussion). To the extent that issues discussed herein are based on legislation that has yet to be subject to judicial or administrative interpretation, there can be no assurance that the views expressed herein will accord with any such interpretation in the future. This discussion is subject to change, including due to amendments under Israeli law or changes to the applicable judicial or administrative interpretations of Israeli law, which change could affect the tax consequences described below, possibly with retroactive effect. The discussion below is not intended, and should not be construed, as legal or professional tax advice and does not cover all possible tax considerations.

Potential investors are urged to consult their own tax advisors as to the Israeli or other tax consequences of the purchase, ownership, and disposition of the Shares, including, in particular, the effect of any foreign, state or local taxes.

General Corporate Tax Structure in Israel

Israeli resident companies are generally subject to corporate tax on their taxable income at the rate of 23% for the 2025 tax year. A corporation will generally be considered as an "Israeli resident company" if it meets one of the following: (i) it was incorporated in Israel; or (ii) the control and management of its business are exercised in Israel.

Taxation of Shareholders

Capital Gains

Capital gain tax is imposed on the disposition of capital assets by an Israeli tax resident and on the disposition of such assets by a non-Israeli resident if those assets are either (i) located in Israel; (ii) are shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel, unless an exemption is available or unless an applicable double tax treaty between Israel and the seller's country of residence provides otherwise. The Israeli Income Tax Ordinance distinguishes between "Real Gain" and the "Inflationary Surplus". "Real Gain" is the excess of the total capital gain over Inflationary Surplus generally computed on the basis of the increase in the Israeli Consumer Price Index between the date of purchase and the date of disposition. Inflationary Surplus is not currently subject to tax.

In 2025, the Real Gain accrued by individuals on the sale of the Shares will be taxed at the rate of 25%. However, if the individual shareholder is a "Substantial Shareholder" (i.e., a person who holds, directly or indirectly, alone or together with another, 10% or more of one of the Israeli resident company's Means Of Control) at the time of sale or at any time during the preceding 12-month period, such gain will be taxed at the rate of 30%. "Means Of Control" generally include the right to vote, receive profits, nominate a director or other general manager or like the same, receive assets upon liquidation, or order someone who holds any of the aforesaid rights how to act, regardless of the source of such right.

Corporate and individual shareholders dealing in securities in Israel are taxed at the tax rates applicable to business income (23% for corporations in 2025), and a marginal tax rate of up to 47% in 2025 for individuals (not including Excess Tax, as discussed below).

Notwithstanding the foregoing, capital gains generated from the sale of our Shares by a non-Israeli resident shareholder may be exempt from Israeli capital gain tax under the Israeli Income Tax Ordinance provided (among other conditions) that the seller does not have a permanent establishment in Israel to which the generated capital gain is attributed. However, non-Israeli resident corporations will not be entitled to the foregoing exemption if Israeli residents: (i) have a 25% or more interest in such non-Israeli corporation or (ii) are the beneficiaries of, or are entitled to, 25% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly. In addition, such exemption would not be available to a person whose gains from selling or otherwise disposing of the securities are deemed to be business income.

In addition, the sale of the Shares may be exempt from Israeli capital gains tax under the provisions of an applicable double tax treaty. For example, the Convention Between the Government of the United States of America and the Government of the State of Israel with Respect to Taxes on Income, or the U.S.-Israel Double Tax Treaty, exempts a U.S. resident (for purposes of the U.S.-Israel Double Tax Treaty) from Israeli capital gain tax in connection with the sale, exchange or other disposition of the Shares, provided (among other conditions) that: (i) the U.S. resident owned, directly or indirectly, less than 10% of the voting power of the company at any time within the 12-month period preceding such sale; (ii) the U.S. resident, being an individual, is present in Israel for a period or periods of less than 183 days during the taxable year; and (iii) the capital gain from the sale was not derived through a permanent establishment of the U.S. resident in Israel; however, under the U.S.-Israel Double Tax Treaty, the taxpayer may be permitted to claim a credit for such taxes against the U.S. federal income tax imposed with respect to such sale, exchange or disposition, subject to the limitations under U.S. law applicable to foreign tax credits. The U.S.-Israel Double Tax Treaty does not relate to U.S. state or local taxes.

In some instances where our shareholders may be liable for Israeli tax on the sale of their Ordinary Shares, the payment of the consideration may be subject to withholding of Israeli tax at source. Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale. Specifically, the Israel Tax Authority ("ITA") may require shareholders who are not liable for Israeli capital gain tax on such sale to sign declarations in forms prescribed by the ITA, provide documents (including, for example, a certificate of residency) or obtain a specific exemption from the ITA to confirm their status as non-Israeli residents (and, in the absence of such declarations or exemptions, the ITA may require the purchaser or any applicable payor of the shares to withhold tax at source).

Payers of consideration for the Ordinary Shares, including the purchaser, the Israeli stockbroker or the financial institution through which the Shares are held, are generally obligated, subject to certain exemptions, to withhold tax upon the sale of Shares at a rate of 25% of the consideration for individuals and corporations.

Upon the sale of traded securities, a detailed return, including a computation of the tax due, must be filed and an advance payment must be paid to the Israeli Tax Authority on January 31 and July 31 of every tax year in respect of sales of traded securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Israeli Income Tax Ordinance and regulations promulgated thereunder, such return need not be filed, and no advance payment must be paid. Capital gains are also reportable on annual income tax returns.

Dividends

Dividends distributed by a company to a shareholder who is an Israeli resident individual will generally be subject to income tax at a rate of 25%. However, a 30% tax rate will apply if the dividend recipient is a Substantial Shareholder, as defined above, at the time of distribution or at any time during the preceding 12-month period. If the recipient of the dividend is an Israeli resident corporation, such dividend will generally be exempt from Israeli income tax provided that the income from which such dividend is distributed, derived or accrued within Israel.

Dividends distributed by an Israeli resident company to a non-Israeli resident (either an individual or a corporation) are generally subject to Israeli withholding tax on the receipt of such dividends at the rate of 25% (30% if the dividend recipient is a Substantial Shareholder at the time of distribution or at any time during the preceding 12-month period). These rates may be reduced under the provisions of an applicable double tax treaty. For example, under the U.S.-Israel Double Tax Treaty, the following tax rates will apply in respect of dividends distributed by an Israeli resident company to a U.S. resident: (i) if the U.S. resident is a corporation that holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding shares of the voting share capital of the Israeli resident paying corporation and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain types of interest or dividends the tax rate is 12.5%; (ii) if both the conditions mentioned in clause (i) above are met and the dividend is paid from an Israeli resident company's income which was entitled to a reduced tax rate under The Law for the Encouragement of Capital Investments, 1959, the tax rate is 15%; and (iii) in all other cases, the tax rate is 25%. The aforementioned rates under the U.S.-Israel Double Tax Treaty will not apply if the dividend income is attributed to a permanent establishment of the U.S. resident in Israel.

To the extent any payment of dividends by the Company is subject to Israeli withholding taxes, the Company (or its withholding agent) shall make the required withholding and remit such taxes to the ITA.

Excess Tax

Individual holders who are subject to tax in Israel (whether any such individual is an Israeli resident or non-Israeli resident) are also subject to an additional tax at a rate of 3% on annual income including, but not limited to, income derived from dividends, interest and capital gains, exceeding a certain threshold (currently NIS 721,560 for years 2024 through 2027, which amount will be updated annually starting January 1, 2028, based on the change in the Israeli consumer price index) (the "Threshold Amount"). An additional 2% tax applies to "capital income" earned as of January 1, 2025 (including capital gains, dividends, and interest) exceeding the Threshold Amount.

Estate and Gift Tax

Israel does not currently impose estate or gift taxes if the Israeli Tax Authority is satisfied that the gift was made in good faith and on condition that the recipient of the gift is not a non-Israeli resident.

Foreign Exchange Regulations

Non-residents of Israel who hold our Shares are able to receive any dividends, and any amounts payable upon the dissolution, liquidation and winding up of our affairs, repayable in non-Israeli currency at the rate of exchange prevailing at the time of conversion. However, Israeli income tax is generally required to have been paid or withheld on these amounts. In addition, the statutory framework for the potential imposition of currency exchange control has not been eliminated and may be restored at any time by administrative action.

Material U.S. Federal Income Tax Considerations

The following is a summary of the material U.S. federal income tax consequences relating to the acquisition, ownership, and disposition of the ADSs by U.S. Holders, as defined below. This summary addresses solely U.S. Holders who acquire ADSs and who hold ADSs as capital assets for tax purposes. This summary is based on current provisions of the Internal Revenue Code of 1986, as amended (the "Code"), current and proposed U.S. Treasury regulations promulgated thereunder, and administrative and judicial decisions as of the date hereof, all of which are subject to change, possibly on a retroactive basis. In addition, this section is based in part upon representations of the depositary and the assumption that each obligation in the Deposit Agreement and any related agreement will be performed in accordance with its terms. This summary does not address all U.S. federal income tax matters that may be relevant to a particular holder or all tax considerations that may be relevant with respect to an investment in the ADSs.

This summary does not address tax considerations applicable to a holder of the ADSs that may be subject to special tax rules including, without limitation, the following:

- dealers or traders in securities, currencies, or notional principal contracts;
- banks, insurance companies, and other financial institutions;
- real estate investment trusts or regulated investment companies;
- persons or corporations subject to an alternative minimum tax;
- tax-exempt organizations;
- traders that have elected mark-to-market accounting;
- corporations that accumulate earnings to avoid U.S. tax;
- pension plans;
- investors that hold the ADSs as part of a "straddle," "hedge," or "conversion transaction" with other investments;
- persons that actually or constructively own 10 percent or more of our Ordinary Shares outstanding by vote or by value;
- persons that are treated as partnerships or other pass-through entities for U.S. federal income purposes; and
- U.S. Holders whose functional currency is not the U.S. dollar.

This summary does not address the effect of any U.S. federal taxation other than U.S. federal income taxation, and does not include any discussion of state, local, or foreign tax consequences to a holder of the ADSs. In addition, this summary does not include any discussion of the U.S. federal income tax consequences to any holder of ADSs that is not a U.S. Holder.

You are urged to consult your own tax advisor regarding the foreign and U.S. federal, state, and local income and other tax consequences of an investment in the ADSs, including the potential effects of any proposed legislation, if enacted.

For purposes of this summary, a "U.S. Holder" means a beneficial owner of an Ordinary Share or ADS that is for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the U.S.;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in the U.S. or under the laws of the U.S., any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (1) if (a) a court within the U.S. is able to exercise primary supervision over the administration of the trust and (b) one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

If an entity or arrangement that is classified as a partnership for U.S. federal tax purposes holds Ordinary Shares or ADSs, the U.S. federal tax treatment of its partners will generally depend upon the status of the partners and the activities of the partnership. Entities or arrangements that are classified as partnerships for U.S. federal tax purposes and persons holding Ordinary Shares or ADSs through such entities should consult their own tax advisors.

In general, and assuming that all obligations under the Deposit Agreement will be satisfied in accordance with the terms of the Deposit Agreement, if you hold ADSs, you will be treated as the holder of the underlying Ordinary Shares represented by those ADSs for U.S. federal income tax purposes. Accordingly, gain or loss generally will not be recognized if you exchange ADSs for the underlying Ordinary Shares represented by those ADSs.

Distributions

If we make any distribution with respect to the Securities, subject to the discussion under "- Passive Foreign Investment Companies" below, the gross amount of any distribution actually or constructively received by a U.S. Holder (through the Depositary) with respect to a Security will generally be taxable to the U.S. Holder as foreign-source dividend income to the extent of our current and accumulated earnings and profits as determined under U.S. federal income tax principles. The amount distributed will include the amount of any Israeli taxes withheld from such distribution, as described above under the caption "Material Tax Considerations-Israeli Tax Considerations." A U.S. Holder will not be eligible for any dividends received deduction in respect of the dividends paid by us, which deduction is otherwise available to a corporate U.S. Holder in respect of dividends received from a domestic corporation. Distributions in excess of earnings and profits will be non-taxable to the U.S. Holder to the extent of the U.S. Holder's adjusted tax basis in its Securities. Distributions in excess of such adjusted tax basis will generally be taxable to a U.S. Holder as capital gain from the sale or exchange of property as described below under "-Sale or Other Disposition of ADSs." If we do not report to a U.S. Holder the portion of a distribution that exceeds earnings and profits, then the distribution will generally be taxable as a dividend. The amount of any distribution of property other than cash will be the fair market value of that property on the date of distribution.

Under the Code, certain qualified dividends received by non-corporate U.S. Holders will be subject to U.S. federal income tax at the preferential long-term capital gains of, currently, a maximum of 20%. This preferential income tax rate is applicable only to dividends paid by a "qualified foreign corporation" that is not a PFIC (as defined below under "- Passive Foreign Investment Companies,") for the year in which the dividend is paid or for the preceding taxable year, and only with respect to the Securities held by a qualified U.S. Holder (i.e., a non-corporate holder) for a minimum holding period (generally 61 days during the 121-day period beginning 60 days before the ex-dividend date) and certain other holding period requirements are met. If such holding period requirements are met, dividends we pay with respect to the Securities generally will be qualified dividend income. However, if we were a PFIC, dividends paid by us to individual U.S. Holders would not be eligible for the reduced income tax rate applicable to qualified dividends. As discussed below under "- Passive Foreign Investment Companies," we do not anticipate being treated as a PFIC for this year; however, there can be no assurance that we will not be treated as a PFIC for our current taxable or future taxable years. You should consult your own tax advisor regarding the availability of this preferential tax rate under your particular circumstances.

The amount of any distribution paid in a currency other than U.S. dollars (a "foreign currency"), including the amount of any withholding tax thereon, will be included in the gross income of a U.S. Holder in an amount equal to the U.S. dollar value of the foreign currency calculated by reference to the exchange rate in effect on the date of the U.S. Holder's (or, in the case of ADSs, the Depositary's) receipt of the dividend, actively or constructively, regardless of whether the foreign currency is converted into U.S. dollars. If the foreign currency is converted into U.S. dollars on the date of receipt, a U.S. Holder generally should not be required to recognize a foreign currency gain or loss in respect of the dividend. If the foreign currency received in the distribution is not converted into U.S. dollars on the date of receipt, a U.S. Holder will have a basis in the foreign currency equal to its U.S. dollar value on the date of receipt. Any gain or loss on a subsequent conversion or other disposition of the foreign currency will be treated as U.S. source ordinary income or loss and will not be eligible for the preferential rate applicable to qualified dividend income.

Subject to certain conditions and limitations, any Israeli taxes withheld on dividends may be creditable against a U.S. Holder's U.S. federal income tax liability, subject to generally applicable limitations. The rules relating to foreign tax credits and the timing thereof are complex. You should consult your own tax advisors regarding the availability of a foreign tax credit in your particular situation.

Sale, Exchange or Other Disposition of ADSs

Subject to the discussion under "- Passive Foreign Investment Companies" below, a U.S. Holder that sells or otherwise disposes of its Securities will recognize gain or loss for U.S. federal income tax purposes in an amount equal to the difference between the amount realized on the sale or other disposition and such U.S. Holder's adjusted basis in the Securities. Such gain or loss generally will be capital gain or loss and will be a long-term capital gain or loss if the U.S. Holder's holding period of the Securities exceeds one year at the time of the sale or other disposition. Long-term capital gains realized by non-corporate U.S. Holders are generally subject to a preferential U.S. federal income tax rate. In general, gain or loss recognized by a U.S. Holder on the sale or other disposition of the Securities will be U.S. source gain or loss for purposes of the foreign tax credit limitation. However, if we are a PFIC, any such gain will be subject to the PFIC rules, as discussed below, rather than being taxed as a capital gain. As discussed below in "-Passive Foreign Investment Companies," we do not anticipate being a PFIC for this year; however, there can be no assurance that we will not be treated as a PFIC for our current taxable year and future taxable years.

If a U.S. Holder receives foreign currency upon a sale or exchange of the Securities, gain or loss will be recognized in the manner described above under "- Distributions." However, if such foreign currency is converted into U.S. dollars on the date received by the U.S. Holder, the U.S. Holder generally should not be required to recognize any foreign currency gain or loss on such conversion.

As discussed above under the heading "Material Tax Considerations-Israeli Tax Considerations-Taxation of Shareholders," a U.S. Holder who holds Securities through an Israeli broker or other Israeli intermediary may be subject to Israeli withholding tax on any capital gains recognized on a sale or other disposition of the Securities. Any Israeli tax paid under circumstances in which an exemption from (or a refund of or a reduction in) such tax was available will not be creditable for U.S. federal income tax purposes. U.S. Holders are advised to consult their Israeli broker or intermediary regarding the procedures for obtaining an exemption or reduction.

Medicare Tax on Unearned Income

Non-corporate U.S. Holders whose income exceeds certain thresholds are required to pay an additional 3.8% tax on their net investment income, which includes dividends paid on the Securities and capital gains from the sale or other disposition of the Securities.

Passive Foreign Investment Companies

The treatment of the Company as a PFIC is based on the value and composition of our assets, and no assurance can be given that we will not be treated as a PFIC for U.S. federal income tax purposes for our current taxable year or future taxable years. We will be considered a PFIC for any taxable year if:

- at least 75% of its gross income for such taxable year is passive income; or
- at least 50% of the value of its assets (based on an average of the fair market values of the assets determined at the end of each quarter during a taxable year) is attributable to assets that produce or are held for the production of passive income.

For purposes of the above calculations, if we own, directly or indirectly, 25% or more of the total value of the outstanding shares of another corporation, we will be treated as if we (a) held a proportionate share of the assets of such other corporation and (b) received a proportionate share of the income of such other corporation directly. Passive income generally includes, among other things, dividends, interest, rents, royalties and certain capital gain, but generally excludes rents and royalties that are derived in the active conduct of a trade or business and which are received from a person other than a related person.

A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). Because the value of our assets for purposes of the asset test will generally be determined by reference to the market price of the Ordinary Shares or ADSs, our PFIC status will depend in large part on the market price of the Ordinary Shares or ADSs, which may fluctuate significantly.

If we are a PFIC for any year during which a U.S. Holder holds Ordinary Shares or ADSs, such Ordinary Shares or ADSs generally will continue to be treated as Ordinary Shares or ADSs in a PFIC with respect to such U.S. Holder for all succeeding years during which such U.S. Holder holds the Ordinary Shares or ADSs, unless we cease to be a PFIC and such U.S. Holder makes a "deemed sale" election with respect to the Ordinary Shares or ADSs such U.S. Holder holds. If such election is made, a U.S. Holder will be deemed to have sold the Ordinary Shares or ADSs it holds at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale would be subject to the U.S. federal income tax treatment described below. After the deemed sale election, the Ordinary Shares or ADSs with respect to which the deemed sale election was made will not be treated as Ordinary Shares or ADSs in a PFIC unless we subsequently become a PFIC.

For each taxable year for which we are treated as a PFIC with respect to a U.S. Holder, such U.S. Holder will be subject to special tax rules with respect to any "excess distribution" it receives and any gain it realizes from a sale or other disposition (including a pledge) of the Ordinary Shares or ADSs, unless it makes a "mark-to-market" election or a "qualified electing fund" election as discussed below. Distributions that a U.S. Holder receives in a taxable year that are greater than 125% of the average annual distributions it received during the shorter of the three preceding taxable years or its holding period for the Ordinary Shares or ADSs will be treated as an excess distribution. Under these special tax rules, if a U.S. Holder receives any excess distribution or realizes any gain from a sale or other disposition of the Ordinary Shares or ADSs:

- the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period for the Ordinary Shares or ADSs;
- the amount of excess distribution or gain allocated to the current taxable year, and any taxable year before the first taxable year in which we were a PFIC, must be included in the U.S. Holder's gross income (as ordinary income) for the current tax year; and

- the amount allocated to each other year will be subject to the highest marginal tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to such amounts allocated to each other year.

The tax liability for amounts allocated to years before the year of disposition or "excess distribution" cannot be offset by any losses for such years. Additionally, any gains realized on the sale of the Ordinary Shares or ADSs cannot be treated as capital gains.

If we are treated as a PFIC with respect to a U.S. Holder for any taxable year, to the extent any of our subsidiaries are also PFICs, such U.S. Holder will be deemed to own its proportionate share of any such subsidiaries that are PFICs, and such U.S. Holder may be subject to the rules described in the preceding two paragraphs with respect to the shares of such subsidiaries that are PFICs it will be deemed to own. As a result, a U.S. Holder may incur liability for any "excess distribution" described above if we receive a distribution from such subsidiaries that are PFICs or if we dispose of, or are deemed to dispose of, any shares in such subsidiaries that are PFICs. You should consult your own tax advisor regarding the application of the PFIC rules to any of our subsidiaries.

Alternatively, a U.S. Holder of "marketable stock" (as defined below) in a PFIC may make a mark-to-market election for such stock to elect out of the general tax treatment for PFICs discussed above. If a U.S. Holder makes a mark-to-market election for the ADSs, such U.S. Holder will include in income for each year we are a PFIC an amount equal to the excess, if any, of the fair market value of the ADSs as of the close of such U.S. Holder's taxable year over such U.S. Holder's adjusted basis in such ADSs. A U.S. Holder is allowed a deduction for the excess, if any, of the adjusted basis of the ADSs over their fair market value as of the close of the taxable year. However, deductions are allowable only to the extent of any net mark-to-market gains on the ADSs included in a U.S. Holder's income for prior taxable years. Amounts included in a U.S. Holder's income under a mark-to-market election, as well as gain on the actual sale or other disposition of the ADSs, are treated as ordinary income. Ordinary loss treatment also applies to the deductible portion of any mark-to-market loss on the ADSs, as well as to any loss realized on the actual sale or disposition of the ADSs to the extent the amount of such loss does not exceed the net mark-to-market gains previously included for the ADSs. A U.S. Holder's basis in the ADSs will be adjusted to reflect any such income or loss amounts. If a U.S. Holder makes a valid mark-to-market election, the tax rules that apply to distributions by corporations that are not PFICs will apply to distributions by us, except the lower applicable tax rate for qualified dividend income will not apply. If we cease to be a PFIC when a U.S. Holder has a mark-to-market election in effect, gain or loss realized by such U.S. Holder on the sale of the ADSs will be a capital gain or loss and taxed in the manner described above under "- Sale, Exchange, or Other Disposition of ADSs."

The mark-to-market election is available only for "marketable stock," which is a stock that is traded in other than de minimis quantities on at least 15 days during each calendar quarter, or regularly traded, on a qualified exchange or another market, as defined in applicable U.S. Treasury regulations. Any trades that have as their principal purpose meeting this requirement will be disregarded. The ADSs are listed on Nasdaq and, accordingly, provided the ADSs are regularly traded, the mark-to-market election will be available to a U.S. Holder of ADSs if we are a PFIC. Once made, the election cannot be revoked without the consent of the IRS unless the ADSs cease to be marketable stock. If we are a PFIC for any year in which the U.S. Holder owns the ADSs but before a mark-to-market election is made, the interest charge rules described above will apply to any mark-to-market gain recognized in the year the election is made. If any of our subsidiaries are or become PFICs, the mark-to-market election will not be available with respect to the shares of such subsidiaries that are treated as owned by a U.S. Holder. Consequently, a U.S. Holder could be subject to the PFIC rules with respect to income of the lower-tier PFICs the value of which already had been taken into account indirectly via mark-to-market adjustments. You should consult your own tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

In certain circumstances, a U.S. Holder of stock in a PFIC can make a "qualified electing fund" election to mitigate some of the adverse tax consequences of holding stock in a PFIC by including in income its share of the corporation's income on a current basis. However, we do not currently intend to prepare or provide the information that would enable a U.S. Holder to make a qualified electing fund election.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual information return on IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualifying Electing Fund) containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file such annual information return could result in the imposition of penalties and the extension of the statute of limitations with respect to U.S. federal income tax. You should consult your own tax advisors regarding the requirements of filing such information returns under these rules, taking into account the uncertainty as to whether we are currently treated as or may become a PFIC.

YOU ARE STRONGLY URGED TO CONSULT YOUR OWN TAX ADVISOR REGARDING THE IMPACT AND APPLICATION OF THE PFIC RULES ON YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs.

Backup Withholding and Information Reporting

Payments of dividends with respect to Ordinary Shares or ADSs and the proceeds from the sale, retirement, or other disposition of Ordinary Shares or ADSs made by a U.S. paying agent or other U.S. intermediary will generally be reported to the IRS and to the U.S. Holder as may be required under applicable U.S. Treasury regulations. We, or an agent, a broker, or any paying agent, as the case may be, may be required to withhold tax (backup withholding), currently at the rate of 24%, if a non-corporate U.S. Holder that is not otherwise exempt fails to provide an accurate taxpayer identification number and comply with other IRS requirements concerning information reporting. Certain U.S. Holders (including, among others, corporations and tax-exempt organizations) are not subject to backup withholding. Backup withholding is not an additional tax. Any amount of backup withholding withheld may be used as a credit against your U.S. federal income tax liability or may be refunded provided that the required information is timely furnished to the IRS. U.S. Holders should consult their own tax advisors as to their qualification for exemption from backup withholding and the procedure for obtaining an exemption.

You should consult your own tax advisors regarding the backup withholding tax and information reporting rules.

Foreign Asset Reporting

Certain U.S. Holders who are individuals are required to report information relating to an interest in the Securities, subject to certain exceptions (including an exception for shares held in accounts maintained by financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. Holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of the Securities.

EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF AN INVESTMENT IN OUR ORDINARY SHARES OR ADSs IN LIGHT OF SUCH INVESTOR'S PARTICULAR CIRCUMSTANCES.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act, applicable to foreign private issuers, and under those requirements, we file reports with the SEC. Those other reports or other information are available to the public through the SEC's website at http://www.sec.gov.

As a foreign private issuer, we are exempt from the rules under the Exchange Act, related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act, to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we are required to comply with the informational requirements of the Exchange Act, and, accordingly, file Reports of Foreign Private Issuer on Form 6-K, Annual Reports on Form 20-F and other information with the SEC.

We maintain a corporate website at *www.redhillbio.com*. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk is the risk of loss related to changes in market prices, including interest rates and foreign exchange rates, of financial instruments that may adversely impact our financial position, results of operations or cash flows. Our overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on our financial performance.

Risk of Interest Rate Fluctuation and Credit Exposure Risk

At present, our exposure to credit risk arises from cash and cash equivalents, deposits with banks, as well as accounts receivable. Some of our liquid instruments are invested in short-term deposits.

We estimate that because the liquid instruments are invested mainly for the short-term and with highly-rated institutions, the credit risk associated with these balances is low. The primary objective of our investment activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing risk and loss.

We are no longer exposed to a material risk of interest rate fluctuation due to the extinguishment of our Credit Agreement with HCRM and the limited cash held in short-term deposits.

Foreign Currency Exchange Risk

Although the U.S. dollar is our functional currency and reporting currency, a portion of our expenses is denominated in NIS and in Euro. Our NIS expenses consist principally of payments to employees or service providers and office-related expenses in Israel. Our Euro expenses primarily involve payments to vendors for our therapeutic candidates and certain manufacturers of APIs for Talicia®. Because only a relatively small portion of our transactions are currently denominated in NIS and Euro and a negligible sum is held in NIS, we do not believe we are subject to a material risk of foreign currency exchange risk.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Each of the American Depositary Shares, or ADSs, represents 10,000 Ordinary Shares. The ADSs trade on the Nasdaq Capital Market under the symbol "RDHL". Each ADS represents ten thousand (10,000) Ordinary Shares.

The form of the deposit agreement for the ADSs and the form of American Depositary Receipt ("ADR") that represents an ADS have been incorporated by reference as exhibits to this Annual Report. Copies of the deposit agreement are available for inspection at the principal office of The Bank of New York Mellon, located at 240 Greenwich Street, New York, New York 10286.

Fees and Expenses

***Persons depositing or withdrawing shares or American Depositary Shareholders must pay*:**	***For*:**
$5.00 (or less) per 100 American Depositary Shares (or portion of 100 American Depositary Shares)	● Issuance of American Depositary Shares, including issuances resulting from a distribution of shares or rights or other property ● Cancellation of American Depositary Shares for the purpose of withdrawal, including if the deposit agreement terminates
$0.05 (or less) per American Depositary Share	● Any cash distribution to American Depositary Shareholders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of American Depositary Shares	● Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to American Depositary Shareholders
$0.05 (or less) per American Depositary Shares per calendar year	● Depositary services
Registration or transfer fees	● Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	● Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement) ● Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian have to pay on any American Depositary Share or share underlying an American Depositary Share, for example, stock transfer taxes, stamp duty or withholding taxes	● As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	● As necessary

The depositary collects its fees for delivery and surrender of American Depositary Shares directly from investors depositing shares or surrendering American Depositary Shares for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of the distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us or share its revenue with us from the fees collected from American Depositary Shareholders or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the American Depositary Share program. In performing its duties under the deposit agreement, the depositary may use brokers, dealers or other service providers that are affiliates of the depositary and that may earn or share fees or commissions.

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

We, together with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2024. Our disclosure controls and procedures are designed to ensure that information required to be disclosed to the SEC is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act, is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, have concluded that our disclosure controls and procedures (as defined in Rules 13a - 15(e) and 15d - 15(e) of the Exchange Act) as of the end of the period covered by this Annual Report were not effective. This assessment reflects a material weakness in internal control over financial reporting that was previously identified in 2022 and disclosed in our Annual Reports on Form 20-F for the years ended December 31, 2022 and 2023. While we have implemented a remediation plan, as of December 31, 2024, we had not yet concluded that the material weakness had been fully remediated.

(b) Management's Annual Report on Internal Control over Financial Reporting

Our management, under the supervision of our Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. The Company's internal control over financial reporting is a process designed 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. Internal control over financial reporting includes policies and procedures that:

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

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, 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.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we assessed the effectiveness of our internal control over financial reporting as of December 31, 2024, based on the framework for Internal Control-Integrated Framework set forth by The Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013).

Based on our assessment, management has concluded that our internal control over financial reporting was not effective as of December 31, 2024.

A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. A material weakness in internal control over financial reporting was previously identified in 2022 and disclosed in our Annual Reports on Form 20-F for the years ended December 31, 2022 and 2023 relating to lack of sufficient controls which impacted the calculation of allowance for deductions from revenues. We lacked enough financial reporting personnel with an appropriate level of knowledge, experience, and training commensurate with our financial reporting requirements. This control deficiency contributed to the fact that not all data and information available to us was taken into consideration. While we have implemented a remediation plan, we have not yet conclusively determined that the material weakness has been fully remediated as of December 31, 2024.

Remediation Efforts

Our management, with the support of external experts, in collaboration with our internal auditor and with the oversight of the Audit Committee of the Board of Directors, has continued the process of remediating the material weakness. We have made further progress in implementing changes to our internal control over financial reporting and are committed to maintaining a strong internal control environment. The actions taken include:

- Enhancing and supplementing the finance team with resources with knowledge and experience in internal control over financial reporting, including individuals responsible for the design and implementation of internal controls.
- Designing and implementing additional formal policies, procedures and documentation to ensure transactions are properly initiated, recorded, processed, reported, and appropriately authorized and approved, including enhancement to our internal review procedures.

While we have made progress in implementing our remediation plan , we have not yet concluded that the material weakness has been fully remediated as of December 31, 2024.

(c) Attestation Report of Registered Public Accounting Firm

Not applicable.

(d) Changes in Internal Control Over Financial Reporting

Other than the remedial measures we are currently in the process of implementing as described above, there were no material changes in our internal control over financial reporting that occurred during the year ended December 31, 2024, that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Mr. Ofer Tsimchi is an audit committee financial expert. Mr. Tsimchi, Dr. Mamluk and Dr. Reed are independent directors for the purposes of the Nasdaq Listing Rules.

ITEM 16B. CODE OF ETHICS

As of the date of this Annual Report, we have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. This code of ethics is posted on our website, https://s28.q4cdn.com/226515471/files/doc_downloads/gov_docs/Standards-of-Business-Conduct-and-Ethics.pdf. We intend to post on our website any amendments or waivers to the code of ethics that apply to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Registered Public Accounting Firm

The following table sets forth, for each of the years indicated, the aggregate fees billed by our independent registered public accounting firm for professional services.

Services Rendered	Year Ended December 31, 2024	2023
	(U.S. dollars in thousands)	
Audit fees (1)	157	177
Audit-related fees (2)	50	32
Tax fees (3)	2	2
Total	209	211

(1) Audit fees consist of services that would normally be provided in connection with statutory and regulatory filings or engagements, including services that generally only the independent accountant can reasonably provide.
(2) Audit-related fees relate to work regarding prospectus supplements and ongoing consultation.
(3) Tax fees relate to tax compliance, planning, and advice.

Audit Committee Pre-Approval Policies and Procedures

Our audit committee's specific responsibilities in carrying out its oversight of the quality and integrity of the accounting, auditing and reporting practices of the Company include the approval of audit and non-audit services to be provided by the external auditor. The audit committee approves in advance the particular services or categories of services to be provided to the Company during the following yearly period and also sets forth a specific budget for such audit services. All non-audit services are pre-approved by the audit committee.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

Nasdaq Stock Listing Rules and Home Country Practices

As a foreign private issuer, we are permitted to follow Israeli corporate governance practices instead of the Nasdaq Listing Rules, provided that we disclose which requirements we are not following and the equivalent Israeli requirement. We rely on this "foreign private issuer exemption" with respect to the following items:

- *Shareholder Approval* - We seek shareholder approval for all corporate actions requiring such approval in accordance with the requirements of the Israeli Companies Law, which are different from the shareholder approval requirements of the Nasdaq Listing Rules. The Nasdaq Listing Rules require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity-based compensation plans and arrangements, issuances that will result in a change in control of a company, certain transactions other than a public offering involving issuances of 20% or more of the shares or voting power in a company, and certain acquisitions of the stock or assets of another company involving issuances of 20% or more of the shares or voting power in a company or if any director, officer or holder of 5% or more of the shares or voting power of the company has a 5% or greater interest in the company or assets to be acquired or consideration to be paid and the transaction could result in an increase in the outstanding common shares or voting power by 5% or more;
- Under the Israeli Companies Law, shareholder approval is required for any transaction, including any grant of equity-based compensation, to a director or a controlling shareholder, but is not generally required to establish or amend an equity-based compensation plan. Similarly, shareholder approval is required for a private placement that is deemed an "extraordinary private placement" or that involves a director or controlling shareholder. An "extraordinary private placement" is a private placement in which a company issues securities representing 20% or more of its voting rights prior to the issuance and the consideration received pursuant to such issuance is not comprised, in whole or in part, solely of cash or securities registered for trade on an exchange or which is not made pursuant to market conditions, and as a result of which the shareholdings of a 5% holder of the shares or voting rights of the company increases or as a result of which a person will become a holder of 5% of the shares or voting rights of the company or a controlling shareholder after the issuance;
- *Quorum* - As permitted under the Israeli Companies Law, pursuant to our articles of association, the quorum required for an ordinary meeting of shareholders consists of at least two shareholders present in person or by proxy who hold or represent at least 25% of the voting rights of our shares (and at an adjourned meeting, with some exceptions, any number of shareholders), instead of 33 1/3% of the issued share capital required under the Nasdaq Listing Rules; and
- *Nominations Committee* - As permitted by the Israeli Companies Law, our board of directors selects director nominees subject to the terms of our articles of association which provide that incumbent directors are re-nominated for additional terms. Directors are not selected, or recommended for board of director selection, by independent directors constituting a majority of the board's independent directors or by a nominations committee comprised solely of independent directors as required by the Nasdaq Listing Rules.

Otherwise, we comply with the rules generally applicable to U.S. domestic companies listed on the Nasdaq Stock Market. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq Listing Rules related to corporate governance. We also comply with Israeli corporate governance requirements under the Israeli Companies Law as applicable to us.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

ITEM 16J. INSIDER TRADING POLICIES

The Company's Board of Directors adopted an Insider Trading Policy in May 2022, of which a copy is included as Exhibit 11.1 to this Annual Report, that governs the trading in the Company's securities by its directors, officers, employees and certain other covered persons, and which is reasonably designed to promote compliance with applicable insider trading laws, rules and regulations and applicable Nasdaq listing standards.

ITEM 16K. CYBERSECURITY

We operate in the biopharmaceutical industry, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees or customers; violation of privacy laws and other litigation and legal risk; and reputational risk. We recognize the critical importance of developing, implementing, and maintaining cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data. We currently have security measures in place to protect all required information and prevent data loss and other security breaches, including a cybersecurity risk assessment program.

Our current cybersecurity risk assessment program consists of an annual review of the technical safeguards that have been implemented to ensure they align with industry best practices and evolving risks. As part of this program, we leverage the advice of third-party consultants and auditors to help us assess and identify risks from cybersecurity threats, including the threat of a cybersecurity incident, and manage our risk assessment program. Among other things, these providers perform regular audits, ongoing monitoring of network traffic and system logs for suspicious activity, periodic employee training on cybersecurity best practices, and implementation of encryption protocols for sensitive data. Our cybersecurity risk assessment program outlines governance, policies and procedures and technology to oversee and identify risks from cybersecurity threats, and we are informed by previous cybersecurity incidents we have observed both within the Company and in our industry. All cyber incidents are reported to a designated RedHill email after a review by our Security Operation Center ("SOC"). Such emails contain a full description as to what has happened and how the incident was mitigated.

Our management, with assistance of our virtual Chief Information Security Officer ("vCISO"), is responsible for the day-to-day assessment and management of risks from cybersecurity threats, including the prevention, mitigation, detection, and remediation of cybersecurity incidents. The individuals currently serving in these roles are Razi Ingber, our CFO, and Eli Migdal, Founder and Head of Cyber Security for Migdal Computing Solutions LTD. Migdal Computing Solutions LTD also provides us with certain cybersecurity services, including vCISO, Security Operation Center, risk assessment, risk quantification, server-level penetration testing, planning, deployment and management of most modern cybersecurity solutions. Pursuant to our cybersecurity risk assessment program, our vCISO is notified about every cybersecurity event, and as the vCISO he approves the actions that were taken and transforms SOC cases to be marked as completed.

Our Board of Directors is responsible for the oversight of risks from cybersecurity threats in conjunction with our Audit Committee. Our Board of Directors and our Audit Committee receive from time to time reports and updates from our management with respect to the management of risks from cybersecurity threats. Such reports cover the Company's information technology security program, including its current status, capabilities, objectives and plans, as well as the evolving cybersecurity threat landscape. Additionally, the Board of Directors and Audit Committee consider risks from cybersecurity threats as part of their oversight of the Company's business strategy, risk management, and financial oversight.

We also have policies and procedures to oversee and identify the risks from cybersecurity threats associated with our use of third-party service providers. We require any third party to comply to with such our policies and procedures, which include, but are not limited to:

1. When vendors connect into our system, they undergo the same "identity protection" process as Redhill users, including mandatory multi-factor authentication and conditional access.

2. We require any active third-party supplier to work with Single Sign On in our system, using our identity provider, all except the financial SAP system in which we separate from information technology by design.

3. We inquire about the supplier disaster recovery ability, and in some cases we will provide our own additional backup of the materials. For example, we backup our email mailboxes to external storage servers.

As of the date of this Annual Report, no cybersecurity incident (or aggregation of incidents) or cybersecurity threat has materially affected our results of operations or financial condition. However, an actual or perceived breach of our security could damage our reputation, interfere with our efforts to pursue regulatory approvals for our product candidates, or subject us to third-party lawsuits, regulatory fines or other actions or liabilities, any of which could adversely affect our business, operating results or financial condition. To the best of our knowledge and ability, we have attempted to preemptively mitigate the financial impact of any cybersecurity incident. For further information on how a cybersecurity threat might affect us, see also Item 3D. Risk Factors – General Risks – "Our business is subject to cybersecurity risks."

ITEM 17. FINANCIAL STATEMENTS

Not applicable.

ITEM 18. FINANCIAL STATEMENTS

The financial statements required by this item are found at the end of this Annual Report, beginning on page F-1.

ITEM 19. EXHIBITS

See Exhibit Index on page 163.

Glossary of Terms

Certain standards and other terms that are used in this Annual Report are defined below:

H. pylori (*Helicobacter pylori****)*** **-** a Gram-negative bacterium found in the stomach. It was identified in 1982 by Dr. Barry Marshall and Dr. Robin Warren and is associated with peptic ulcer disease and the development of gastric cancer.

IND - Investigational New Drug - a status assigned by the FDA to a drug before allowing its use in humans, so that experimental clinical trials may be conducted.

IRB - Institutional Review Board - Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects.

ITT - intention-to-treat – intention-to-treat analysis means all of the patients who were enrolled and randomized into a clinical study are included in the analysis.

Mycobacterium avium subspecies paratuberculosis **(MAP) -** an obligate pathogenic bacterium in the genus Mycobacterium. MAP is the causative agent of Johne's disease, a chronic granulomatous ileitis occurring mainly in ruminants. MAP has been suspected as the cause of Crohn's disease in humans.

NDA - New Drug Application - an application by drug sponsors to the FDA for approval of a new pharmaceutical for sale and marketing in the U.S.

NTM - Nontuberculous Mycobacteria– a class of Mycobacteria also known as environmental mycobacteria, atypical mycobacteria and mycobacteria other than tuberculosis (MOTT).

Ondansetron - a drug in a class of medications called serotonin 5-HT_3 receptor antagonists. Ondansetron works by blocking the action of serotonin, a natural substance that may cause nausea and vomiting.

Orphan Drug Designation - the designation of orphan drug designation to drugs that are in the process of development for the treatment of rare diseases, affecting fewer than 200,000 people in the U.S. This status provides tax reductions and the exclusive rights to the cure for a specific condition for a period of seven years post-approval.

PK - pharmacokinetics - the study of the absorption, distribution, metabolism, and excretion of drugs in the body.

QIDP - Qualified Infectious Disease Product - designation granted under the FDA's Generating Antibiotic Incentives Now Act, which is intended to encourage the development of new antibiotic drugs for the treatment of serious or life-threatening infections that have the potential to pose a serious threat to public health**.**

Sphingosine kinase-2 (SK2) - an enzyme catalyzes the phosphorylation of sphingosine to generate sphingosine 1-phosphate. There are two isotypes of sphingosine enzyme, SK1 and SK2. Both isotypes have a key role in a variety of diseases, including the development of a range of solid tumors and are promising anti-cancer therapeutic targets.

TNFα - Tumor necrosis factor alpha is a cell-signaling protein (cytokine) involved in systemic inflammation.

REDHILL BIOPHARMA LTD

EXHIBIT INDEX

1.1	Articles of Association of the Registrant, as amended (unofficial English translation) (incorporated by reference to Exhibit 1.1 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 8, 2024).
2.1	Form of Deposit Agreement among the Registrant, the Bank of New York Mellon, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued hereunder (incorporated by reference to Exhibit 1 to the Registration Statement on Form F-6 filed by The Bank of New York Mellon with the Securities and Exchange Commission on December 6, 2012).
2.2	Form of American Depositary Receipt (incorporated by reference to Exhibit 1 to the Registration Statement on Form F-6 filed by The Bank of New York Mellon with the Securities and Exchange Commission on December 6, 2012).
2.3*	Description of Share Capital.
2.4	Form of Warrant (incorporated by reference to Exhibit 1.3 of the Form 6-K filed with the Securities and Exchange Commission on December 5, 2022).
2.5	Form of Placement Agent Warrant (incorporated by reference to Exhibit 1.5 of the Form 6-K filed with the Securities and Exchange Commission on April 3, 2023).
2.6	Form of Placement Agent Warrant (incorporated by reference to Exhibit 1.3 of the Form 6-K filed with the Securities and Exchange Commission on July 25, 2023).
2.7	Form of Placement Agent Warrant regarding Warrant Reprice and Reload Letter (incorporated by reference to Exhibit 1.6 of the Form 6-K filed with the Securities and Exchange Commission on July 25, 2023).
2.8	Form of Placement Agent Warrant issued to the Placement Agent in the January 2024 Offering (incorporated by reference to Exhibit 1.3 of the Form 6-K filed with the Securities and Exchange Commission on January 26, 2024).
2.9	Form of Warrant issued to purchasers in the January 2024 Offering (incorporated by reference to Exhibit 1.2 of the Form 6-K filed with the Securities and Exchange Commission on January 26, 2024).
2.10	Form of Warrant issued to purchasers in the April 2024 Offering (incorporated by reference to Exhibit 1.2 of the Form 6-K filed with the Securities and Exchange Commission on April 3, 2024).
4.1+	Asset Purchase Agreement, dated August 11, 2010, by and between the Registrant and Giaconda Limited (RHB-104, 105, 106) (incorporated by reference to Exhibit 4.4 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated December 3, 2012).
4.2	Amendment to Asset Purchase Agreement by and between the Registrant and Giaconda Limited (RHB-104, 105, 106) dated February 27, 2014 (incorporated by reference to Exhibit 4.2 of the Annual Report on Form 20 F filed with the Securities and Exchange Commission on February 26, 2019).
4.3+	Exclusive License Agreement, dated March 30, 2015, by and between the Registrant and Apogee Biotechnology Corp (incorporated by reference to Exhibit 4.7 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).

4.4†	Amendment #1 dated January 23, 2017, to the Exclusive License Agreement dated March 30, 2015, by and between the Registrant and Apogee Biotechnology Corp. (incorporated by reference to Exhibit 4.6 of the Annual Report on Form 20-F/A filed with the Securities and Exchange Commission on May 15, 2019).
4.5+	Amendment #2 dated June 22, 2017, to the Exclusive License Agreement dated March 30, 2015, by and between the Registrant and Apogee Biotechnology Corp. (incorporated by reference to Exhibit 4.5 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 22, 2018).
4.6	Amendment #5 dated January 23, 2019, to the Exclusive License Agreement dated March 30, 2015, by and between the Registrant and Apogee Biotechnology Corp. (incorporated by reference to Exhibit 4.10 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2019).
4.7	Form of Letter of Exemption and Indemnity adopted on June 22, 2022, as amended (unofficial English translation) (incorporated by reference to Exhibit 4.9 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 28, 2023).
4.8	Amended and Restated Award Plan (2010) (incorporated by reference to Exhibit 4.10 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 28, 2023).
4.9	Compensation Policy (incorporated by reference to Exhibit 4.11 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 28, 2023).
4.10*	Global Termination Agreement, dated July 19, 2024, by and among RedHill Biopharma Ltd., Movantik Acquisition Co., Valinor Pharma, LLC, and HCR Redhill SPV, LLC.
4.11†	Clinical Trial Agreement dated January 2, 2024, by and between RedHill Biopharma Ltd. and the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (incorporated by reference to Exhibit 10.26 to the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on February 9, 2024).
4.12	Form of Securities Purchase Agreement dated March 30, 2023, by and among RedHill Biopharma Ltd. and the purchasers signatory thereto (incorporated by reference to Exhibit 1.1 of the Form 6-K filed with the Securities and Exchange Commission on April 3, 2023).
4.13	Form of Securities Purchase Agreement dated July 21, 2023, by and among RedHill Biopharma Ltd. and the purchasers signatory thereto (incorporated by reference to Exhibit 1.1 of the Form 6-K filed with the Securities and Exchange Commission on July 25, 2023).
4.14	Form of Securities Purchase Agreement dated January 25, 2024, by and among RedHill Biopharma Ltd. and the purchasers signatory thereto (incorporated by reference to Exhibit 1.1 of the Form 6-K filed with the Securities and Exchange Commission on January 26, 2024).
4.15	Form of Warrant Reprice and Reload Letter (incorporated by reference to Exhibit 1.4 of the Form 6-K filed with the Securities and Exchange Commission on July 25, 2023).
4.16	Form of Inducement Letter by and between the Company and holders, dated September 28, 2023 (incorporated by reference to Exhibit 1.1 of the Form 6-K filed with the Securities and Exchange Commission on September 29, 2023)
4.17	Form of Securities Purchase Agreement dated March 29, 2024, by and among RedHill Biopharma Ltd. and the purchasers signatory thereto (incorporated by reference to Exhibit 1.1 of the Form 6-K filed with the Securities and Exchange Commission on April 3, 2024).

4.18	At The Market Offering Agreement, dated February 3, 2025, by and between RedHill Biopharma Ltd. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 1.1 of the Form 6-K filed with the Securities and Exchange Commission on February 3, 2025).
8.1	Subsidiary List (incorporated by reference to Exhibit 8.1 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 22, 2018).
11.1*	Insider Trading Policy.
12.1*	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
12.2*	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
13**	Certification by Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1*	Consent of Independent Registered Public Accounting Firm.
97.1	RedHill Biopharma Ltd. Policy for Recovery of Erroneously Awarded Compensation (incorporated by reference to Exhibit 97.1 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 8, 2024).
101	The following financial statements from the Company's 20-F for the fiscal year ended December 31, 2024, formatted in Inline XBRL: (i) Consolidated Statements of Comprehensive Loss, (ii) Consolidated Statements of Financial Position, (iii) Consolidated Statements of Changes in Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to the Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

** Furnished herewith.

\+ Confidential treatment granted with respect to certain portions of this exhibit.

† Certain identified confidential information in this exhibit has been omitted because such identified confidential information is (i) the type the Company treats as private or confidential and (ii) is not material. A copy of the omitted portions will be furnished to the SEC upon its request.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

REDHILL BIOPHARMA LTD

By: /s/ Dror Ben-Asher
Name: Dror Ben-Asher
Title: Chief Executive Officer and Chairman of the Board of Directors

By: /s/ Razi Ingber
Name: Razi Ingber
Title: Chief Financial Officer

Date: April 10, 2025

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REDHILL BIOPHARMA LTD.

2024 CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of RedHill Biopharma Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of RedHill Biopharma Ltd. and its subsidiary (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of comprehensive income (loss), of changes in equity (capital deficiency) and of cash flows for each of the three years in the period ended December 31, 2024, including the related notes (collectively referred to as the "consolidated financial statements").

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024 in conformity with IFRS Accounting Standards as issued by the International Accounting Standards Board.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1(a)(3) to the consolidated financial statements, the Company has an accumulated deficit, and management expects that the Company will incur additional losses. Management believes that there is presently insufficient funding available to fund its activities for a period exceeding one year from the date of issuance of the consolidated financial statements. These conditions and events indicate that a material uncertainty exists that may cast significant doubt (or raise substantial doubt as contemplated by PCAOB standards) about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1(a)(3). The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. This matter is also described in the "Critical Audit Matters" section of our report.

Basis for Opinion

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

Kesselman & Kesselman, Derech Menachem Begin 146 Tel Aviv-Yafo 6492103 Israel,
P.O Box 7187 Tel-Aviv 6107120 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Recognition and measurement of allowance for certain rebates

As described in Note 2(i)(1) to the consolidated financial statements, the Company offers various rebate and patient discount programs, which result in discounted prescriptions to qualified patients, of which the most significant are Managed Care (commercial rebates), Medicare Part D and Medicaid (and similar state programs). Rebates provided to patients under these arrangements are accounted for as variable consideration, and recognized as a reduction in revenue, for which unsettled amounts are accrued. The allowance for these rebates is calculated based on historical and estimated utilization of the rebate programs in accordance with the specific terms in the individual agreement, the estimated product in the channel and the projected duration of the Company to sell the units in the channel. The allowance reported as of December 31, 2024 for revenue deductions amounted to $9.3 million, with a significant portion relating to Managed Care, Medicare Part D, and Medicaid.

The principal considerations for our determination that performing procedures related to recognition and measurement of the allowance for rebates is a critical audit matter are the significant estimations made by management due to the measurement uncertainty involved in developing the allowance, as the reserves are based on assumptions developed using contractual and mandated terms with payors and historical experience. This in turn led to a high degree of auditor judgment and subjectivity in applying procedures relating to these assumptions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, developing an independent expectation of the allowance for Managed Care (commercial rebates), Medicare Part D and Medicaid (and similar state programs), using the terms of the specific rebates programs and the historical trend of actual rebates claims paid; comparing the independent estimate to management’s estimate recorded by the Company; and testing rebates claims processed by the Company, including evaluating those claims for consistency with the contractual and mandated terms of the Company’s arrangements.

Kesselman & Kesselman, Derech Menachem Begin 146 Tel Aviv-Yafo 6492103 Israel,
P.O Box 7187 Tel-Aviv 6107120 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il

The Company's ability to continue as a going concern

As described above and in Note 1(a)(3) to the consolidated financial statements, the Company has an accumulated deficit and its activities have been funded primarily through offerings of the Company's securities and borrowing. There is no assurance that the Company's business will generate sustainable positive cash flows to fund its business. Management expects that the Company will incur additional losses as it continues to focus its resources on advancing the development of its therapeutic candidates, as well as advancing its commercial operations, that will result in negative cash flows from operating activities. Management believes that there is presently insufficient funding available to allow the Company to fund its activities for a period exceeding one year from the date of issuance of the consolidated financial statements. These conditions and events indicate that a material uncertainty exists that may cast significant doubt (or raise substantial doubt as contemplated by PCAOB standards) about the Company's ability to continue as a going concern.

The principal considerations for our determination that performing procedures related to the Company's ability to continue as a going concern is a critical audit matter are the estimation and execution uncertainty regarding the Company's future cash flows and the risk of bias in management's judgments and assumptions in estimating these cash flows to conclude the Company would have sufficient liquidity to fund its operations for at least a year from the date of issuance of the consolidated financial statements. This in turn led to a high degree of auditor subjectivity and judgment to evaluate the audit evidence supporting the liquidity conclusions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with our overall opinion on the consolidated financial statements. Our audit procedures included, among others, testing the reasonableness of the forecasted revenue, operating expenses, and uses and sources of cash used in management's assessment of whether the Company has sufficient liquidity to fund operations for at least a year from the consolidated financial statements issuance date. We assessed the appropriateness of forecast assumption by comparing prior period forecasts to actual results, comparing forecasted revenue to recent historical financial information, inquiring of management regarding the mitigating actions to reduce costs and manage cash flows and assessing whether the mitigating actions were within the Company's control, testing the underlying data generated to prepare the forecast scenarios and determined whether there was adequate support for the assumptions underlying the forecast, and evaluating management's analysis of the impact of the above assumptions on the forecasted cash flows. We assessed the adequacy of the Company's going concern disclosures included in Note 1(a)(3) to the consolidated financial statements.

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member of PricewaterhouseCoopers International Limited

Tel-Aviv, Israel
April 10, 2025
We have served as the Company's auditor since 2010.

REDHILL BIOPHARMA LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Note	Year Ended December 31,		
		2024	2023	2022
		U.S. dollars in thousands		
NET REVENUES	19	8,043	6,530	61,800
COST OF REVENUES	7,10	3,192	3,459	33,337
GROSS PROFIT		4,851	3,071	28,463
RESEARCH AND DEVELOPMENT EXPENSES	20	1,588	3,528	7,279
SELLING AND MARKETING EXPENSES	21	5,950	14,756	35,442
GENERAL AND ADMINISTRATIVE EXPENSES	22	9,567	16,219	28,586
OTHER INCOME (EXPENSES)	15(6)	(2,359)	44,064	—
OPERATING INCOME (LOSS)		(14,613)	12,632	(42,844)
FINANCIAL INCOME		8,401	20,889	13,562
FINANCIAL EXPENSES		2,056	9,605	42,387
FINANCIAL INCOME (EXPENSES), net	23	6,345	11,284	(28,825)
INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS) FOR THE YEAR		(8,268)	23,916	(71,669)
EARNINGS (LOSS) PER ORDINARY SHARE, basic and diluted (U.S. dollars)	25	(0.00)	0.01	(0.12)

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

REDHILL BIOPHARMA LTD.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31, 2024	December 31, 2023
		U.S. dollars in thousands	
CURRENT ASSETS:			
Cash and cash equivalents	5	4,617	5,569
Restricted cash	14	—	790
Trade receivables		2,539	2,591
Prepaid expenses and other receivables	6	1,104	2,801
Inventory	7	3,651	4,389
		11,911	16,140
NON-CURRENT ASSETS:			
Restricted cash	14	148	147
Fixed assets	8	135	193
Right-of-use assets	9	302	989
Intangible assets	10	5,547	5,578
		6,132	6,907
TOTAL ASSETS		18,043	23,047
CURRENT LIABILITIES:			
Account payable		1,168	3,278
Lease liabilities	9	353	718
Allowance for deductions from revenue	13	9,288	10,654
Derivative financial instruments	4,17	1,421	*741
Accrued expenses and other current liabilities	12	9,993	4,592
		22,223	19,983
NON-CURRENT LIABILITIES:			
Lease liabilities	9	3	455
Royalty obligation	15(3)	500	540
		503	995
TOTAL LIABILITIES		22,726	20,978
EQUITY (CAPITAL DEFICIENCY):	17		
Ordinary shares		35,036	21,441
Additional paid-in capital		375,082	388,363
Accumulated deficit		(414,801)	(407,735)
TOTAL EQUITY (CAPITAL DEFICIENCY)		(4,683)	2,069
TOTAL LIABILITIES AND EQUITY (CAPITAL DEFICIENCY)		18,043	23,047

*See note 2(m)(1)

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

REDHILL BIOPHARMA LTD.

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (CAPITAL DEFICIENCY)

	Ordinary shares	Additional paid-in capital	Accumulated deficit	Total equity (capital Deficiency)
	U.S. dollars in thousands			
BALANCE AT JANUARY 1, 2022	1,495	375,246	(367,866)	8,875
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2022:				
Share-based compensation to employees and service providers	—	—	5,675	5,675
Issuance of ordinary shares, net of issuance costs	1,326	7,393	—	8,719
Issuance of ordinary shares for vested RSUs	14	(14)	—	—
Comprehensive loss	—	—	(71,669)	(71,669)
BALANCE AT DECEMBER 31, 2022	2,835	382,625	(433,860)	(48,400)
BALANCE AT JANUARY 1, 2023	2,835	382,625	(433,860)	(48,400)
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2023:				
Share-based compensation to employees and service providers	—	—	2,209	2,209
Issuance of ordinary shares (including resulting from warrants exercise), net of issuance costs	18,556	5,788	—	24,344
Issuance of ordinary shares for vested RSUs	50	(50)	—	—
Comprehensive income	—	—	23,916	23,916
BALANCE AT DECEMBER 31, 2023	21,441	388,363	(407,735)	2,069
BALANCE AT JANUARY 1, 2024	21,441	388,363	(407,735)	2,069
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2024:				
Share-based compensation to employees and service providers	—	—	1,202	1,202
Issuance of ordinary shares, net of expenses	13,135	(12,821)	—	314
Issuance of ordinary shares for vested RSUs	460	(460)	—	—
Comprehensive loss	—	—	(8,268)	(8,268)
BALANCE AT DECEMBER 31, 2024	35,036	375,082	(414,801)	(4,683)

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

REDHILL BIOPHARMA LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2024	2023	2022
	U.S. dollars in thousands		
OPERATING ACTIVITIES:			
Income (loss)	(8,268)	23,916	(71,669)
Adjustments in respect of income and expenses not involving cash flow:			
Share-based compensation to employees and service providers	665	1,647	5,675
Depreciation	588	1,445	2,136
Amortization of intangible assets	31	545	6,018
Gains from the transfer of rights in Movantik® and extinguishment of debt obligations, see below	—	(56,082)	—
Gains from early termination of leases, and impairment of fixed assets, net	(22)	(543)	—
Non-cash expenses related to borrowing and payable in respect of intangible assets purchase	—	—	33,151
Loss from global termination agreement (See note 15(6)(b)) and below	2,359	—	—
Fair value (gains) losses on derivative financial instruments, recognition of day 1 loss and changes in royalty obligation	(8,268)	5,359	(13,422)
Loss from modification of warrants terms as part of a new issuance, see notes 17(d) and 17(f)	—	1,459	—
Issuance costs in respect of warrants	1,497	2,034	958
Exchange differences and revaluation of bank deposits	(4)	19	(40)
	(3,154)	(44,117)	34,476
Changes in assets and liability items:			
Decrease (increase) in trade receivables	52	31,930	(2,845)
Decrease in prepaid expenses and other receivables	1,697	1,586	274
Decrease in inventories	738	2,387	3,801
Decrease in accounts payable	(2,110)	(952)	(7,434)
Decrease in accrued expenses and other liabilities	3,042	(13,354)	(2,947)
Increase (decrease) in allowance for deductions from revenue	(1,366)	(37,216)	17,159
	2,053	(15,619)	8,008
Net cash used in operating activities	**(9,369)**	**(35,820)**	**(29,185)**
INVESTING ACTIVITIES:			
Purchase of fixed assets	(9)	(11)	(198)
Change in investment in current bank deposits	—	15	8,500
Net cash provided by (used in) investing activities	**(9)**	**4**	**8,302**
FINANCING ACTIVITIES:			
Proceeds from issuance of ordinary shares and warrants, net of issuance costs	8,263	13,959	23,806
Repayment of payable in respect of intangible asset purchase	—	(6,555)	(10,878)
Decrease in restricted cash	790	15,210	—
Payment of principal with respect to lease liabilities	(636)	(1,175)	(1,475)
Net cash provided by financing activities	**8,417**	**21,439**	**11,453**
DECREASE IN CASH AND CASH EQUIVALENTS	(961)	(14,377)	(9,430)
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	9	(22)	(76)
BALANCE OF CASH AND CASH EQUIVALENTS AT THE BEGINNING OF PERIOD	5,569	19,968	29,474
BALANCE OF CASH AND CASH EQUIVALENTS AT THE END OF PERIOD	4,617	5,569	19,968
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	131	138	84
SUPPLEMENTARY INFORMATION ON INTEREST PAID IN CASH	55	367	8,182
SUPPLEMENTARY INFORMATION ON NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Acquisition of right-of-use assets by means of lease liabilities	—	270	5,590
Decrease in lease liability (with corresponding decrease in right of use asset in amount of $166 in 2024, and $4,697 in 2023) resulting from early termination of lease.	188	5,413	587
Transfer of rights in Movantik® and extinguishment of debt obligations:			
Decrease in Intangible asset		(59,503)	
Decrease in Inventories		(4,233)	
Decrease in Payable in respect of Intangible asset		4,602	
Decrease in Borrowing		115,216	
Gains from the transfer of the rights in Movantik® and extinguishment of debt obligations		56,082	

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

REDHILL BIOPHARMA LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 - GENERAL:

a. General:

1) RedHill Biopharma Ltd. (the "Company"), incorporated on August 3, 2009, together with its wholly-owned subsidiary, RedHill Biopharma Inc. ("RedHill Inc."), incorporated in Delaware, U.S. on January 19, 2017, is a specialty biopharmaceutical company primarily focused on gastrointestinal ("GI") diseases and infectious diseases.

The Company's ordinary shares were traded on the Tel-Aviv Stock Exchange ("TASE") from February 2011 to February 2020, after which the Company voluntarily delisted from trading on the TASE, effective February 13, 2020. The Company's American Depositary Shares ("ADSs") were traded on the Nasdaq Capital Market from December 27, 2012, were listed on the Nasdaq Global Market ("Nasdaq") from July 20, 2018, and have been again listed on the Nasdaq Capital Market since November 15, 2023.

On March 23, 2023, the Company changed the ADS ratio from 1 ADS representing 10 ordinary shares to 1 ADS representing 400 ordinary shares. On August 20, 2024, the Company changed the ADS to ordinary share ratio from 1 ADS representing 400 ordinary shares to 1 ADS representing 10,000 ordinary shares. All data denominated in ADS were adjusted for these ratio changes.

The Company's registered address is 21 Ha'arba'a St, Tel-Aviv, Israel.

2) Since the Company established its commercial presence in the U.S. in 2017, it has promoted or commercialized various GI-related products that were either developed internally or acquired through in-licensing agreements. As of the date of approval of these financial statements, the Company commercializes in the U.S. Talicia®, for the treatment of Helicobacter pylori infection in adults, the first product approved by the U.S. Food and Drug Administration ("FDA") being developed primarily internally by the Company. Until February 1, 2023, the Company commercialized Movantik® in the U.S, for the treatment of opioid-induced constipation. See also note 15 (6) regarding the transfer of the Company's rights in Movantik® to HCR Collateral Management, LLC ("HCRM") in exchange for all the Company's debt obligations under the Credit Agreement with HCRM, as well as the Global Termination Agreement, which terminated all remaining credit ties related to this transaction. The Company also continues to advance the development part of its late-stage therapeutic candidates.

3) Through December 31, 2024, the Company has an accumulated deficit and negative working capital, and its activities have been funded primarily through public and private offerings of the Company's securities and senior secured borrowing (now fully extinguished, see note 15(6)). There is no assurance that the Company's business will generate sustainable positive cash flows to fund its business.

The Company plans to further fund its future operations through commercialization and out-licensing of its therapeutic candidates, commercialization of in-licensed or acquired products and raising additional capital through equity or debt financing or through other non-dilutive financing. Furthermore, the Company actively pursuing and in discussions with multiple parties regarding strategic business transaction although there is no guarantee the discussions will result in any strategic business transactions. The Company's current cash resources are not sufficient to complete the research and development of any or all of its therapeutic candidates and to fully support its commercial operations until generation of sustainable positive cash flows. Management expects that the Company will incur additional losses as it continues to focus its resources on advancing the development of its therapeutic candidates, as well as advancing its commercial operations, based on a prioritized plan that will result in negative cash flows from operating activities. Management believes that there is presently insufficient funding available to allow the Company to fund its activities for a period exceeding one year from the date of this filing. These conditions and events indicate that a material uncertainty exists that may cast significant doubt (or raise substantial doubt as contemplated by PCAOB standards) about the Company's ability to continue as a going concern.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

4) In October 2023, Israel was attacked by a terrorist organization and entered a state of war. As of the date of these consolidated financial statements, sustained conflict in the region is ongoing. During the year ended December 31, 2024 and 2023, the impact of this war on the Company results and financial condition was immaterial, but such impact may increase.

b. Approval of the financial statements:

The date of the approval of these financial statements by the Board of Directors (the "BoD") is April 10, 2025.

NOTE 2 - SUMMARY OF MATERIAL ACCOUNTING POLICIES:

a. Basis for presentation of the financial statements

The consolidated financial statements of the Company have been prepared in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board. ("IASB").

The material accounting policies described below have been applied consistently in relation to all the periods presented, except for the adoption of IAS 1 amendments effective January 1, 2024, as described in note 2(m)(1).

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in applying the Company's accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are material to the financial statements, are disclosed in note 3. Actual results could differ significantly from those estimates and assumptions.

b. Translation of foreign currency transactions and balances

1) Functional and presentation currency

Items included in the consolidated financial statements are measured using the currency of the primary economic environment in which the Company and its subsidiary operate (the "Functional Currency"). The consolidated financial statements are presented in U.S. dollars ("$"), which is the Company's functional and presentation currency.

2) Transactions and balances

Foreign currency transactions in currencies different from the Functional Currency (hereafter foreign currency, mostly New Israeli Shekel ("NIS") and Euro are translated into the Functional Currency using the exchange rates at the dates of the transactions. Foreign exchange differences resulting from the settlement of such transactions and from the translation of period-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recorded in the Consolidated Statements of Comprehensive Income (Loss) under financial income or financial expenses.

c. Trade receivables

Trade receivables are recognized initially at the amount of consideration that is unconditional. They are subsequently measured at amortized cost, less allowance for expected credit losses. The Company measures the loss allowance for expected credit losses on trade receivables based on lifetime expected credit losses.

d. Inventory

The Company's inventory is stated at the lower of cost or net realizable value. Cost of inventory is determined using the first-in, first-out method.

Net realizable value is the estimated selling price in the ordinary course of business, less the estimated costs of completion and the estimated costs necessary to make the sale.

The Company continually evaluates inventory for potential loss due to excess quantity or obsolete or slow-moving inventory by comparing sales history and sales projections to the inventory on hand. When evidence indicates that the carrying value of a product may not be recoverable, a charge is recorded to reduce the inventory to its current net realizable value.

e. Fixed assets

Fixed assets items are stated at cost less accumulated depreciation.
Depreciation is computed by the straight-line method, to reduce the cost of fixed assets to their residual value over their estimated useful lives as follows:

	%
Computer equipment	33
Office furniture and equipment	8-15

Leasehold improvements are depreciated by the straight-line method over the shorter of the term of the lease or the estimated useful life of the improvements.

f. Intangible assets

1) Licenses

The Company's intangible assets represent in-licenses of development-phase compounds acquired by the Company, where the Company continues or has the option to continue to do the development work ("R&D assets"), as well as commercialization rights for approved products ("Commercialization assets") which were fully derecognized in 2023 as part of the sale of the rights to Movantik® asset (See also note 15(6)).

R&D assets that are available for use are stated at cost and amortized on a straight-line basis over their useful life from the time they are available for use. R&D assets that are not available for use are not amortized and are tested for impairment at least annually.

Amounts due for future payments based on contractual agreements are accrued upon reaching the relevant milestones.

All intangible assets are tested for impairment if any events have occurred or changes in circumstances have taken place which might indicate that their carrying amounts may not be recoverable. See also note 3 for key assumptions used in the determination of the recoverable amounts.

2) Research and development

Research expenses are recognized as an expense as incurred.

Research and development costs for the performance of pre-clinical trials, clinical trials, and manufacturing by subcontractors are recognized as expenses when incurred.

g. Financial liabilities

Non-derivative financial liabilities are initially recognized at their fair value minus transaction costs and are subsequently measured at amortized cost. In case there is a difference between the fair value at initial recognition and the transaction price ("day 1 loss"), the financial liabilities are adjusted to reflect the day 1 loss and changes are recorded to profit or loss while unrecognized day 1 loss is amortized over the contractual life of the instrument. Any amounts not recognized in profit or loss before the date of exercise or maturity will be recognized in profit or loss on that date.

Warrants exercisable to the Company's ordinary shares are classified as an equity instrument only if the warrants are settled by the Company exchanging a fixed amount of cash for a fixed number of its own equity instruments (the 'fixed for fixed' criteria). Otherwise, the warrants are classified as a derivative financial liability measured at fair value through profit or loss.

Transaction costs relating to the issuance of derivative financial liabilities measured at fair value through profit or loss are expensed to profit or loss.

Financial liabilities are included in current liabilities, except for those with maturities greater than 12 months after the Statements of Financial Position date (for which they are classified as noncurrent liabilities).

Financial liabilities are derecognized when, and only when, they are extinguished. The difference between the carrying amount of the financial liability extinguished and the consideration paid, including any non-cash assets transferred, is recognized in profit or loss. As for the accounting for the extinguishment of the financial liability to HCR, as well as the Global Termination Agreement which terminated all remaining credit ties related to this transaction, see note 15(6).

h. Share-based payments.

The Company operates several equity-settled, share-based compensation plans to employees and service providers. As part of the plans, the Company grants employees and service providers, from time to time and at its discretion, options to purchase Company shares. For employees, the total amount recognized as an expense over the vesting period of the options is determined by reference to the fair value of the options at the grant date. For service providers, the Company measures the awards based on the fair value of the asset or service received. The amounts are recorded against the accumulated deficit within equity.

Vesting conditions (other than market conditions) are included in the assumptions about the number of options that are expected to vest.

At the end of each reporting period, the Company revises its estimates of the number of options that are expected to vest based on non-market vesting conditions. The Company recognizes the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to accumulated deficit.

When exercising options, the Company issues new shares. The proceeds, less directly attributable transaction costs, are recognized as share capital (par value) and additional paid-in capital.

i. Revenue from contracts with customers

The Company generated revenue in the years presented in these financial statements mainly from product sales, including in-licensed products.

1) Revenue from the sale of products

The Company sells products mainly to wholesale distributors. Revenue is recognized at a point in time when control over the product is transferred to the customer (upon delivery), at the net selling price, which reflects reserves for variable consideration, including discounts and allowances.

The Company estimates variable consideration and includes it in the transaction price only to the extent it is highly probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The specific considerations the Company uses in estimating these amounts related to variable consideration are as follows:

Trade discounts and distribution fees - The Company offers discounts to its customers, as an incentive for prompt payment. The Company records these discounts as a reduction of revenue in the period the related revenue from the sale of products is recognized. In addition, distribution fees are paid to certain distributors based on contractually determined rates from the gross consideration. As the fee paid to the customer is not for a distinct good or service, it is recognized as a reduction of revenue in the period the related revenue from the sale of products is recognized.

Rebates and patient discount programs - The Company offers various rebate and patient discount programs, which result in discounted prescriptions to qualified patients. The Company estimates the allowance for these rebates and coupons based on historical and estimated utilization of the rebate and discount programs, at the time the revenues are recognized. These estimates are recognized as a reduction of revenue. See also notes 3 and 13.

Product returns - The Company offers customers a right of return of expired products. The Company estimates the amount of product sales that may be returned by its customers and records this estimate as a reduction of revenue at the time of sale, based on historical rates of return, or, if such historical data is not available, the Company estimates product returns based on its own sales information, its visibility into the inventory remaining in the distribution channel and product dating.

2) Practical expedients and exemptions

The Company expenses sales commissions when incurred since the amortization period of the asset that the Company otherwise would have recognized would have been for less than one year. These costs are recorded as selling and marketing expenses.

3) Revenues from licensing

Licenses of intellectual property (“IP”) rights are distinct from other promises in a contract with a customer (such as manufacturing and supply services) if the customer can benefit from the IP either on its own or together with other resources that are readily available to the customer and if the Company’s promise to license the IP is separately identifiable from other promises in the contract.

If the promise to grant the license is distinct, the Company determines whether the nature of the promise in granting the license is to provide the customer with either a right to access the Company’s IP as it exists throughout the license period or a right to use the Company’s IP as it exists at the point in time at which the license is granted. Accordingly, revenue from a license providing a right of use to the Company’s IP is recognized at the point in time when control of the distinct license is transferred to the customer.

Sales -based royalties that are allocated to license of IP are recognized only when (or as) the later of the following occurs: (a) the subsequent sale occurs; and (b) the performance obligation to which some or all the sales-based royalty has been allocated has been satisfied (or partially satisfied).

The Company applies a practical expedient in the standard and does not adjust the transaction price for the effects of significant financing components if, at contract inception, the Company expects the period between customer payment and the transfer of goods or services to be one year or less.

Revenue from achieving additional milestones is recognized only when it is highly probable that a significant reversal of cumulative revenues will not occur, usually upon achievement of the specific milestone, in accordance with the relevant agreement.

j. Earnings (Loss) per share

The computation of basic earnings (loss) per share is based on the Company's earnings (loss) divided by the weighted average number of ordinary shares and pre-funded warrants outstanding during the period.

In calculating the diluted earnings (loss) per share, using the treasury stock method, the Company adds the weighted average of the number of shares to be issued to the average number of shares outstanding including pre-funded warrants used to calculate the basic earnings (loss) per share, assuming all shares that have a potentially dilutive effect have been exercised into shares.

k. Deferred taxes

Since the Company is unable to assess whether it will have taxable income in the foreseeable future, no deferred tax assets were recorded in these financial statements.

l. Leases

The leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Company. Each lease payment is allocated between the liability and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

The right-of-use asset is depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of fixed lease payments and variable lease payments that are based on an index or a rate.

The lease payments are discounted using the lessee's incremental borrowing rate, as the interest rate implicit in the lease is not readily determined.

Right-of-use assets are measured at cost being the amount of the initial measurement of the lease liability.

Payments associated with short-term leases and leases of low-value assets are not recognized as right-of-use assets or lease liabilities but are recognized on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less. Low-value assets include IT-equipment and small items of office furniture.

Contracts may contain both lease and non-lease components. For leases of properties, the Company allocates the consideration in the contract to the lease and non-lease components based on their relative stand-alone prices. However, for leases of vehicles, the Company has elected not to separate lease and non-lease components and instead accounts for these as a single lease component.

m. New international financial reporting standards, amendments to standards and new interpretations:

1) Classification of Liabilities as Current or Non-Current (Amendment to IAS 1)

The narrow-scope amendments to IAS 1, "Presentation of Financial Statements," clarify that liabilities are classified as either current or noncurrent, depending on the rights that exist at the end of the reporting period. Classification is unaffected by the entity's expectations or events after the reporting date. The amendments also clarify what IAS 1 means when it refers to the settlement' of a liability. The amendments may affect the classification of liabilities, particularly for entities that previously considered management's intentions to determine classification and for some liabilities that can be converted into equity. The Company adopted these amendments effective January 1, 2024. The impact on the Company's financial statements of these amendments was the reclassification of the Company's derivative financial instruments from non-current to current as of its effective date, as the Company does not have the right to defer settlement of liability for at least twelve months after the reporting period. The Company has retrospectively applied the amendments in these interim financial statements and, accordingly, has retrospectively adjusted the comparative balance sheet for December 31, 2023, to reclassify its warrant liabilities ($741 as of December 31, 2023) from non-current to current. Adoption of the amendments had no other impact on the Company's financial statements.

2) In its July 2024 Board meeting, the IASB approved an IFRIC agenda decision on 'Disclosure of Revenues and Expenses for Reportable Segments (IFRS 8 Operating Segments)'. IFRS 8 Operating Segments requires an entity to disclose specific information about assets, liabilities and profit or loss by segment. Specifically, IFRS 8 paragraph 23 requires an entity to disclose certain specified items of profit or loss if these are included in the measure of segment profit or loss reviewed by the chief operating decision maker or are otherwise regularly provided to the chief operating decision maker, even if not included in that measure of segment profit or loss. Management of the Company has implemented the agenda decision in these December 2024 annual financial statements (see note 24).

3) IFRS 18, Presentation and Disclosure in the Financial Statements

This standard replaces the international accounting standard IAS 1, "Presentation of Financial Statements." As part of the new disclosure requirements, companies will be required to present new defined subtotals in the statements of income, as follows: (1) operating profit and (2) profit before financing and tax. In addition, income statement items will be classified into three defined categories: operating, investment and financing. The standard also includes a requirement to provide a separate disclosure in the financial statements regarding the use of management-defined performance measures ("non-GAAP measures"), and specific instructions were added for the grouping and splitting of items in the financial statements and in the notes to the financial statements. IFRS 18 is effective for annual reporting periods beginning on or after January 1, 2027, with an option for early adoption.

NOTE 3 - CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS:

The preparation of financial statements requires management to make estimates which, by definition, will seldom equal the actual results and will affect the reported amounts in the Company's consolidated financial statements and the accompanying notes. Some of the policies described in note 2 of the Company's consolidated financial statements involve a high degree of judgment or complexity. The Company believes that the most critical accounting policies and significant areas of judgment and estimation are in:

- Recognition and measurement of allowance for rebates and patient discount programs.
- Impairment reviews of intangible research and development assets.

Recognition and measurement of allowance for rebates and patient discount programs

The Company offers various rebate and patient discount programs, which result in discounted prescriptions to qualified patients. These rebates and discounts, provided to wholesalers and patients, are accounted for as variable consideration, and recognized as a reduction in revenue, for which unsettled amounts are accrued. Rebate allowances are calculated based on historical and estimated utilization at revenue recognition.

The main estimates used in recognizing and measuring these allowances relate to the amount of products sold to customers not yet prescribed to patients (units "in the channel") and the projected duration of selling these units. The Company periodically evaluates its estimates against actual results and, if necessary, updates the estimates accordingly.

Impairment reviews of intangible R&D assets

The Company reviews annually or when events or changes in circumstances indicate the carrying value of the R&D assets may not be recoverable.

When and if necessary, an impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is determined using discounted cash flow calculations where the asset's expected post-tax cash flows are risk-adjusted over their estimated remaining useful economic life. The risk-adjusted cash flows are discounted using the estimated Company's post-tax weighted average cost of capital ("WACC") which is 18.1%.

The main estimates used in calculating the recoverable amount include: outcome of the therapeutic candidates' R&D activities; probability of success in gaining regulatory approval, size of the potential market and the Company's asset's specific share in it; amount and timing of projected future cash flows and the Company's main interest rate risk during the periods.

In the years presented in these financial statements, there were no impairments recorded for intangible R&D assets.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT:

a. Financial risk management:

1) Financial risk factors

The Company's faces various financial risks: market risks (including foreign exchange and interest risks), credit risk and liquidity risk. The Company's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Company's results of operations and financial position.

Risk management is performed by the Chief Financial Officer of the Company who identifies and evaluates financial risks in close cooperation with the Company's Chief Executive Officer.

The Company's finance department is responsible for carrying out financial risk management activities in accordance with policies approved by its BoD. The BoD provides general guidelines for overall financial risk management, as well as policies dealing with specific areas, such as exchange rate risk, interest rate risk, credit risk, use of financial instruments, and investment of excess cash. In order to minimize market risk and credit risk, the Company invests the majority of its cash balances in low-risk investments, such as highly rated bank deposits with terms of up to one-year term with exit points.

(a) Market risks

The Company may face foreign exchange risk due to payments and investments in currencies other than the U.S. dollar, its functional currency. The Company manages the foreign exchange risk by aligning its liquidity currencies with the currencies of expected expenses, based on projected cash flows. A 5% appreciation of the U.S. dollar against the NIS, assuming all other variables remained constant, would have resulted in a negligible change in expenses across all the reported years, indicating immaterial foreign exchange risks.

(b) Credit risk

Credit risk arises mainly from cash and cash equivalents, bank deposits, restricted cash, and trade receivables. The Company estimates that since the liquid instruments are mainly invested with highly rated institutions, the credit and interest risks associated with these balances are low.

Credit risk from trade receivables involves the potential non-payment by customers. The Company manages this risk by setting credit limits, performing controls and monitoring qualitative and quantitative indicators of trade receivable balances such as the period of credit taken and overdue payments. Customer credit risk also arises due to revenue concentration among major customers. The Company primarily sells to three major U.S. wholesalers with virtually no historical losses. Considering this and forward-looking customer analyses, no loss allowance for trade receivables was recorded as of December 31, 2024, and December 31, 2023. See also note 24(b).

(c) Liquidity risk

Prudent liquidity risk management requires maintaining sufficient cash or the availability of funding through an adequate amount of committed credit facilities. Management monitors rolling forecasts of the Company's liquidity reserve (comprising of cash and cash equivalents and deposits). This is generally carried out based on the expected cash flow in accordance with practices and limits set by the management of the Company.

As of December 31, 2024, the Company has generated revenues from commercialization activities. However, as further described in note 1, no sufficient revenue was generated to compensate for operating expenses. leading to liquidity risks and raising significant doubt about its ability to continue as a going concern.

The tables below break down the Company's financial liabilities into relevant maturity groupings based on their contractual and estimated maturities. The amounts disclosed in the tables are the contractual and estimated undiscounted cash flows.

Contractual maturities of financial liabilities As of December 31, 2024	**Less than 1 year**	**2-5 years**	**More than 5 years**	**Total contractual cash flows**	**Carrying amount**
			U.S. Dollars in Thousands		
Account payable	1,168	—	—	1,168	1,168
Lease liabilities	365	3	—	368	356
Accrued expenses and other current liabilities	9,993	—	—	9,993	9,993
Royalty obligation	—	137	1,246	1,383	500
Total	11,526	140	1,246	12,912	12,018

Contractual maturities of financial liabilities As of December 31, 2023	**Less than 1 year**	**2-5 years**	**More than 5 years**	**Total contractual cash flows**	**Carrying amount**
			U.S. Dollars in Thousands		
Accounts payable	3,278			3,278	3,278
Lease liabilities	766	475	—	1,241	1,173
Accrued expenses and other current liabilities	4,592	—	—	4,592	4,592
Royalty obligation	—	282	1,553	1,835	540
Total	8,636	757	1,553	10,946	9,583

REDHILL BIOPHARMA LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2) Capital risk management

The Company's objectives when managing capital are to safeguard the Company's ability to continue as a going concern in order to provide returns for shareholders, maintain optimal capital structure, and to reduce the cost of capital.

3) Fair value estimation

The carrying amount of cash equivalents, restricted cash, bank deposits, receivables, account payables and accrued expenses approximate their fair value due to their short-term characteristics.

The fair value of the Royalty obligation balance is not materially different from its carrying amount.

The following table presents the change in derivative liabilities measured at level 3 for the year ended December 31, 2024, and December 31, 2023:

	Derivative financial instruments Year Ended December 31,	
	2024	2023
	U.S. dollars in thousands	
Balance at beginning of the period	741	2,623
Initial recognition of financial liability	9,860	10,932
Initial recognition of unrecognized day 1 loss	(952)	—
Exercise of financial liability	—	(18,383)
Fair value adjustments and recognition of day 1 loss recognized in profit or loss	(8,228)	5,569
Balance at end of the period	1,421	741

As of December 31, 2024, the unrecognized day 1 loss is $0.8 million.

See also notes 17(b) - 17 (f) and 17(i)-17(j).

REDHILL BIOPHARMA LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Financial Instruments:

	U.S. dollars in thousands						
			Non-cash changes				
	January 1, 2024	Principal and interest payments (includes credits)	Addition during the year	Decreases during the year	Interest expense	Foreign exchange movement	12/31/2024
Payables in respect to the global termination agreement (See note 15(6)(b))	—	—	11,443	(4,750)	—	—	6,693
Lease liabilities	1,173	(691)	—	(188)	55	7	356

			Non-cash changes				
	January 1, 2023	Principal and interest payments	Addition during the year	Decreases during the year	Interest expense	Foreign exchange movement	12/31/2023
Borrowing	115,216	—	—	(115,216)	—	—	—
Payable in respect of intangible assets purchase	11,157	(6,555)	—	(4,602)	—	—	—
Lease liabilities	7,475	(1,529)	270	(5,413)	367	3	1,173

			Non-cash changes				
	January 1, 2022	Principal and interest payments	Addition during the year	Decreases during the year	Interest expense	Foreign exchange movement	12/31/2022
Borrowing	83,620	(7,507)	—	—	39,103	—	115,216
Payable in respect of intangible assets purchase	20,480	(11,123)	—	—	1,800	—	11,157
Lease liabilities	4,192	(2,010)	5,003		430	(140)	7,475

NOTE 5 - CASH AND CASH EQUIVALENTS:

	December 31,	
	2024	2023
	U.S. dollars in thousands	
Cash in bank	1,882	5,569
Short-term bank deposits	2,735	-
	4,617	5,569

The carrying amounts of the cash and cash equivalents approximate their fair values.

NOTE 6 - PREPAID EXPENSES AND OTHER RECEIVABLES:

	December 31,	
	2024	2023
	U.S. dollars in thousands	
Advance to suppliers	77	1,310
Government institutions	334	694
Prepaid expenses and others	693	797
	1,104	2,801

The fair value of other receivables which constitute financial assets approximate their carrying amount.

REDHILL BIOPHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 7 - INVENTORY:

	December 31,	
	2024	2023
	U.S. dollars in thousands	
Raw materials	513	828
Work in progress	308	233
Finished goods	2,830	3,328
	3,651	4,389

During the years ended December 31, 2024, 2023, and 2022, the Company recognized amounts of $3.4 million, $4.4 million, and $9.7 million respectively, in inventory cost as part of cost of revenues.

The amounts recognized include write-downs of inventories to net realizable value amounted to $0.2 million in 2024, $1.3 million in 2023, and $2.4 million in 2022. These were recognized as an expense, included in cost of revenues in the Consolidated Statements of Comprehensive Income (Loss).

NOTE 8 - FIXED ASSETS:

The composition of assets and accumulated depreciation are grouped by major classifications:

	Cost		Accumulated depreciation		Depreciated balance	
	December 31		December 31		December 31	
	2024	2023	2024	2023	2024	2023
	U.S. dollars in thousands					
Office furniture and equipment (including computers)	1,068	1,059	988	956	80	103
Leasehold improvements	379	379	324	289	55	90
	1,447	1,438	1,312	1,245	135	193

NOTE 9 - LEASES:

Amounts recognized in the consolidated statements of financial position:

	December 31,	
	2024	2023
	U.S dollars in thousands	
Right-of-use assets:		
Properties	302	773
Vehicles	—	216
	302	989
Lease liabilities:		
Current	353	718
Non-current	3	455
	356	1,173

For the year ended December 31, 2023, there were additions of $0.3 million. Decrease in lease liability during the year ended December 31, 2024, and 2023, were $0.2 million and $5.4 million respectively (with corresponding decrease in right of use asset in an amount of $0.2 million and $4.7 million respectively) resulting from early terminations of leases in 2024 and 2023.

REDHILL BIOPHARMA LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

In June 2023, the company terminated a U.S. office lease signed in March 2022 resulting in a $0.7 million gain. The termination, part of ongoing cost reduction efforts, followed a decrease in headcount, that reduced the Company's need for the office lease.

Amounts recognized in the consolidated statements of comprehensive loss:

	Year Ended December 31,	
	2024	2023
Depreciation charge of right-of-use assets		
Properties	470	798
Vehicles	51	478
	521	1,276
Interest expense	55	367
Foreign exchange differences	7	3

Expenses relating to short-term leases and leases of low-value assets are immaterial.
The total cash outflow for leases in 2024 and 2023 was $0.7 million and $1.5 million respectively.

NOTE 10 - INTANGIBLE ASSETS:

a. The Company’s intangible assets represent in-licenses of R&D assets. The changes in those assets are as follows:

	Year Ended December 31,	
	2024	2023
	U.S. dollars in thousands	
R&D assets:		
Cost:		
Balance at beginning of year	5,757	5,757
Balance at end of year	5,757	5,757
Accumulated amortization:		
Balance at beginning of year	(179)	(148)
Amortization charges	(31)	(31)
Balance at end of year	(210)	(179)
	5,547	5,578
Commercialization assets:		
Cost:		
Balance at beginning of year	11,788	89,373
Disposal during the year	(11,788)	(77,585)
Balance at end of year	—	11,788
Accumulated impairments and amortization:		
Balance at beginning of year	(11,788)	(29,356)
Amortization and impairment charges	—	(514)
Disposal during the year	11,788	18,082
Balance at end of year	—	(11,788)
	5,547	5,578

The Company estimated the useful life of the assets related to Talicia® at approximately 15 years from marketing approval date November 2019. The amortization expenses are recognized under Cost of Revenues in the Consolidated Statements of Comprehensive Income (Loss).

See also note 15 (6) regarding the transfer of the Company's rights in Movantik® to HCRM in exchange for all the Company's debt obligations under the Credit Agreement with HCRM.

In July 2024, the Company terminated its license agreement with Cosmo Technologies Ltd. ("Cosmo") for Aemcolo® (see note 15(9)), effective October 8, 2024. Following the termination, the Company derecognized the remaining carrying amounts related to the Aemcolo® intangible asset, including its cost and accumulated amortization and impairment. As the asset had been fully written off as of December 31, 2022, the derecognition had no effect on the Consolidated Statements of Financial Position or Consolidated Statements of Comprehensive Income (Loss).

NOTE 11 - LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT:

The Company's pension liability and the Company's liability for payment of severance pay for employees in Israel for whom the liability is within the scope of Section 14 of the Severance Pay Law, is covered by ongoing deposits with defined contribution plans. The amounts deposited are not included in the Statements of Financial Position.

The amounts charged as an expense with respect to defined contribution plans in 2024, 2023, and 2022 were $156,000, $206,000, and $261,000, respectively.

NOTE 12- ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES:

	December 31,	
	2024	2023
	U.S. dollars in thousands	
Accrued expenses	2,698	3,765
Payable in respect to the Global Termination Agreement (see note 15(6)(b))	6,693	-
Employees and related liabilities	510	727
Government institutions	92	100
	9,993	4,592

REDHILL BIOPHARMA LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 13 - ALLOWANCE FOR DEDUCTIONS FROM REVENUES:

The following table shows the movement of the allowance for deductions from revenue:

	Rebates and patient discount programs	Product returns	Total
	U.S. dollars in thousands		
As of January 1, 2024	8,087	2,567	10,654
Increases	9,712	259	9,971
Decreases (utilized)	(10,423)	(2,500)	(12,923)
Adjustments	487	1,099	1,586
As of December 31, 2024	7,863	1,425	9,288

	Rebates and patient discount programs	Product returns	Total
	U.S. dollars in thousands		
As of January 1, 2023	46,636	1,234	47,870
Increases	21,225	859	22,084
Decreases (utilized)	(60,498)	(2,969)	(63,467)
Adjustments	724	3,443	4,167
As of December 31, 2023	8,087	2,567	10,654

	Rebates and patient discount programs	Product returns	Total
	U.S. dollars in thousands		
As of January 1, 2022	29,742	969	30,711
Increases	123,878	2,547	126,425
Decreases (utilized)	(108,531)	(2,192)	(110,723)
Adjustments	1,547	(90)	1,457
As of December 31, 2022	46,636	1,234	47,870

NOTE 14 – BORROWING:

Credit agreement with HCRM

On February 23, 2020 (“Closing Date”), RedHill Inc. entered into a credit agreement and certain security documents (the “Credit Agreement”) with HCRM.

The Credit Agreement contained certain customary affirmative and negative covenants, including a financial covenant requiring RedHill Inc. to maintain a minimum level of cash, as well as a covenant requiring it to maintain minimum net sales. In 2022, the Company did not maintain certain covenants in the Credit Agreement. Subsequently, on February 2, 2023, the Company and RedHill Inc. reached an agreement with HCRM resulting in the extinguishment of all of RedHill Inc. debt obligations (including all principal, interest, revenue interest, prepayment premiums and exit fees) under the Credit Agreement in exchange for the transfer of its rights in Movantik® to Movantik Acquisition Co., an affiliate of HCRM. On July 15, 2024, the Company and RedHill Inc signed a Global Termination Agreement with Movantik Acquisition Co., Valinor Pharma, LLC, and HCR Redhill SPV, LLC, affiliates of HCRM. This agreement terminates the Credit Agreement from February 23, 2020, which was amended on February 2, 2023. See also note 15(6).

As described above, the Credit Agreement contained a financial covenant requiring the Company to maintain a level of cash liquidity, on any business day from the Closing Date to the maturity date, in accounts that are subject to HCRM's control. Therefore, the amounts of minimum cash and cash equivalents are excluded from cash and cash equivalents in the Statements of Cash Flows for the relevant periods. Instead, the movements in this restricted cash are presented as financing activities in the Statements of Cash Flows. See also note 15(6).

NOTE 15 - COMMITMENTS:

Agreements to purchase intellectual property and commercial products:

1) On August 11, 2010, the Company acquired intellectual property for three gastrointestinal therapeutic candidates through an asset purchase agreement with a publicly-traded Australian company. Pursuant to the asset purchase agreement, as amended, the Company paid the Australian company an initial amount of $500,000 and undertook to pay future payments in the range of 7% - 20% from the Company's revenues that may be generated from the sale and sublicense of the therapeutic candidates, less certain deductible amounts, as detailed in the agreement. Such potential payments are due until termination or expiration of the last of the patents transferred to the Company pursuant to the agreement (each on a product-by-product basis).

   Through December 31, 2024, the Company has paid the Australian company in total $1.5 million.

2) On June 30, 2014, the Company entered into an agreement with a German company that granted the Company the exclusive worldwide (excluding China, Hong Kong, Taiwan, and Macao) development and commercialization rights to all indications to a therapeutic candidate. Under the terms of the agreement, the Company paid the German company an upfront payment of $1 million and agreed to pay the German company potential tiered royalties, less certain deductible amounts, as detailed in the agreement, ranging from mid-teens and up to 30%. Such potential royalties are due until the later of (i) the expiration of the last to expire licensed patent that covers the product in the relevant country and (ii) the expiration of regulatory exclusivity in the relevant country. Through December 31, 2024, the Company has paid the German company only the initial amount mentioned above.

3) On March 30, 2015, the Company entered into an agreement with a U.S.-based private company that granted the Company the exclusive worldwide development and commercialization rights for all indications to a therapeutic candidate, and additional intellectual property rights, targeting multiple oncology, inflammatory and GI indications. Under the terms of the agreement, the Company undertook to pay the U.S. company an initial amount of $1.5 million and an additional amount of $2 million to be paid on a specific date. In addition, the Company undertook to pay up to $2 million in potential development milestone payments, and potential tiered royalties on revenues, less certain deductible amounts starting in the low double-digits, as detailed in the agreement. Such potential royalties are due until the later of (i) the expiration of the last to expire licensed patent that covers the product in the relevant country; and (ii) the expiration of regulatory exclusivity in the relevant country. Through December 31, 2024, the Company paid the U.S. company a total of $3 million.

Following an amendment to the agreement from February 2018, during December 2018, the Company elected to convert the remaining $0.5 million into increased future potential royalty payments. The liability is adjusted based on the Company's expectations for future royalty payments. As of December 31, 2024, and December 31, 2023, the Company recognized $0.50 million and $0.54 million, respectively, as a non-current liability for the potential royalty payments.

4) **Movantik® acquisition:**

Effective April 1, 2020 (the ("Effective Date"), RedHill Inc. entered into an exclusive license agreement with AstraZeneca, granting RedHill Inc. exclusive, worldwide (excluding Europe, Canada) commercialization and development rights to Movantik® (naloxegol).

The total acquisition consideration, including upfront payment, discounted present value of the deferred payment amounted to approximately $65 million amortized over 12.5 years from the effective date.

See also note 15 (6) regarding the transfer of the Company's rights in Movantik® to HCRM in exchange for all the Company's debt obligations under the Credit Agreement with HCRM.

5) As part of the Movantik® acquisition, RedHill Inc. assumed an existing co-commercialization agreement with DSI. Effective July 1, 2020, this agreement was replaced with a new agreement, under which RedHill Inc. committed to payments totaling $15.1 million, of which $10.1 million paid during 2022, and the remaining of $5 million was assumed by HCRM under the agreement described in note 15(6)(a).

6) **Movantik Transactions:**

a) On February 2, 2023, the Company and RedHill Inc. reached an agreement with HCRM resulting in the extinguishment of all of RedHill Inc. debt obligations (including all principal, interest, revenue interest, prepayment premiums and exit fees) under the Credit Agreement in exchange for the transfer of its rights in Movantik® to Movantik Acquisition Co., an affiliate of HCRM. HCRM assumed substantially all post-closing liabilities, and RedHill Inc. retained substantially all pre-closing liabilities relating to Movantik®. As part of the parties' arrangement, and to ensure continuous patient care, RedHill Inc. also provided nine months of paid transition services. HCRM retained security interests in certain of the Company's assets until substantially all pre-closing liabilities of Movantik® have been paid or other specific conditions are met. Following the agreement, the $16 million held as restricted cash under the Credit Agreement was deposited into an escrow account to pay pre-closing liabilities of Movantik®. As of December 31, 2023, the amount held in the escrow account was $0.8 million.

Accounting treatment:

Prior to the sale of Movantik®, the Company presented the rights to Movantik® as an intangible asset in its consolidated statement of financial position (classified under the non-current assets).

In addition, due to the condition described in note 14(a), at the sale date, the carrying amount of the borrowing from HCRM reflected all amounts owing or payable under the Credit Agreement as being immediately due (classified under the current liabilities).

The gains from transferring Movantik® rights and extinguishment of debt obligations include: (1) the gain from the sale of Movantik®, reflecting the difference between the carrying value and fair value of the assets transferred, presented as other income in the amount of $35.5 million and (2) the gain from the debt extinguishment, reflecting the difference between the carrying amount (the amortized cost) of the financial liability to HCRM and the fair value of the assets transferred, presented as financial income in the amount of $20.6 million.

To determine the fair value of the rights to Movantik®, the Company based its estimate on the terms outlined in a non-binding term sheet with a third party which ultimately did not materialize, which included a cash payment of $95 million for the rights to Movantik®.

The fair value of nonmonetary assets relating to Movantik® transferred to settle debt obligations was used to measure debt extinguishment gain. The service fees relating to the transition services are presented in the Company's consolidated statement of comprehensive income (loss) as other income.

b) On July 15, 2024, the Company and RedHill Inc signed a Global Termination Agreement with Movantik Acquisition Co., Valinor Pharma, LLC, and HCR Redhill SPV, LLC, affiliates of HCRM (the "Global Termination Agreement"). This agreement terminates the Credit Agreement dated February 23, 2020, as amended on February 2, 2023, which included a lien on Talicia® and Aemcolo® assets and established an escrow account with restricted funds for Movantik® liabilities (for further details, see note 1(a)(2) above and notes 14(a), 15(4), 15(5), and 15(6)(a)).

The Global Termination Agreement terminated all existing credit ties, removing the aforementioned lien and restoring control over the restricted escrow funds and settlement of trade balances resulting from the transition services. In connection with the agreement, the Company received approximately $9.9 million in cash for the settlement of liabilities related to Movantik®, that were allocatable to HCRM and its affiliates under their agreements with the Company. As the cash received was less than the total net amount of these liabilities (approximately $12.2 million), the Company recognized a loss of approximately $2.3 million resulting from the termination agreement, presented under other expenses in the Consolidated Statements of Comprehensive Income (Loss). In addition, the Company gained full control over $0.7 million previously held in the restricted account.

7) In October 2021, the Company entered into a license agreement with Gaelan Medical Trade LLC ("Gaelan") for Talicia® in the United Arab Emirates (UAE). The Company received a $2 million upfront payment in April 2022 and is eligible for additional milestone payments and tiered royalties up to mid-teens on net sales of Talicia® in the UAE. Gaelan is responsible for obtaining and maintaining regulatory approvals, and any and required clinical or other studies. In March 2022, the agreement was amended to allow Gaelan to sublicense or assign its rights and obligations.

A related supply agreement designates the Company (via a third party CMO) as exclusive manufacturer and supplier of Talicia® to Gaelan during the term of the agreement.

The Company accounted for the license and manufacturing and supply services as distinct performance obligations, mainly due to the manufacturing not being specialized or unique and can be manufactured by others (i.e. – the good or service is capable of being distinct), as well as due to that the license agreement and the manufacturing and supply services do not significantly affect each other (i.e. – the promise is distinct within the context of the contract). During 2022, the Company provided Gaelan substantially all the documentation which represents the right to use the licensed IP, as well as the paperwork relating to the IP itself and its regulatory documents. Accordingly, and since the manufacturing services are priced at their standalone selling price, the Company recognized the $2 million upfront consideration as revenues in the Consolidated Statements of Comprehensive Income (Loss) for the year ended 2022. In August 2024, Gaelan made its first commercial sale in the UAE, triggering a $0.5 million milestone payment due in August 2025. The Company recognized this milestone as revenue in the Consolidated Statements of Comprehensive Income (Loss) for the year ended 2024, along with royalty revenues from sales made during the year (see also Note 19).

8) In March 2022, the Company entered into an exclusive license agreement with Kukbo Co. Ltd ("Kukbo") for oral opaganib for the treatment of COVID-19 in South Korea,. Under the terms of the license agreement, the Company is entitled to an upfront payment of $1.5 million as well as milestone payments and royalties on net sales. Kukbo is entitled under the agreement to the exclusive rights to opaganib in South Korea for COVID-19.

Following Kukbo's default in paying the Company $5 million under a subscription agreement, dated October 25, 2021, in exchange for ADSs, and of the $1.5 million due under the license agreement as described above, the Company filed a lawsuit in NYC against Kukbo in September 2022. Kukbo subsequently filed claims against RedHill.

In December 2024, the court granted summary judgment in the Company's favor, awarding approximately $6.5 million in principal, plus accrued interest at a rate of 9% per annum- amounting to approximately $1.8 million as of December 31, 2024. The court also ruled that the Company is entitled to recover its attorneys' fees, which based on RedHill's records totaled approximately $1.8 million as of December 31, 2024. Kukbo's counterclaims were dismissed in full. Kukbo filed a notice of appeal and retains the right to seek an appeal. As of December 31, 2024, the Company had not recognized any revenue under the license agreement as the criteria for revenue recognition were not yet met.

The Company is party to a contingency fee agreement with its legal firm, Haynes and Boone, LLP, as amended on December 29, 2024. Under the agreement, the firm is entitled to a double-digit percentage of the gross amount recovered if the case results in a final favorable outcome, not subject to further appeal. If no collection is made within six months of such an outcome, the Company must pay the firm its standard hourly fees incurred since entering into the agreement (approximately $1.1 million as of December 31, 2024). If a recovery is later collected, the Company must pay the balance up to the full contingency-based amount. As the case remains ongoing and has not yet reached a final favorable outcome, the legal fees incurred since entering into the agreement have not been recognized as expenses, as no payment is due unless the Company prevails.

9) In July 2024, the Company terminated its license agreement with Cosmo for Aemcolo®, a treatment for traveler's diarrhea. The agreement, initially dated October 17, 2019, was officially terminated on October 8, 2024. Upon termination, the Company ceased all commercialization of Aemcolo® and all rights under the agreement reverted to Cosmo.

NOTE 16 - INCOME TAX:

a. Taxation of the Company in Israel:

1) Measurement of results for tax purposes

The Company elected to compute its taxable income in accordance with Income Tax Regulations (Rules for Accounting for Foreign Investors Companies and Certain Partnerships and Setting their Taxable Income), 1986. Accordingly, the Company's taxable income or loss is calculated in U.S. dollars.

The results of the Company are measured for tax purposes in accordance with Accounting Principles Generally Accepted in Israel (Israeli GAAP). These financial statements are prepared in accordance with IFRS. The differences between IFRS and Israeli GAAP, both on an annual and a cumulative basis cause differences between taxable results and the results are reflected in these financial statements.

2) Tax rates

The net income of the Company is subject to the Israeli corporate tax rate. Israeli corporate tax rates is 23%.

b. U.S. subsidiary:

The Company's subsidiary is incorporated in the U.S. and is taxed under U.S. tax laws. The applicable corporate tax rate is 21%.

As a general rule, inter-company transactions between the Israel-resident Company and its U.S-resident subsidiary are subject to the reporting provisions of the Income Tax Regulations, section 85-A, 2006 of the Israeli Tax Ordinance of the Israeli Tax Ordinance.

c. Carryforward losses:

As of December 31, 2024, the Company had net operating loss ("NOLs") carried forward of approximately $350 million. Under Israeli tax laws, carryforward tax losses have no expiration date.

As of December 31, 2024, the U.S. subsidiary had a net operating loss carryforward of approximately $45 million, with no expiriation date, but is limited to offset 80% of the net income in the year it is utilized.

Under U.S. tax laws, for NOLs arising after December 31, 2017, the 2017 Act limits a taxpayer's ability to utilize NOL carryforwards to 80% of taxable income. In addition, NOLs arising after 2017 can be carried forward indefinitely, but carryback is generally prohibited. Furthermore, in accordance with Coronavirus Aid, Relief, and Economic Security Act (CARES Act) of 2020, losses from tax years beginning in 2018, 2019 or 2020 can be carried back 5 years.

Deferred tax assets on losses for tax purposes carried forward to subsequent years are recognized if utilization of the related tax benefit against a future taxable income is expected. The Company has not created deferred taxes on its carryforward losses since their utilization is not expected in the foreseeable future.

d. Deductible temporary differences:

The amount of cumulative deductible temporary differences, other than carryforward losses (as mentioned in c. above), for which deferred tax assets have not been recognized in the Statements of Financial Position as of December 31, 2024, and 2023, were $3 million and $6 million, respectively. These temporary differences have no expiration dates.

e. Tax assessments:

The Company has not been assessed for tax purposes since its incorporation. The Company's tax assessments for 2018 are therefore considered final.

NOTE 17 - SHARE CAPITAL:

a. Composition:

Company share capital is composed of shares of NIS 0.01 par value, as follows:

	Number of shares	
	December 31,	
	2024	2023
Authorized ordinary shares (1)	39,994,000,000	19,994,000,000
Authorized preferred shares (reserved)	6,000,000	6,000,000
Issued and paid ordinary shares	12,899,831,000	7,869,853,000
Issued and paid – in ADSs term (2)	1,290,000	787,000

(1) On March 21, 2024, the extraordinary general meeting of shareholders approved the increase of the authorized share capital of the Company to NIS 400,000,000, consisting of (i) 39,994,000,000 Ordinary Shares, NIS 0.01 par value per share, and (ii) 6,000,000 preferred shares, NIS 0.01 par value per share

(2) On March 23, 2023, the Company changed the ADS ratio from 1 ADS representing 10 ordinary shares to 1 ADS representing 400 ordinary shares. On August 20, 2024, the Company changed the ADS to ordinary share ratio from 1 ADS representing 400 ordinary shares to 1 ADS representing 10,000 ordinary shares. All data denominated in ADS were adjusted for this ratio changes.

b. On January 26, 2024, the Company issued 400,000 ADSs at a purchase price of $20 per ADS and warrants to purchase 400,000 ADSs at an exercise price of $25 per ADS. These warrants may be exercised in cash or on a cashless basis, are immediately exercisable, and expire in five years. The Company also issued to the placement agent warrants to purchase 24,000 ADSs under the same terms. The gross proceeds from the offering were $8 million, before deducting approximately $0.9 million in fees and expenses.

The warrants were classified as a financial liability due to a net settlement provision. These derivatives were recognized and subsequently measured at fair value through profit or loss. Upon initial recognition the fair value of the warrants was adjusted to reflect the unrecognized day 1 loss. This unrecognized day 1 loss is amortized over the warrants' contractual life. Issuance expenses amounted to $0.9 million allocated to the warrants were recorded directly in the Consolidated Statements of Comprehensive Income (Loss). See also note 4.

c. On April 3, 2024, the Company issued 85,779 ADSs at a purchase price of $14.57 per ADS and warrants to purchase 85,779 ADSs at an exercise price of $18.75 per ADS. These warrants may be exercised in cash or on a cashless basis, are immediately exercisable and expire in five years. The gross proceeds from the offering were $1.25 million, before deducting offering expenses approximately $0.1 million in expenses.

The warrants were classified as a financial liability due to a net settlement provision. These derivatives were recognized and subsequently measured at fair value through profit or loss. The consideration, net of issue expenses, was allocated to the various issued instruments. Out of the gross consideration, $0.9 million was allocated to the warrants. The remainder of approximately $0.35 million was allocated to equity. Issuance expenses allocated to the liability instruments were recorded directly in the Consolidated Statements of Comprehensive Income (Loss), while those allocated to equity were recorded against additional paid in capital. See also note 4.

d. During 2024, the Company issued 17,218 ADSs resulting from vested RSUs that had been issued to employees officers, directors and consultants of the Company.

e. On April 3, 2023, the Company completed a registered direct offering to an existing shareholder with gross proceeds to the Company of approximately $6 million, before deducting offering expenses of approximately $0.7 million. The offering consisted of 60,000 ADSs (or ADS equivalents which consist of pre-funded warrants with an exercise price of $0.025 per pre-funded warrant) as well as granted (i) Series A unregistered private warrants to purchase up to 60,000 ADSs, which had an exercise price of $118.75 per ADS (subsequently reduced to $33.75 per ADS as described below), were exercisable immediately after the issuance date and had a term of 5 years and (ii) Series B unregistered private warrants to purchase up to 60,000 ADSs, which had an exercise price of $100.00 per ADS (subsequently reduced to $45 per ADS as described below), were exercisable immediately after the issuance date and had a term of 9 months. In addition, as part of the offering the Company has agreed to amend certain existing warrants to purchase up to 13,204 ADSs with an exercise price of $1,480 per ADS and a termination date of November 11, 2027. The amended warrants have a reduced exercise price of $118.75 per ADS and a termination date of 5 years following the closing of the offering.

The warrants that were issued to the investors may be exercised either for cash or on a cashless basis and were classified as financial liability due to a net settlement provision. Loss from modification of warrants terms as part of the new registered offering with an existing shareholder, in an amount of $0.9 million, was included as a financial expense. See also note 17(c) regarding amendment to the above warrants.

The Company has issued to the placement agent warrants to purchase up to 3,600 ADSs with an exercise price of $125 per ADS, exercisable for 5 years. These warrants were classified to the Equity.

f. On July 25, 2023, the Company completed a registered direct offering to existing shareholders of 52,077 ADSs (or ADS equivalent which consist of pre-funded warrants with an exercise price of $0.025 per pre-funded warrant), for gross proceeds of approximately $1.8 million, before deducting offering expenses of approximately $0.4 million. In connection with this offering, the Company also agreed with the investors in this offering on the following:

(i) To reduce the exercise price to $45.00 per ADS to the following existing warrants: (1) warrants originally issued on May 11, 2022 and subsequently amended on April 3, 2023, to purchase up to an aggregate of 13,204 ADSs at an exercise price of $118.75 per ADS, (2) warrants issued on December 6, 2022 to purchase up to an aggregate of 38,873 ADSs at an exercise price of $115.76 per ADS, and (3) Series B Warrants issued on April 3, 2023 to purchase up to an aggregate of 60,000 ADSs at an exercise price of $100.00 per ADS.

(ii) Series A Warrants issued on April 3, 2023, to purchase 60,000 ADSs, will be exercised at a reduced exercise price of $33.75 per ADS, for gross proceeds of $2 million. New unregistered private warrants to purchase up to 60,000 ADSs will be granted to the same investor. The new warrants have an exercise price of $45.00 per ADS, are exercisable 6 months after the issuance date and have a term of 5 years.

The warrants that were issued to the investors may be exercised either for cash or on a cashless basis and were classified as financial liability due to a net settlement provision.

As part of the offering, the Company has issued to the placement agent warrants (i) to purchase up to 3,125 ADSs with an exercise price of $42.19 per ADS, exercisable for 5 years (ii) to purchase up to 3,600 ADSs with an exercise price of $42.19 per ADS, exercisable for 4.7 years. These warrants were classified to the Equity.

g. On September 28, 2023, the Company entered into a warrant reprice and reload letter of certain existing warrants to purchase (i) up to 13,204 ADSs with an exercise price of $45.00 per ADS and a termination date of April 3, 2028, (ii) up to 38,873 ADSs with an exercise price of $45.00 per ADS and a termination date of December 6, 2027, (iii) up to 60,000 ADSs with an exercise price of $45.00 per ADS and a termination date of January 3, 2024, and (iv) up to 60,000 ADSs with an exercise price of $$45.00 per ADS and a termination date of April 3, 2028, pursuant to which such investors agreed to exercise their existing warrants in full at a reduced exercise price of $11.75 per ADS for aggregate gross proceeds of approximately $2.0 million, before deducting offering expenses of approximately $0.2 million. In exchange, the exercising holders received new unregistered warrants to purchase up to an aggregate 344,154 ADSs at an exercise price of $11.75 per ADS and with exercise terms ranging from eighteen months to five years.

As part of the offering, the Company has issued to the placement agent warrants to purchase up to 10,325 ADSs with an exercise price of $14.69 per ADS, exercisable for 5 years. These warrants were classified to the Equity.

h. Between November 27, 2023, and November 29, 2023, the warrants issued in September 2023 as described above were exercised for a total of approximately $4 million gross proceeds to the Company.

i. The fair value of the warrants that were issued to the investors was computed using the Black and Scholes option pricing model. The fair value of the outstanding warrants that were issued to the investors as of December 31, 2024, was based on the price of an ADS on December 31, 2024, and based on the following parameters: risk-free interest rates of 4.27%-4.34% and an average standard deviation of 131.6%-148.37%.

j. During 2023, the Company issued 1,893 ADSs resulting from vested RSUs that had been issued to employees and consultants of the Company.

NOTE 18 - SHARE-BASED PAYMENTS:

On May 30, 2010, a general meeting of shareholders approved the option plan of the Company (the "Option Plan"), after being approved by the BoD. In 2017 the Option Plan was amended and restated as the 2010 Award Plan (the "Award Plan"). As of December 31, 2024, the Award Plan allows the Company to allocate up to 2,717,305,440 options to purchase ordinary shares and RSUs (equivalent to 271,730 ADSs) to employees, consultants, and directors and are reserved by the BoD for issuance under the Award Plan. The terms and conditions of the grants were determined by the BoD and are according to the Award Plan.

b. On June 24, 2024, the BoD granted 41,760 RSUs to employees and consultants. These RSUs will vest in 8 equal quarterly installments over two years and had a fair value of $0.4 million on the grant date, based on the ADS price on that date. In addition, the general meeting of the Company's shareholders held on September 18, 2024, subsequent to approval of the Company's BoD in June 2024, approved grant of 15,320 RSUs for directors and the Company's Chief Executive Officer and Chief Commercial Officer in the same terms. The fair value of these RSUs on the date of approval was $0.1 million.

During 2024, approximately 2,584 options and RSUs were forfeited, resulting in $0.3 million in reversed expenses.

c. On July 1, 2023, The Board of Directors of the Company granted 7,500 RSUs to the employees and consultants of the Company. The RSUs will vest in 12 equal quarterly installments over a three-year period. The fair value for the RSUs grant on the date of the grant was $0.2 million. The fair value of the RSUs was determined based on the price of an ADS on the date the RSUs were granted.

During 2023, approximately 2,720 options and RSUs were forfeited, resulting in $1.6 million in reversed expenses.

REDHILL BIOPHARMA LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

c. Changes in the number of options in ADSs and weighted averages of exercise prices are as follows:

	Year Ended December 31,			
	2024		2023	
	Number of options	Weighted average of exercise price ($)	Number of options	Weighted average of exercise price ($)
Outstanding at beginning of year	3,894	6,324.50	5,259	6,390.00
Exercised	—	—	—	—
Expired and forfeited	(1,275)	6,277.89	(1,365)	6,560.75
Outstanding at end of year	2,619	6,329.96	3,894	6,324.50
Exercisable at end of year	2,525	6,310.15	3,455	6,228.50

d. Changes in the number of RSUs in ADSs during the period are as follows:

	Year Ended December 31,	
	2024	2023
	Number of RSUs	Number of RSUs
Outstanding at beginning of year	7,121	3,646
Exercised	(23,938)	(2,658)
Expired and forfeited	(2,497)	(1,367)
Granted	57,080	7,500
Outstanding at end of year	37,766	7,121

e. The following is information about the exercise price and remaining useful life of outstanding options at year-end:

Year Ended December 31,					
2024			2023		
Number of options outstanding at end of year	Exercise price range	Weighted average of remaining useful life	Number of options outstanding at end of year	Exercise price range	Weighted average of remaining useful life
2,619	$1,670-$10,370	5.04	3,894	$1,670-$10,900	5.2

f. Expenses recognized in profit or loss for the options and RSUs are as follows:

Year Ended December 31,		
2024	2023	2022
U.S. dollars in thousands		
665	1,647	5,675

The remaining compensation expenses as of December 31, 2024, are $0.2 million and will be expensed in full by December 2026.

REDHILL BIOPHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 19 - NET REVENUES:

	Year Ended December 31,		
	2024	2023	2022
	U.S dollars in thousands		
Licensing revenues (1)	547	—	2,000
Sales of products (2)	7,496	6,530	59,800
	8,043	6,530	61,800

(1) Revenues related to the license agreement with Gaelan for Talicia® in the UAE, see note 15(7) above.

(2) In 2024 and 2023, the Company recognized contra-revenues of ($0.9) million and ($2.6) million, respectively, for Movantik®, primarily due to returns following its divestiture on February 1, 2023 (see note 15(6) above). In 2022, net revenues for Movantik® were $52.1 million. Correspondingly, in 2024, 2023 and 2022, net revenues from sales of other products (mainly Talicia®) were $8.4 million, $9.1 million, and $7.7 million, respectively.

NOTE 20 - RESEARCH AND DEVELOPMENT EXPENSES:

	Year Ended December 31,		
	2024	2023	2022
	U.S. dollars in thousands		
Payroll and related expenses	222	390	661
Professional services	708	605	1,210
Share-based payments	156	138	1,151
Clinical and pre-clinical trials	114	1,891	3,872
Intellectual property development	238	222	180
Other	150	282	205
	1,588	3,528	7,279

NOTE 21 - SELLING AND MARKETING EXPENSES:

	Year Ended December 31,		
	2024	2023	2022
	U.S. dollars in thousands		
Payroll and related expenses	3,076	9,656	19,235
Share-based payments	(41)	(51)	553
Professional services	1,913	3,056	6,596
Samples	—	54	836
Travel, Fleet, meals and related expenses	302	736	5,136
Office-related expenses	329	566	1,510
Other	371	739	1,576
	5,950	14,756	35,442

REDHILL BIOPHARMA LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 22 - GENERAL AND ADMINISTRATIVE EXPENSES:

	Year Ended December 31,		
	2024	2023	2022
	U.S. dollars in thousands		
Payroll and related expenses	4,515	7,035	10,521
Share-based payments	550	1,560	3,971
Professional services and supply chain	3,118	5,391	10,787
Medical affairs	131	818	1,214
Office-related expenses	749	958	1,434
Other	504	457	659
	9,567	16,219	28,586

NOTE 23 - FINANCIAL INCOME (EXPENSES), net:

	Year Ended December 31,		
	2024	2023	2022
	U.S dollars in thousands		
Financial income:			
Fair value gains on derivative financial instruments	8,228	—	13,422
Gains on extinguishment of debt obligations by transfer of the rights in Movantik	—	20,585	—
Other Income	40	210	—
Interest from bank deposits	133	94	140
	8,401	20,889	13,562
Financial expenses:			
Interest for lease liabilities	55	367	430
Issuance cost in respect of warrants	1,497	2,034	958
Loss from changes in exchange rates	31	115	40
Fair value loss on derivative financial instruments	—	5,569	—
Loss from modification of warrants terms as part of a new issuance, see notes 17(b) and 17(d)	—	1,459	—
Interest expenses related to borrowing and payable in respect of intangible assets purchase	—	—	40,903
Other	473	61	56
	2,056	9,605	42,387
Financial income (expenses), net	6,345	11,284	(28,825)

NOTE 24 - SEGMENT INFORMATION:

The Chief Executive Officer is the Company's Chief Operating Decision Maker ("CODM"). The CODM allocates resources and assesses the Company's performance based on the following segmentation: Commercial Operations and Research & Development.

Adjusted EBITDA represents net loss before depreciation, amortization, and financial income (expenses), adjusted to exclude share-based compensation, gains from early termination of leases, and other income, which includes income from service provided to HCRM and gain from the sale of Movantik®, and other expense from the Global Termination Agreement.

REDHILL BIOPHARMA LTD.

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The following table presents segment profitability and a reconciliation to the consolidated net income (loss) and comprehensive income (loss) for the periods indicated:

	Year Ended December 31,		
	2024	2023	2022
	U.S. dollars in thousands		
Commercial Operations Segment Adjusted EBITDA	(5,864)	(20,173)	(16,595)
Research And Development Adjusted EBITDA	(5,129)	(8,165)	(12,420)
Financial income (expenses), net	6,346	11,284	(28,825)
Share-based compensation to employees and service providers	(665)	(1,647)	(5,675)
Depreciation	(588)	(1,445)	(2,136)
Amortization of intangible assets	(31)	(545)	(6,018)
Gain from early termination of lease	22	543	—
Other income (expenses)	(2,359)	44,064	—
Consolidated Comprehensive income (loss)	(8,268)	23,916	(71,669)
Supplementary information on material income or expense items included in the segment results:			
Licensing revenues included in the Research And Development Adjusted EBITDA	547	—	2,000
Loss from Global Termination Agreement included in the Commercial Operations Segment, not included in the Adjusted EBITDA	(2,359)	—	—
Gain from the sale of Movantik®, included in the Commercial Operations Segment, not included in the Adjusted EBITDA	—	44,064	—

b. Major customers

The following table represents the percentages of total net revenues from the major customers:

	Year Ended December 31,		
	2024	2023	2022
Customer A	36%	30%	32%
Customer B	22%	28%	30%
Customer C	30%	37%	33%

The Company's revenues were entirely in the U.S. except for approximately $1 million from licensing revenues (including royalties) and sales of product to Gaelan in the UAE in 2024, no revenues outside the U.S. in 2023, and $2 million from licensing revenues to Gaelan in the UAE in 2022. The payment terms for all customers are 31 to 68 days.

c. Assets by geographic location

The Company's non-current assets located in Israel as of December 31, 2024, amount to $6.1 million (mainly intangible assets - $5.5 million and right-of-use assets - $0.3 million).

The Company's non-current assets located in Israel as of December 31, 2023, amount to $6.4 million (mainly intangible assets - $5.6 million and right-of-use assets - $0.6 million). The remainder of the consolidated non-current assets as of December 31, 2023, amount to $0.5 million and are located in the U.S (consisting mainly right-of-use assets - $0.4 million).

REDHILL BIOPHARMA LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 25 – EARNINGS (LOSS) PER ORDINARY SHARE:

a. Basic

The following is data taken into account in the computation of basic loss per share:

	Year Ended December 31,		
	2024	2023	2022
Earnings (Loss) (U.S. dollars in thousands)	(8,268)	23,916	(71,669)
Weighted average number of ordinary shares outstanding during the period (in thousands)	12,322,721	2,591,222	616,299
Basic earnings (loss) per share (U.S. dollars)	(0.00)	0.01	(0.12)

b. Diluted

The Company had three categories of potentially dilutive ordinary shares: warrants issued to investors and options issued to employees and service providers. The effect of these options, RSUs and warrants for all reporting years is anti-dilutive.

The calculation of diluted earnings (loss) per share as of December 31, 2024, does not include 5,606,626,800 of ordinary shares underlying warrants, 26,190,400 of ordinary shares underlying options and 377,659,600 of ordinary shares underlying RSUs, because the effect would be anti-dilutive.

NOTE 26 - RELATED PARTIES:

a. Key management includes members of the Board of Directors, including the Company's Chief Commercial Officer and Chief Executive Officer:

	Year Ended December 31,		
	2024	2023	2022
	U.S. dollars in thousands		
Key management compensation:			
Salaries and other short-term employee benefits	1,030	1,189	1,486
Post-employment benefits	49	56	64
Share-based payments	205	407	1,041
Other long-term benefits	31	35	44

b. Balances with related parties:

	December 31,	
	2024	2023
	U.S. dollars in thousand	
Current liabilities -		
Credit balance in "accrued expenses and other current liabilities"	176	206

REDHILL BIOPHARMA LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 27 - EVENTS SUBSEQUENT TO DECEMBER 31, 2024:

1) Through April 10, 2025, the Company sold 453,345 ADSs under its "at-the-market" ("ATM") program at an average price of $4.96 per ADS, generating net proceeds of approximately $2.2 million, net of an immaterial amount of issuance expenses. The Company may sell up to $3.5 million in aggregate gross proceeds under the program.

2) On February 24, 2025, the Company entered into an exclusive license agreement with Hyloris Pharmaceuticals SA for the development and commercialization of RHB-102 (Bekinda®) in all territories outside the United States, Canada and Mexico. Under the agreement, the Company received an upfront payment of $0.1 million and is entitled to up to $60 million in potential milestone payments, and tiered royalties of up to the mid-20% on net sales, subject to certain cost recoupments, with minimum annual payments to the Company.

Exhibit 2.3

DESCRIPTION OF SHARE CAPITAL

The following descriptions of our share capital and provisions of our amended and restated articles of association are summaries and do not purport to be complete. Our amended and restated articles of incorporation are filed with the SEC as an exhibit to our registration statement, of which this prospectus forms a part.

Each of the American Depositary Shares, or ADSs, represents ten thousand (10,000) Ordinary Shares. The ADSs trade on the NASDAQ Capital Market.

The principal office of The Bank of New York Mellon, located at 240 Greenwich Street, New York, New York 10286.

You may hold American Depositary Shares either (A) directly (i) by having an American Depositary Receipt, which is a certificate evidencing a specific number of American Depositary Shares, registered in your name, or (ii) by having American Depositary Shares registered in your name in the Direct Registration System, or (B) indirectly by holding a security entitlement in American Depositary Shares through your broker or other financial institution. If you hold American Depositary Shares directly, you are a registered American Depositary Share holder. This description assumes you are an American Depositary Share holder. If you hold the American Depositary Shares indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of American Depositary Share holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

The Direct Registration System, or DRS, is a system administered by The Depository Trust Company, also referred to as DTC, pursuant to which the depositary may register the ownership of uncertificated American Depositary Shares, which ownership is confirmed by periodic statements sent by the depositary to the registered holders of uncertificated American Depositary Shares.

As an American Depositary Share holder, we will not treat you as one of our shareholders and you will not have shareholder rights. Israeli law governs shareholder rights. The depositary will be the holder of the ordinary shares underlying your American Depositary Shares. As a registered holder of American Depositary Shares, you will have American Depositary Share holder rights. A deposit agreement among us, the depositary and you, as an American Depositary Share holder, and all other persons indirectly holding American Depositary Shares sets out American Depositary Share holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the American Depositary Shares.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of American Depositary Receipt, each of which has been filed as an exhibit to our Registration Statement on Form F-6 filed with the Securities and Exchange Commission.

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay to American Depositary Share holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. You will receive these distributions in proportion to the number of shares your American Depositary Shares represent.

- ***Cash***. The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the U.S. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those American Depositary Share holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the American Depositary Share holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. It will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.*

- ***Shares***. The depositary may, and will if we so request, distribute additional American Depositary Shares representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole American Depositary Shares. It will sell shares which would require it to deliver a fractional American Depositary Share and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional American Depositary Shares, the outstanding American Depositary Shares will also represent the new shares. The depositary may sell a portion of the distributed shares sufficient to pay its fees and expenses in connection with that distribution.

- ***Rights to purchase additional shares***. If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may make these rights available to American Depositary Share holders. If the depositary decides it is not legal and practical to make the rights available but that it is practical to sell the rights, the depositary will use reasonable efforts to sell the rights and distribute the proceeds in the same way as it does with cash. The depositary will allow rights that are not distributed or sold to lapse. *In that case, you will receive no value for them.*

  If the depositary makes rights available to American Depositary Share holders, it will exercise the rights and purchase the shares on your behalf. The depositary will then deposit the shares and deliver American Depositary Shares to the persons entitled to them. It will only exercise rights if you pay it the exercise price and any other charges the rights require you to pay.

  U.S. securities laws may restrict transfers and cancellation of the American Depositary Shares represented by shares purchased upon exercise of rights. For example, you may not be able to trade these American Depositary Shares freely in the U.S. In this case, the depositary may deliver restricted depositary shares that have the same terms as the American Depositary Shares described in this section except for changes needed to put the necessary restrictions in place.

- ***Other Distributions***. The depositary will send to American Depositary Share holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. After consultation with us to the extent practicable, it may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case American Depositary Shares will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than American Depositary Shares) to American Depositary Share holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution.

  The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any American Depositary Share holders. We have no obligation to register American Depositary Shares, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of American Depositary Shares, shares, rights or anything else to American Depositary Share holders. *This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you*.

Deposit, Withdrawal and Cancellation

How are American Depositary Shares issued?
The depositary will deliver American Depositary Shares if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate

number of American Depositary Shares in the names you request and will deliver the American Depositary Shares to or upon the order of the person or persons that made the deposit.

How can American Depositary Share holders withdraw the deposited securities?

You may surrender your American Depositary Shares at the depositary's corporate trust office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the American Depositary Shares to the American Depositary Share holder or a person the American Depositary Share holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its corporate trust office, if feasible.

How do American Depositary Share holders interchange between certificated American Depositary Shares and uncertificated American Depositary Shares?

You may surrender your American Depositary Receipt to the depositary for the purpose of exchanging your American Depositary Receipt for uncertificated American Depositary Shares. The depositary will cancel that American Depositary Receipt and will send to the American Depositary Share holder a statement confirming that the American Depositary Share holder is the registered holder of uncertificated American Depositary Shares. Alternatively, upon receipt by the depositary of a proper instruction from a registered holder of uncertificated American Depositary Shares requesting the exchange of uncertificated American Depositary Shares for certificated American Depositary Shares, the depositary will execute and deliver to the American Depositary Share holder an American Depositary Receipt evidencing those American Depositary Shares.

Voting Rights

How do you vote?

American Depositary Share holders may instruct the depositary to vote the number of deposited shares their American Depositary Shares represent. The depositary will notify American Depositary Share holders of shareholders' meetings and arrange to deliver our voting materials to them if we ask it to. Those materials will describe the matters to be voted on and explain how American Depositary Share holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. *Otherwise, you won't be able to exercise your right to vote unless you withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares.*

The depositary will try, as far as practical, subject to the laws of Israel and of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by American Depositary Share holders. The depositary will only vote or attempt to vote as instructed.

If the depositary solicited your voting instructions but does not receive instructions by the date specified, the depositary will consider you to have instructed it to give a proxy to a person designated by us to vote the deposited shares, unless we notify the depositary that:

- we do not wish to receive a proxy;

- substantial opposition exists; or

- the matter would materially and adversely affect the rights of holders of our ordinary shares.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise your right to vote and there may be nothing you can do if your shares are not voted as you requested.*

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the American Depositary Receipts without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of American Depositary Share holders, it will not become effective for outstanding American Depositary Shares until 30 days after the depositary notifies American Depositary Share holders of the amendment. At the time an amendment becomes effective, you are considered, by continuing to hold your American Depositary Shares, to agree to the amendment and to be bound by the American Depositary Receipts and the deposit agreement as amended.

How may the deposit agreement be terminated?

The depositary will terminate the deposit agreement at our direction by mailing notice of termination to the American Depositary Share holders then outstanding at least 30 days prior to the date fixed in such notice for such termination. The depositary may also terminate the deposit agreement by mailing notice of termination to us and the American Depositary Share holders if 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment.

After termination, the depositary and its agents will do the following under the deposit agreement but nothing else: collect distributions on the deposited securities, sell rights and other property, and deliver shares and other deposited securities upon cancellation of American Depositary Shares. Four months after termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement for the pro rata benefit of the American Depositary Share holders that have not surrendered their American Depositary Shares. It will not invest the money and has no liability for interest. The depositary's only obligations will be to account for the money and other cash. After termination our only obligations will be to indemnify the depositary and to pay fees and expenses of the depositary that we agreed to pay.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of American Depositary Shares

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith;
- are not liable if we are or it is prevented or delayed by law or circumstances beyond our control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of American Depositary Shares to benefit from any distribution on deposited securities that is not made available to holders of American Depositary
  Shares under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;

- have no obligation to become involved in a lawsuit or other proceeding related to the American Depositary Shares or the deposit agreement on your behalf or on behalf of any other person; and

- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of an American Depositary Share, make a distribution on an American Depositary Share, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;

- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver American Depositary Shares or register transfers of American Depositary Shares generally when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Your Right to Receive the Shares Underlying your American Depositary Shares

American Depositary Share holders have the right to cancel their American Depositary Shares and withdraw the underlying shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;

- when you owe money to pay fees, taxes and similar charges; or

- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to American Depositary Shares or to the withdrawal of shares or other deposited securities.

Securities Registers

The transfer agent and registrar for our ADSs is The Bank of New York Mellon, and its address is 101 Barclay Street, New York, NY.

Objects and Purposes

According to Section 4 of our articles of association, we shall engage in any legal business. Our number with the Israeli Registrar of Companies is 514304005.

Private Placements

Under the Israeli Companies Law, if (i) as a result of a private placement a person would become a controlling shareholder or (ii) a private placement will entitle investors to receive 20% or more of the voting rights of a company as calculated before the private placement, and all or part of the private placement consideration is not in cash or in public traded securities or is not in market terms and if as a

result of the private placement the holdings of a substantial shareholder will increase or as a result of it a person will become a substantial shareholder, then, in either case, the allotment must be approved by the board of directors and by the shareholders of the company. A "substantial shareholder" is defined as a shareholder who holds five percent or more of the company's outstanding share capital, assuming the exercise of all of the securities convertible into shares held by that person. In order for the private placement to be on "market terms" the board of directors has to determine, on the basis of detailed explanation, that the private placement is on market terms, unless proven otherwise.

Board of Directors

Under our articles of association, resolutions by the board of directors are decided by a majority of votes of the directors present, or participating, in the case of voting by media, and voting, each director having one vote.

In addition, the Israeli Companies Law requires that certain transactions, actions, and arrangements be approved as provided for in a company's articles of association and in certain circumstances by the compensation or audit committee and by the board of directors itself. Those transactions that require such approval pursuant to a company's articles of association must be approved by its board of directors. In certain circumstances, compensation or audit committee and shareholder approval are also required.

The Israeli Companies Law requires that a member of the board of directors or senior management of the company promptly and, in any event, not later than the first board meeting at which the transaction is discussed, disclose any personal interest that he or she may have, either directly or by way of any corporation in which he or she is, directly or indirectly, a 5% or greater shareholder, director or general manager or in which he or she has the right to appoint at least one director or the general manager, as well as all related material information known to him or her, in connection with any existing or proposed transaction by the company. In addition, if the transaction is an extraordinary transaction, (that is, a transaction other than in the ordinary course of business, otherwise than on market terms, or is likely to have a material impact on the company's profitability, assets or liabilities), the member of the board of directors or senior management must also disclose any personal interest held by his or her spouse, siblings, parents, grandparents, descendants, spouse's descendants, siblings and parents, and the spouses of any of the foregoing.

Once the member of the board of directors or senior management complies with the above disclosure requirement, a company may approve the transaction in accordance with the provisions of its articles of association. Under the provisions of the Israeli Companies Law, whoever has a personal interest in a matter, which is considered at a meeting of the board of directors or the audit committee, may not be present at this meeting or vote on this matter, unless it is not an extraordinary transaction as defined in the Israeli Companies Law. However, if the chairman of the board of directors or the chairman of the audit committee has determined that the presence of a director or an officer with a personal interest is required for the presentation of a matter, such officer holder may be present at the meeting. Notwithstanding the foregoing, if the majority of the directors have a personal interest in a matter, they will be allowed to participate and vote on this matter, but an approval of the transaction by the shareholders in the general meeting will be required.

Our articles of association provide that, subject to the Israeli Companies Law, all actions executed in good faith by the board of directors or by a committee thereof or by any person acting as a director or a member of a committee of the board of directors, will be deemed to be valid even if, after their execution, it is discovered that there was a flaw in the appointment of these persons or that any one of these persons was disqualified from serving in his or her office.

Our articles of association provide that, subject to the provisions of the Israeli Companies Law, the board of directors may appoint board of directors' committees. The committees of the board of directors report to the board of directors their resolutions or recommendations on a regular basis, as prescribed by the
board of directors. The board of directors may cancel the resolution of a committee that has been appointed by it; however, such cancellation will not affect the validity of any resolution of a committee, pursuant to which we acted, vis-à-vis another person, who was not aware of the cancellation thereof. Decisions or recommendations of the committee of the board which require the approval of the board of directors will be brought to the directors' attention a reasonable time prior to the discussion at the board of directors.

According to the Israeli Companies Law, a contract of a company with its directors, regarding their conditions of service, including the grant to them of exemption from liability from certain actions, insurance, and indemnification as well as the company's contract with its directors on conditions of their employment, in other capacities, require the approval of the compensation committee, the board of directors, and the shareholders by a Special Majority.

Description of Securities

Ordinary Shares

Our registered share capital is NIS 400,000,000, divided into (i) 39,994,000,000 registered Ordinary Shares of NIS 0.01 par value each, and (ii) 6,000,000 preferred shares of NIS 0.01 par value each.

Our board of directors has approved an increase in our authorized share capital to NIS 1,600,000,000, divided into (i) 159,994,000,000 registered ordinary shares of NIS 0.01 par value each and (ii) 6,000,000 preferred shares of NIS 0.01 par value each. This proposal is on the agenda for the annual general shareholder meeting scheduled for May 5, 2025.

The Ordinary Shares do not have preemptive rights, preferred rights or any other right to purchase our securities. Neither our articles of association nor the laws of the State of Israel restrict the ownership or voting of Ordinary Shares by non-residents of Israel, except for subjects of countries that are enemies of Israel.

Transfer of Shares. Fully paid Ordinary Shares are issued in registered form and may be freely transferred pursuant to our articles of association unless that transfer is restricted or prohibited by another instrument.

Notices. Under the Israeli Companies Law and our articles of association, we are required to publish notices in two Hebrew-language daily newspapers or our website at least 21 calendar days' prior notice of a shareholders' meeting. However, under regulations promulgated under the Israeli Companies Law, we are required to publish a notice in two daily newspapers at least 35 calendar days prior any shareholders' meeting in which the agenda includes matters which may be voted on by voting instruments. Regulations under the Israeli Companies Law exempt companies whose shares are listed for trading both on a stock exchange in and outside of Israel, from some provisions of the Israeli Companies Law. An amendment to these regulations exempts us from the requirements of the Israeli proxy regulation, under certain circumstances.

According to the Israeli Companies Law and the regulations promulgated thereunder, for purposes of determining the shareholders entitled to notice and to vote at such meeting, the board of directors may fix the record date not more than 60 nor less than four calendar days prior to the date of the meeting, provided that an announcement regarding the general meeting be given prior to the record date.

Election of Directors. The number of directors on the board of directors shall be no less than five and no more than eleven, including any external directors whose appointment is required by law. The general meeting is entitled, at any time and from time to time, in a resolution approved by a majority of 75% or more of the votes cast by those shareholders present and voting at the meeting in person, by proxy or by a voting instrument, not taking into consideration abstaining votes, to change the minimum or maximum number of directors as stated above as well as to amend the board classification under our Articles. A simple majority shareholder vote is required to elect a director for a term of less than three years.

Dividend and Liquidation Rights. Our profits, in respect of which a resolution was passed to distribute them as a dividend or bonus shares, are to be paid pro rata to the amount paid or credited as paid on account of the nominal value of shares held by the shareholders. Pursuant to the Companies Law, subject to certain exceptions with respect to the buyback by the Company of its ordinary shares, the distribution amount is limited to the greater of retained earnings or earnings generated over the previous two years, according to our then last reviewed or audited financial statements, provided that the date of the financial statements is not more than six months prior to the date of the distribution, or we may distribute dividends that do not meet such criteria only with court approval. In the event of our liquidation, the liquidator may, with the general meeting's approval, distribute parts of our property in specie among the shareholders and he may, with similar approval, deposit any part of our property with trustees in favor of the shareholders as the liquidator, with the approval mentioned above deems fit. The terms of our term loan facility prohibit us from paying dividends.

Voting, Shareholders' Meetings and Resolutions. Holders of Ordinary Shares are entitled to one vote for each Ordinary Share held on all matters submitted to a vote of shareholders. The quorum required for an

ordinary meeting of shareholders consists of at least two shareholders present, in person or by proxy, or who has sent us a voting instrument indicating the way in which he is voting, who hold or represent, in the aggregate, at least 25% of the voting rights of our outstanding share capital. A meeting adjourned for lack of a quorum is adjourned to the following day at the same time and place or any time and place as prescribed by the board of directors in the notice to the shareholders. At the reconvened meeting one shareholder at least, present in person or by proxy constitutes a quorum except where such meeting was called at the demand of shareholders. With the agreement of a meeting at which a quorum is present, the chairman may, and on the demand of the meeting he must, adjourn the meeting from time to time and from place to place, as the meeting resolves. Annual general meetings of shareholders are held once every year within a period of not more than 15 months after the last preceding annual general shareholders' meeting. The board of directors may call special general meetings of shareholders. In addition, as a company whose shares are listed for trade on an exchange outside of Israel. Israeli law provides that our board of directors is required to convene a special general meeting of shareholders upon the written request of (i) any two directors or 25% of the directors in office, whichever is the lower, or (ii) by one or more shareholders holding, in aggregate, either (a) 10% or more of our issued share capital and at least 1% of the voting rights, or (b) by shareholders holding at least 10% of our voting rights.

Under Israeli law, one or more shareholders holding at least 1% of the voting rights at the general meeting may request that the board of directors include a matter in the agenda of a general meeting to be convened in the future (or, with respect to a company whose shares are listed for trade on an exchange outside of Israel, such as us, 5% if the matter is the appointment or removal of a director), provided that it is appropriate to discuss such any other matter at the general meeting.

An ordinary resolution requires approval by the holders of a majority of the voting rights present, in person or by proxy, at the meeting and voting on the resolution.

Allotment of Shares. Our board of directors has the power to allot or to issue shares to any person, with restrictions and conditions as it deems fit.

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Israeli Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company.

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the same class for the purchase of all of the issued and outstanding shares of the same class.

If the shareholders who do not respond to or accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class of the shares, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will be accepted if the shareholders who do not accept it hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of the shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition the Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may determine in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class, the acquirer may not acquire shares of

the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

The description above regarding a full tender offer will also apply, with necessary changes, when a full tender offer is accepted, and the offeror has also offered to acquire all of the company's securities.

Special Tender Offer

The Israeli Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of at least 25% of the voting rights in the company. This rule does not apply if there is already another holder of at least 25% of the voting rights in the company.

Similarly, the Israeli Companies Law provides that an acquisition of shares of a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company.

These requirements do not apply if the acquisition (i) occurs in the context of a private offering, on the condition that the shareholders meeting approved the acquisition as a private offering whose purpose is to give the acquirer at least 25% of the voting rights in the company if there is no person who holds at least 25% of the voting rights in the company, or as a private offering whose purpose is to give the acquirer 45% of the voting rights in the company, if there is no person who holds 45% of the voting rights in the company; (ii) was from a shareholder holding at least 25% of the voting rights in the company and resulted in the acquirer becoming a holder of at least 25% of the voting rights in the company; or (iii) was from a holder of more than 45% of the voting rights in the company and resulted in the acquirer becoming a holder of more than 45% of the voting rights in the company.

The special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the special tender offer is accepted by a majority of the votes of those offerees who gave notice of their position in respect of the offer; in counting the votes of offerees, the votes of a holder in control of the offeror, a person who has personal interest in acceptance of the special tender offer, a holder of at least 25% of the voting rights in the company, or any person acting on their or on the offeror's behalf, including their relatives or companies under their control, are not taken into account.

In the event that a special tender offer is made, a company's board of directors is required to express its opinion on the advisability of the offer or must abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention.

An officer in a target company who, in his or her capacity as an officer, performs an action the purpose of which is to cause the failure of an existing or foreseeable special tender offer or is to impair the chances of its acceptance, is liable to the potential purchaser and shareholders for damages resulting from his acts, unless such officer acted in good faith and had reasonable grounds to believe he or she was acting for the benefit of the company. However, officers of the target company may negotiate with the potential purchaser in order to improve the terms of the special tender offer, and may further negotiate with third parties in order to obtain a competing offer.

If a special tender offer was accepted by a majority of the shareholders who announced their stand on such offer, then shareholders who did not respond to the special offer or had objected to the special tender offer may accept the offer within four days of the last day set for the acceptance of the offer. In the event that a special tender offer is accepted, then the purchaser or any person or entity controlling it and any corporation controlled by them must refrain from making a subsequent tender offer for the purchase of shares of the target company and may not execute a merger with the target company for a period of one year from the date of the offer unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Merger

The Israeli Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Israeli Companies Law are met, a majority of each party's shareholders, by a majority of each party's shares that are voted on the proposed merger at a shareholders' meeting.

The board of directors of a merging company is required pursuant to the Israeli Companies Law to discuss and determine whether in its opinion there exists a reasonable concern that, as a result of a proposed
merger, the surviving company will not be able to satisfy its obligations toward its creditors, taking into account the financial condition of the merging companies. If the board of directors has determined that such a concern exists, it may not approve a proposed merger. Following the approval of the board of directors of each of the merging companies, the boards of directors must jointly prepare a merger proposal for submission to the Israeli Registrar of Companies.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares voting at the shareholders meeting (excluding abstentions) that are held by parties other than the other party to the merger, any person who holds 25% or more of the means of control of the other party to the merger or anyone on their behalf including their relatives or corporations controlled by any of them, vote against the merger.

In addition, if the non-surviving entity of the merger has more than one class of shares, the merger must be approved by each class of shareholders. If the transaction would have been approved but for the separate approval of each class of shares or the exclusion of the votes of certain shareholders as provided above, a court may still rule that the company has approved the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the appraisal of the merging companies' value and the consideration offered to the shareholders.

Under the Israeli Companies Law, each merging company must send a copy of the proposed merger plan to its secured creditors. Unsecured creditors are entitled to receive notice of the merger, as provided by the regulations promulgated under the Israeli Companies Law. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the target company. The court may also give instructions in order to secure the rights of creditors.

In addition, a merger may not be completed unless at least 50 days have passed from the date that a proposal for approval of the merger was filed with the Israeli Registrar of Companies and 30 days from the date that shareholder approval of both merging companies was obtained.

Anti-takeover Measures

The Israeli Companies Law allows us to create and issue shares having rights different from those attached to our Ordinary Shares, including shares providing certain preferred or additional rights to voting, distributions or other matters and shares having preemptive rights. We have 6,000,000 authorized unissued preferred shares. Our authorized preferred shares, and any other class of shares other than Ordinary Shares that we may create and issue in the future, depending on the specific rights that may be attached to them, may delay or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their Ordinary Shares. The authorization of a new class of shares will require an amendment to our articles of association which requires the prior approval of a majority of our shares represented and voting at a general meeting. Shareholders voting at such a meeting will be subject to the restrictions under the Israeli Companies Law. In addition, provisions of our articles of our association relating to the election of our directors for terms of three years make it more difficult for a third party to effect a change in control or takeover attempt that our management and board of directors oppose.

Exhibit 4.10

GLOBAL TERMINATION AGREEMENT

This Global Termination Agreement (this "Termination Agreement") is made as of July 19, 2024, by and between RedHill Biopharma Inc., a Delaware corporation ("RedHill"), RedHill Biopharma Ltd., an Israeli company ("RedHill Parent"), Movantik Acquisition Co., a Delaware corporation ("Movantik Acquisition"), Valinor Pharma, LLC, a Delaware limited liability company ("Valinor"), and HCR Redhill SPV, LLC acting as administrative agent ("HCR"). Movantik Acquisition, HCR, Valinor and RedHill are sometimes referred to herein singly as a "Party" and together as the "Parties." Capitalized terms used and not otherwise defined herein shall have the meanings provided in the Transition Services Agreement (as defined below) or the Credit Agreement (as defined below), as the context requires.

RECITALS:

WHEREAS, RedHill and Movantik Acquisition are party to that certain Transition Services Agreement, dated as of February 2, 2023 (as amended, restated, supplemented or otherwise modified from time to time, the "Transition Services Agreement");

WHEREAS, RedHill and HCR entered into that certain Credit Agreement dated as of February 23, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the "Credit Agreement");

WHEREAS, each of the Parties have agreed to terminate the Transition Services Agreement and the Credit Agreement (including for the avoidance of doubt the Collateral Documents entered into therewith), provide releases of all liens arising out of the Credit Agreement or the Transition Services Agreement or otherwise in connection therewith and provide additional mutual releases to the other Parties each as further described herein;

WHEREAS, as a result of the foregoing, the Parties hereto desire to enter into this Termination Agreement to set forth in writing the understanding among the Parties hereto as to the subject matter hereof; and

NOW THEREFORE, in consideration of the promises set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned do hereby agree and acknowledge as follows:

TERMS AND CONDITIONS:

1. Termination of Transition Services Agreement. Each of Movantik Acquisition and RedHill hereby mutually agrees that contingent upon (i) the payment of $9,887,297 to RedHill (the "Final Payment") and (ii) the payment of $$589,610 by Valinor to AstraZeneca AB in respect of such amount owed by RedHill to AstraZeneca AB pursuant to invoice no. #18000032 totaling $572,742 plus agreed upon interest on such invoice, the Transition Services Agreement shall be terminated and cancelled. Both parties acknowledge that the Final Payment is inclusive of, among other things: CMS Medicaid invoices dated through July 12, 2024, totaling $11,416,929, Tricare invoices for the period from Q4 2023 through Q1 2024 totaling $68,009, CMS Coverage GAP invoice for Q1 2024 totaling $26,815 and Branded Prescription Drug Fee for the period from 2023 through the end of 2024 totaling $99,958. Other than as set forth in this Section 1, upon such termination of the Transition Services Agreement, the Transition Services Agreement shall be of no further force and effect and, notwithstanding any provision of the Transition Services Agreement to the contrary, no Party to the Transition Services Agreement shall have any further or continuing or other right, obligation, liability or responsibility with respect to the Transition Services Agreement to the other Party or any other party of any kind whatsoever; provided that those certain terms specified in Section 13 of the Transition Services Agreement (including for the avoidance of doubt

Section 4 of the Transition Services Agreement) shall survive this Termination Agreement and shall continue to apply according to their terms. Each of the Parties hereto hereby waives any and all notice obligations to the other Party that may be set forth in the Transition Services Agreement.

2. Acknowledgement of No Further Payment Obligations. Upon the making of the payments set forth in Section 1 of this of this Termination Agreement, each of RedHill and Movantik Acquisition agree that no other amount shall be owed or payable by either RedHill or Movantik Acquisition pursuant to the Transition Services Agreement related to services, Service Fees, Milestones Payments and Payment Claims (each as defined in the Transition Services Agreement) that are known and invoiced as of the date of this agreement. Furthermore, RedHill agrees that Movantik Acquisition has satisfied all obligations contemplated in the Transition Services Agreement including, but not limited to, those related to any indirect payments related to any government program under the labeler code 57841 for Movantik as of June 30, 2024. For the avoidance of doubt, the Parties acknowledge that Payment Claims not yet invoiced as of the date of this Termination Agreement, as well as Returned Licensed Products not yet processed as of the date hereof, which are the financial responsibility of either RedHill or Movantik Acquisition in accordance with the requirements of the Transition Services Agreement, shall continue to be owed or payable by the applicable Party (including its successors or assigns). Notwithstanding anything to the contrary, this Section 2 shall not apply to the payment obligations set forth in this Termination Agreement and those certain terms specified in Section 13 of the Transition Services Agreement (including for the avoidance of doubt Section 4 of the Transition Services Agreement), which shall survive this Termination Agreement and shall continue to apply according to their terms therein and herein.

3. Termination of Credit Agreement. Notwithstanding anything to the contrary set forth in the Credit Agreement or otherwise, effective as of the date hereof each of Movantik Acquisition, HCR on behalf of itself and the Lenders party to the Credit Agreement from time to time and RedHill hereby mutually agree and acknowledge that the Credit Agreement and all Collateral Documents and related documents entered into connection therewith shall be terminated, all guarantees shall be automatically terminated and other obligations of RedHill shall be automatically released and discharged, and no party thereto shall have any further obligation to any other party thereto without any further action by any person.

4. Release of Liens. Each of HCR and Movantik Acquisition agrees that any lien which HCR or Movantik Acquisition or their affiliates may have asserted pursuant to any commercial relationship between HCR or Movantik Acquisition or their affiliates on one hand and RedHill on the other hand, including anything pursuant to the Credit Agreement or the Transition Services Agreement on any property owned by RedHill is hereby automatically released, discharged and irrevocably terminated. RedHill and its affiliates and their respective attorneys and designees shall be authorized to file any and all necessary terminations and releases, including without limitation, with respect to any Uniform Commercial Code financing statements or other security documents in Israel filed in connection with the Transition Services Agreement, the Movantik Asset Purchase Agreement, the Credit Agreement or any other agreement between the Parties to effectuate the foregoing, including with respect to security documents filed on assets owned by RedHill Parent related to such agreements. HCR and its affiliates shall deliver to RedHill executed instruments of release pertaining to the security interests and liens described herein as RedHill may reasonably request to effectuate, or reflect of public record, the release and discharge of all such security interests and liens. HCR shall, from and after the date hereof, in good faith, promptly take all other reasonable additional steps and deliver such other termination statements, releases, instruments, signatures or documents as RedHill may from time to time reasonably request to effectuate, or reflect of public record, the release of such security interests and liens described herein. All of the foregoing shall be without any condition or representation or warranty of any kind, express or implied.

5. Redirection of Talicia and Aemcolo Revenue. Effective as of the date hereof, Movantik Acquisition agrees that all Talicia and Aemcolo revenue collection shall be redirected to RedHill accounts via wholesalers as directed by RedHill and Redhill shall commence such transition within five (5) business

days of the date hereof. Following the execution of this Termination Agreement, HCR, Movantik Acquisition, Valinor and their affiliates shall, as soon as commercially practicable initiate an internal reconciliation process and thereafter transfer to RedHill any payment which, per the terms of this Termination Agreement, belongs to RedHill and is received by HCR, Movantik Acquisition, Valinor or their affiliates after the date hereof. All amounts due and payable under this Section 4 shall be due and payable by the paying party in immediately available funds.

6. RedHill's Release of the Movantik Released Parties. RedHill, on behalf of itself and its affiliates, and each of its and their respective employees, direct and indirect equity holders, members, owners, directors, managers, officers, representatives, agents, successors and assigns, hereby irrevocably and unconditionally releases and forever discharges Movantik Acquisition, Valinor and HCR, their affiliates and their respective employees, direct and indirect equity holders, members, owners, directors, managers, officers, representatives, agents, successors and assigns (the "Movantik Released Parties"), from any and all claims, counterclaims, damages, losses, duties, obligations, liabilities, charges, demands, actions or causes of action and agreements of every kind, known or unknown, suspected or unsuspected, asserted or unasserted, in law or in equity, that arise out of or are related to the Transition Services Agreement or the Credit Agreement, except for RedHill's right to receive the Final Payment, any other obligations described in this Termination Agreement (including, but not limited to, as set forth in Section 1 of this of this Termination Agreement) and any claims arising out of or in connection with this Termination Agreement (the "RedHill Released Claims"). For the avoidance of doubt, the foregoing release shall not limit any rights or claims available to RedHill pursuant to that certain Asset Purchase Agreement, dated as of February 2, 2023, by and between RedHill, Movantik Acquisition, and RedHill Biopharma LTD (collectively with all ancillary agreements, amendments, supplements and modifications related thereto, the "Movantik Asset Purchase Agreement") other than the RedHill Released Claims.

7. The Movantik Released Parties Release of RedHill. The Movantik Released Parties, on behalf of themselves and their affiliates, and each of their respective employees, direct and indirect equity holders, members, owners, directors, managers, officers, representatives, agents, successors and assigns, hereby irrevocably and unconditionally releases and forever discharges RedHill and its affiliates and their respective employees, direct and indirect equity holders, members, owners, directors, managers, officers, representatives, agents, successors and assigns from any and all claims, counterclaims, damages, losses, duties, obligations, liabilities, charges, demands, actions or causes of action and agreements of every kind, known or unknown, suspected or unsuspected, asserted or unasserted, in law or in equity, that arise out of or are related to the Transition Services Agreement or the Credit Agreement, any other obligations described in this Termination Agreement and any claims arising out of or in connection with this Termination Agreement (the "Movantik Parties Released Claims"). For the avoidance of doubt, the foregoing release shall not limit any rights or claims available to Movantik Acquisition or Valinor pursuant to the Movantik Purchase Agreement other than the Movantik Parties Released Claims.

8. Release of Escrow Funds. The Parties agree to execute the Joint Escrow Committee Certificate (the "Joint Instruction") attached hereto as Exhibit A, pursuant to Section 7.2 of the Movantik Asset Purchase Agreement. and deliver the Joint Instruction to the Escrow Agent (as defined in that certain Escrow Agreement (the "Escrow Agreement"), dated as of February 2, 2023, by and between the Parties) and thereby authorize the Escrow Agent to disburse all Escrow Property (as defined under the Escrow Agreement) pursuant to Section 3(b) of the Escrow Agreement to RedHill. The Parties acknowledge that, pursuant to Section 7 of the Escrow Agreement, the Escrow Agreement and any of the Parties' rights thereunder shall be terminated upon the distribution of such Escrow Property.

9. Past Royalties. The Parties hereby acknowledge and agree as follows:

a. RedHill shall have no further obligations to pay any royalties (including any unpaid royalties accrued or attributable to the period prior to the date hereof) or fulfill any

other related obligations to or on behalf of HCR or any other party under any agreement, including (i) that certain Co-Commercialization Agreement, dated as of March 18, 2015, by and between Daiichi Sankyo, Inc. ("Daiichi") and AstraZeneca UK Limited, as assigned by AstraZeneca UK Limited to RedHill on March 31, 2020, and that certain Termination Agreement dated as of July 1, 2020, by and between RedHill and Daiichi (together, with all amendments thereto and assignments thereof, the "DSI Royalty Agreements"), and (ii) that certain License Agreement, dated as of February 23, 2020, by and between AstraZeneca AB and RedHill, as assigned by RedHill to HCR on February 2, 2023 (together, with all amendments thereto and assignments thereof, "AZ License Agreement").

b. Except for any adjustments reflected in the Final Payment, including any refunds for payments made by RedHill for the H2 period of 2023 and for the H1 period of 2024[1], none of the Parties shall have any claims to any adjustment, re-calculation, restatement or other changes to the calculations on which any royalty was historically paid under the DSI Royalty Agreements, the AZ License Agreement and the License Agreement between AstraZeneca and Nektar Therapeutics dated as of September 20, 2009, as amended by that certain Amendment No. 1 to License Agreement dated as of August 8, 2013.

10. Representations and Warranties. Each of the Parties hereto represents and warrants that the execution of this agreement by such Party has been duly authorized by all necessary actions, that the person signing on behalf of such Party has been duly authorized to do so, and that this agreement constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with the terms hereof.

11. Severability. If any provision of this Termination Agreement is held by a court of competent jurisdiction to be illegal, void or unenforceable, such provision shall have no effect; however, the remaining provisions shall be enforced to the maximum extent possible. Further, if a court should determine that any portion of this Termination Agreement is overbroad or unreasonable, such provision shall be given effect to the maximum extent possible by narrowing or enforcing in part that aspect of the provision found overbroad or unreasonable.

12. Counterparts. This Termination Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument. The Parties agree that facsimile and electronically transmitted portable document format (.pdf) signatures shall be deemed originals.

13. Entire Termination Agreement; Survival. This Termination Agreement constitutes the entire contract and agreement between the Parties pertaining to the subject matter hereof and supersedes all prior agreements, understandings, negotiations and discussions, whether written or oral, of the Parties related hereto, and there are no representations, warranties or other agreements among the Parties in connection with the subject matter hereof, except as specifically set forth herein. No change, modification or amendment of this Termination Agreement shall be valid unless the same be in writing and signed by each of the Parties to be bound. No waiver of any provision of this Termination Agreement shall be valid unless in writing and signed by the Party to be charged.

14. Language Construction. Each of the Parties acknowledges that no single Party bears sole responsibility for the preparation and drafting of this Termination Agreement. Consequently, no rule of

[1] The Final Payment shall include an adjustment for the H2 2023 HCR and Daiichi refunds and the H1 2024 Daiichi refund.

construction to the effect that ambiguities are to be resolved against the drafting Party should be employed in the interpretation of this Termination Agreement.

15. Successors and Assigns. This Termination Agreement shall inure to the benefit of and bind the respective successors and permitted assigns of the Parties. Nothing expressed or referred to in this Termination Agreement is intended or shall be construed to give any person other than the Parties to this Termination Agreement or their respective successors or permitted assigns any legal or equitable right, remedy or claim under or in respect of this Termination Agreement or any provision contained herein, it being the intention of the Parties to this Termination Agreement that this Termination Agreement be for the sole and exclusive benefit of such Parties or such successors and assigns and not for the benefit of any other person. In furtherance of the foregoing, no Party may assign its obligations hereunder without the consent of the other Party.

16. Governing Law. This Termination Agreement shall be governed by the internal law of the State of New York, without regard to conflict of law principles that would result in the application of any law other than the law of the State of New York.

17. Waiver. No delay or omission on the part of any Party hereto in exercising any right hereunder shall operate as a waiver of such right or any other right under this Termination Agreement.

18. Headings. The headings contained in this Termination Agreement are inserted for convenience only and shall not affect the meaning or interpretation of this Termination Agreement.

* * * * *

IN WITNESS WHEREOF, the undersigned have executed this Global Termination Agreement as of the date first set forth above.

REDHILL BIOPHARMA INC.

By: */s/ Rick Scruggs*
Name: Rick Scruggs
Title: President & Chief Commercial Officer

REDHILL BIOPHARMA LTD.

By: */s/ Dror Ben-Asher*
Name: Dror Ben-Asher
Title: Chief Executive Officer

By: */s/ Razi Ingber*
Name: Razi Ingber
Title: Chief Financial Officer

[Signature Page – Global Termination Agreement]

MOVANTIK ACQUISITION CO.

By: */s/ Todd Smith*
Name: Todd Smith
Title: Chief Executive Officer

HCR REDHILL SPV, LLC

By: */s/ Clarke B. Futch*
Name: Clarke B. Futch
Title: Authorized Agent

VALINOR PHARMA, LLC

By: */s/ Todd Smith*
Name: Todd Smith
Title: Chief Executive Officer

[Signature Page – Global Termination Agreement]

Exhibit A

JOINT ESCROW COMMITTEE CERTIFICATE PURSUANT TO SECTION I.3.b OF THE ESCROW AGREEMENT

July [●], 2024

The Bank of New York Mellon, as Escrow Agent
Corporate Trust Administration

240 Greenwich Street, 7E
New York, New York 10286

Attn.: Escrow Unit, Matthew Louis,
Email: Matthew.Louis@bnymellon.com

This Joint Escrow Committee Certificate is being delivered pursuant to Section I.3.b of the Escrow Agreement, dated as of February 2, 2023 (the "Escrow Agreement"), by and among THE BANK OF NEW YORK MELLON, a New York banking corporation (the "Escrow Agent"), REDHILL BIOPHARMA INC. ("Seller") and REDHILL BIOPHARMA LTD. ("Seller Parent" and, together with Seller, "Sellers") and Movantik Acquisition Co. ("Buyer").

Capitalized terms used herein and not otherwise defined shall have the meaning given to them in the Escrow Agreement.

The Joint Escrow Committee hereby certifies that: (i) the following Movantik Escrow Eligible Liabilities are then due and payable: [●]; (ii) the amount of such Movantik Escrow Eligible Liabilities is $[●]; and (iii) the Escrow Property will be used by Seller to pay such Movantik Escrow Eligible Liabilities.

The wire instructions for the release of the Escrow Property are as follows:

Amount to the Seller:	[●]
Beneficiary:	[●]
ABA Number of Bank:	[●]
Account Number at Bank:	[●]
Beneficiary:	[●]
Reference:	[●]

Callback Contacts: [●]

[Remainder of this page intentionally left blank.]

REDHILL BIOPHARMA INC.

By: _____
Name: Rick Scruggs
Title: Authorized Signatory

MOVANTIK ACQUISITION CO.

By: _____
Name: Clarke B. Futch
Title: Authorized Signatory

Exhibit 11.1

REDHILL BIOPHARMA LTD.

GUIDELINES FOR THE HANDLING OF CORPORATE INFORMATION TO AVOID INSIDE INFORMATION LIABILITY

These guidelines relate to the handling of material non-public information and are designed to promote compliance with securities laws by the members of the board of directors, executive officers, employees, and consultants who are team members identified by the Chief Executive Officer (the "CEO") of RedHill Biopharma Ltd. (the "Company"), as well as other Company consultants identified by the CEO as having access to material non-public information (for the purposes of these guidelines, together with the Company directors, executive officers, employees and consultants who are team members, hereinafter together referred to as the "Associates").

I. Legal Background

Both Israeli and U.S. federal laws seek to ensure that all investors in shares, options, bonds, etc. ("Securities") of a public company have timely and equal access to material information concerning such a company when making a decision to buy or sell that company's Securities. The purchase or sale of Securities while in possession of material non-public information relating to the issuer of the Securities or the selective disclosure of such information to others ("Tipping") is prohibited under Israeli and U.S. federal laws.

II. Policy Statement

In order to avoid even the appearance of improper conduct on the part of any Company Employee, the Company has adopted the following policy statement ("Policy Statement"):

> *An Employee of the Company who has access to Inside Information (as defined below) relating to the Company (an "Insider") may not buy or sell Securities of the Company, directly or indirectly, while in possession of such information and may not engage in any other action which may result in an advantage when using such information or passing such information to others. This Company Policy Statement also applies to Inside Information relating to any other company with which the Company has business relationships, including customers or suppliers.*
>
> *These restrictions also extend to an Insider's Family Members ("Family Members", including a spouse, brothers, sisters, parents, grandparents, descendants, spouse's descendants and the spouse of any of the above), as well as any trust, corporation or other association which the Employee or his/her Family Members control.*

This Policy Statement includes the following restrictions:

1. No Trading in Company Securities when in Possession of Inside Information

During the time when there may be Inside Information affecting the Company that has not

yet been disclosed to the general public (for example, because such information concerns transactions that have not been completely finalized or confidential negotiations with third parties), any Employee of the Company who has access to such Inside Information must refrain from trading in the Company's Securities so long as such information has not been disclosed to the general public.

2. Prohibition against "Tipping"

Company Associates have a duty not only to refrain from making personal use of Inside Information, but also to refrain from passing such information to outsiders (except in the course of properly conducting business activities on behalf of the Company). Breach of the prohibition against Tipping may, under certain circumstances, result in liability both for the recipient of the Inside Information who uses Inside Information to trade advantageously in the Company's Securities and for the Employee who makes the prohibited disclosure (even if the Employee does not share any profit realized by the recipient of the Inside Information nor otherwise receives any benefit from such information).

III. Definition of "Inside Information"

If an Insider possesses material non-public information relating to the Company, the Company's development or expected development, any change or expected change of the Company's situation or any other information which, had it become public, could materially affect the trading price of Company's securities, such information shall be deemed to be "**Inside Information**". Generally, Inside Information has three defining characteristics: (1) it concerns or is related to the Company, (2) it is non-public, and (3) it is material.

Material information is any information which a reasonable investor would consider important in making a decision to buy, hold or sell securities. There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by enforcement authorities with the benefit of hindsight.

The following are common examples of information that will frequently be regarded as material: annual or quarterly financial results, projections of future earnings or losses, news of a pending or proposed merger, acquisition or tender offer, news of a significant sale of assets or the disposition of a subsidiary, changes in dividend policies or the declaration of a stock split or the offering of additional Securities, major management changes, significant new products, discoveries or study results, financial liquidity problems, major business developments, information about possibility of insolvency of company or any affiliate, major employment conflicts, information regarding legal procedures, and gain or loss of a substantial customer or supplier; Either positive or negative information may be material.

Additionally, under Israeli regulations, when a "Key Insider" (as defined below) sells a company's Securities within three months following the purchase of such Securities, or alternatively, when a Key Insider purchases Securities within three months following the sale of such Securities, a rebuttable presumption arises that the Key Insider used Inside Information. A Key Insider is an officer or anyone who fills the position of an officer, a Family Member of an officer, a shareholder who holds 5% or more of the Company's securities or voting rights or can appoint at least one director, or a corporation who is controlled by them.

IV. Consequences of Violations

The purchase or sale of Securities by an Insider while in possession of Inside Information or the disclosure of Inside Information to others who then trade in the Company's Securities is prohibited by Israeli and U.S. federal laws. Punishment for insider trading violations is severe and could include significant fines and imprisonment. Enforcement also extends beyond the individuals who trade, or who tip Inside Information to others who trade. Specifically, U.S. federal securities laws impose liability on companies and other "controlling persons" if they fail to take reasonable steps to prevent insider trading by company personnel.

In addition, an Employee's failure to comply with this Policy Statement may subject such Employee to Company-imposed sanctions, including dismissal for cause, whether or not the Employee's failure to comply results in a violation of law. Needless to say, a violation of law, or even an investigation that does not result in prosecution, can tarnish a person's reputation and irreparably damage a career.

V. Procedures to Preserve Confidentiality

Each individual who has access to Inside Information should exercise the utmost caution in keeping the necessary confidentiality of that information. No Inside Information should be disclosed to any third party, except when clearly necessary or authorized in connection with the Company's business. As a general rule, Associates should not expose any document, memo, e-mail, report or any other instrument containing confidential information, to any unauthorized third party and should consider their immediate surrounding when handling confidential information.

Associates should take every practicable step to preserve the confidentiality of information. For example:

- Do not discuss material information in public places (such as elevators, hallways, restaurants, airplanes and taxicabs) or any place where the discussion can be overheard.
- Do not gossip about confidential information.
- Do not read confidential documents in public places where others can view them and do not discard them where they can be retrieved by others.
- Do not carry confidential documents in public places in a manner in which they can be viewed by others.
- Beware of the carrying quality of conversations conducted on speaker telephones in offices, and the potential for eavesdropping on conversations conducted on car or airplane telephones, mobile devices, tablets, etc.
- Do not leave confidential documents in unattended conference rooms; do not leave confidential documents behind when the meeting is over.
- Cover confidential documents in private offices before leaving the room; do not leave confidential papers lying where others can see them.
- Be careful when giving out the whereabouts of Associates who are out of the office or revealing the presence of visitors to the office. The mere knowledge of a meeting taking place or the destination of a trip may reveal something confidential.

- Under no circumstances are Associates to provide confidential Company documents or confidential information in any format to third parties without express consent of their supervisor. This includes, but is not limited to, any confidential Company documents relating to customers, competitors or suppliers of the Company.

A list such as the one above can only be suggestive. It is the responsibility of each Employee to take every practicable step appropriate to preserve the confidentiality of information.

Any Employee who becomes aware of a leak or a potential leak of non-public information, whether inadvertent or otherwise, should report the incident immediately to **Razi Ingber, CFO, at razi@redhillbio.com ("CFO") or at +972-3-541-3131.**

If someone outside the Company, such as the news media or a securities analyst or investor, asks you questions, either directly or through another person, do not attempt to answer them. Associates should obtain the name of the person making the inquiry and immediately notify the CFO (as defined above).

VI. Limitations on Trading

1. Prohibition of Speculative Transactions

Associates and their Family Members are prohibited from making short sales (selling Company's Securities not yet owned by the seller) or engaging in transactions involving puts, calls and/or other types of options in Company's Securities, including, but not limited to, equity swaps and similar derivative transactions, at any time, unless the CFO has expressly authorized such transactions in advance in writing.

2. Pre-Clearance Procedure

Associates who intend to engage in any transaction involving the Company's Securities, must first pre-clear the transaction with the CFO, and in the CFO's absence, the Company's chief executive officer. The CFO himself is advised to first consult with the Company's chief executive officer if he intends to engage in any transaction involving the Company's Securities.

Irrespective of the pre-clearance procedure, Associates shall not engage in any transactions in the Company's Securities during the Blackout Periods (defined below).

3. Blackout Periods

Because Associates may be deemed likely to have advance access to periodic financial and other material non-public information, the Company has established regular "Blackout Periods" to further restrictions on Securities trading by Company Associates.

3.1 Quarterly Blackout Periods

Due to the potential impact of the release of financial information at the end of each fiscal quarter on the price of Company's Securities, Associates with access to sensitive financial information who trade near the end of a fiscal quarter incur greater risks of being party to a future inquiry and/or lawsuit than other Associates, based on allegations that they are trading on Inside Information. To provide a measure of security with a view to preventing inadvertent violations and avoiding

even the appearance of an improper transaction, the Company has instituted quarterly Blackout Periods subject to the trading restrictions outlined below.

A quarterly Blackout Period will commence seven days prior to the end of the Company's fiscal quarter Israel time and end after the first full trading day in the U.S. after the public announcement of the Company's financial reports for that fiscal quarter.

3.2 Special Blackout Periods

Additional Special Black-out Periods may be imposed or existing Blackout Periods may be extended. Usually this will occur when the Company is considering imminent significant decisions, for example, a public offering of Company Securities, an acquisition or a major commercial transaction, or when there is a major development in a Company R&D activity. At those times Associates will receive a separate communication from the Company advising them of the commencement of a special Blackout Period or extension of a regular Blackout Period. Special Blackout Periods will end one full trading day in the U.S. after the public announcement by the Company of the relevant event or on such other date determined by the CFO.

3.3 No Trading during Black-Out Periods

During a Blackout Period, all Associates or specific Associates as indicated in the decision, must refrain from buying or selling Company Securities.

4. Exceptions

This Policy Statement does not apply to holding and/or exercising for cash of (i) options or other derivative securities granted to an Employee according to the Company's option plans or any other incentive plans adopted by the Company or (ii) warrants or other derivative securities issued by the Company because the other party to the transaction is the Company and the price does not vary with the market but is fixed by the terms of the option agreement, warrant, or other derivative securities or plan, as the case may be (in each case not including a sale of underlying shares).

In addition, trades in the Company's Securities that are executed pursuant to an approved 10b5-1 plan are not subject to the restrictions set forth herein relating to pre-clearance procedures and Blackout Periods.

VII. Post-Termination Transactions

The trading prohibitions and restrictions set forth in these guidelines continue to apply to Associates following the termination of any such Employee's service or employment with the Company until all material, non-public information possessed by such Associates has become public or is no longer deemed Inside Information.

* * * *

Exhibit 12.1

CERTIFICATION BY CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dror Ben-Asher, certify that:

1. I have reviewed this annual report on Form 20-F of RedHill Biopharma Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company'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 company 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 company, 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 company'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 company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting;
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company'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 company'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 company's internal control over financial reporting.

Date: April 10, 2025

/s/ Dror Ben-Asher
Dror Ben-Asher
Chief Executive Officer

Exhibit 12.2

CERTIFICATION BY CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Razi Ingber certify that:

1. I have reviewed this annual report on Form 20-F of RedHill Biopharma Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company'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 company 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 company, 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 company'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 company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting;
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company'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 company'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 company's internal control over financial reporting.

Date: April 10, 2025

/s/ Razi Ingber
Razi Ingber
Chief Financial Officer

Exhibit 13

CERTIFICATION BY CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUAN TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of RedHill Biopharma Ltd. (the "Company") on Form 20-F for the period ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to such officer's 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

Dated: April 10, 2025

/s/ Dror Ben-Asher
Dror Ben-Asher
Chief Executive Officer

/s/ Razi Ingber
Razi Ingber
Chief Financial Officer

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form F-3 (file No. 333-281417, file No. 333-274957, file No. 333-273709, and file No. 333-254848) and the Registration Statements on Form S-8 (file No. 333-286082, file No. 333-280327, file No. 333-273001, file No. 333-265845, file No. 333-262099, file No. 333-255710, file No. 333-254692, file No. 333-232776, file No. 333-225122, file No. 333-219441, file No. 333-207654 and file No. 333-188286) of RedHill Biopharma Ltd. of our report dated April 10, 2025, relating to the financial statements which appears in this Form 20-F.

/s/ Kesselman & Kesselman
Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

Tel-Aviv, Israel
April 10, 2025

Kesselman & Kesselman, Derech Menachem Begin 146 Tel Aviv-Yafo 6492103 Israel,
P.O Box 7187 Tel-Aviv 6107120 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il