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

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of September 2022
Report No. 2

Commission file number: 001-40753

ICECURE MEDICAL LTD.
(Translation of registrant's name into English)

7 Ha'Eshel St., PO Box 3163
Caesarea, 3079504 Israel
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

CONTENTS

This Report of Foreign Private Issuer on Form 6-K, or Report, consists of the Registrant's: (i) Unaudited Interim Condensed Consolidated Financial Statements as of and for the six months ended June 30, 2022, which are attached hereto as Exhibit 99.1; and (ii) Management's Discussion and Analysis of Financial Condition and Results of Operations as of and for the six months ended June 30, 2022, which is attached hereto as Exhibit 99.2.

This Report is incorporated by reference into the Registrant's Registration Statements on [Form F-3](#) (Registration No. 333-267272) and Form S-8 (File No. [333-262620](#) and File No. [333-264578](#)), filed with the Securities and Exchange Commission, to be a part thereof from the date on which this Report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit No.

99.1	IceCure Medical Ltd.'s Unaudited Interim Condensed Consolidated Financial Statements as of and for the Six Months Ended June 30, 2022.
99.2	IceCure Medical Ltd.'s Management's Discussion and Analysis of Financial Condition and Results of Operations as of and for the Six Months Ended June 30, 2022.
EX-101.INS	Inline XBRL Taxonomy Instance Document
EX-101.SCH	Inline XBRL Taxonomy Extension Schema Document
EX-101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document
EX-101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
EX-101.LAB	Inline XBRL Taxonomy Label Linkbase Document
EX-101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: September 22, 2022

IceCure Medical Ltd.

By: /s/ Eyal Shamir

Name: Eyal Shamir

Title: Chief Executive Officer

ICECURE MEDICAL LTD.

UNAUDITED INTERIM CONDENSED CONSOLIDATED BALANCE SHEET
(U.S. dollars in thousands, except share data and per share data)

	As of June 30, 2022	As of December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	13,468	25,621
Deposit	4,257	-
Trade accounts receivable	184	456
Inventory	2,651	1,955
Prepaid expenses and other receivables	1,003	2,290
Total current assets	21,563	30,322
NON-CURRENT ASSETS		
Prepaid expenses and other long-term assets	330	333
Right of use assets	818	913
Property and equipment, net	1,102	713
Total non-current assets	2,250	1,959
TOTAL ASSETS	23,813	32,281
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Trade accounts payable	937	881
Lease liabilities	195	224
Other current liabilities	3,194	2,915
Total current liabilities	4,326	4,020
NON-CURRENT LIABILITIES		
Long-term lease liabilities	542	685
Other long-term liabilities	69	618
Total non-current liabilities	611	1,303
TOTAL LIABILITIES	4,937	5,323
SHAREHOLDERS' EQUITY		
Ordinary shares, No par value; Authorized 2,500,000,000 shares; Issued and outstanding: 36,814,554 and 35,780,335 shares as of June 30, 2022 and December 31, 2021, respectively	-	-
Additional paid-in capital	86,275	85,389
Accumulated deficit	(67,399)	(58,431)
Total shareholders' equity	18,876	26,958
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	23,813	32,281

The accompanying notes are an integral part of the consolidated financial statements.

ICECURE MEDICAL LTD.

UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(U.S. dollars in thousands, except share data and per share data)

	<u>Note</u>	<u>Six months ended June 30, 2022</u>	<u>Six months ended June 30, 2021</u>
Revenues	4	1,512	2,073
Cost of revenues		694	880
Gross profit		<u>818</u>	<u>1,193</u>
Research and development expenses		4,649	2,730
Sales and marketing expenses		1,533	625
General and administrative expenses		3,342	1,584
Operating loss		<u>8,706</u>	<u>3,746</u>
Financial expenses (income), net		262	101
Net loss and comprehensive loss		<u>8,968</u>	<u>3,847</u>
Basic and diluted net loss per share		<u>0.244</u>	<u>0.156</u>
Weighted average number of shares outstanding used in computing basic and diluted net loss per share		<u>36,814,382</u>	<u>24,696,706</u>

The accompanying notes are an integral part of the consolidated financial statements.

ICECURE MEDICAL LTD.

UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(U.S. dollars in thousands, except share data and per share data)

	<u>Ordinary shares</u>		<u>Treasury shares</u>		<u>Pre- funded warrants</u>		<u>Additional paid- in capital</u>	<u>Accumulated deficit</u>	<u>Total shareholders' equity</u>
	<u>Number</u>	<u>Amount</u>	<u>Number</u>	<u>Amount</u>	<u>Number</u>	<u>Amount</u>			
Balance as of January 1, 2022	35,780,335	-	-	-	1,034,000	-	85,389	(58,431)	26,958
Share-based compensation related to options granted	-	-	-	-	-	-	885	-	885
Options exercised	219	-	-	-	-	-	-	-	-
Pre- funded warrants exercised	1,034,000	-	-	-	(1,034,000)	-	1	-	1
Loss for the period	-	-	-	-	-	-	-	(8,968)	(8,968)
Balance as of June 30, 2022	36,814,554	-	-	-	-	-	86,275	(67,399)	18,876
Balance as of January 1, 2021	20,218,220	-	(5,434)	(41)	-	-	54,225	(48,536)	5,648
Issuance of ordinary shares, net(*)	11,485,697	-	-	-	-	-	14,586	-	15,586
Options exercised ordinary shares	69,018	-	-	-	-	-	56	-	56
Share-based compensation related to options granted to employees	-	-	-	-	-	-	184	-	184
Cancellation of treasury shares	-	-	5,434	41	-	-	-	-	-
Loss for the period	-	-	-	-	-	-	-	(3,847)	(3,847)
Balance as of June 30, 2021	31,772,935	-	-	-	-	-	69,010	(52,383)	16,627

(*) Net of issuance cost of approximately \$414

The accompanying notes are an integral part of the consolidated financial statements.

ICECURE MEDICAL LTD.

UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands, except share data and per share data)

	Six months ended June 30, 2022	Six months ended June 30, 2021
Cash flows from operating activities:		
Net loss	(8,968)	(3,847)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	104	50
Share-based compensation	885	184
Exchange rate changes in cash and cash equivalents and short time deposits	562	97
Changes in assets and liabilities:		
Decrease in trade accounts receivable	272	-
Increase in inventory	(696)	(401)
Decrease (increase) in prepaid expenses and other receivables	1,287	(103)
Decrease in right of use assets	95	19
Increase in trade accounts payable	56	159
Decrease in lease liabilities	(172)	(59)
Increase in other current liabilities	279	368
Decrease in other long-term liabilities	(549)	(28)
Net cash used in operating activities	(6,845)	(3,561)
Cash flows from investing activities:		
Realization (investment in) of deposits	(4,277)	4,621
Investment in long term deposits	-	(295)
Purchase of property and equipment	(493)	(247)
Net cash provided by (used in) investing activities	(4,770)	4,079
Cash flows from financing activities:		
Issuance of ordinary shares, net of issuance cost	-	14,586
Exercise of pre-funded warrants	1	-
Exercise of options to ordinary shares	-	56
Net cash provided by financing activities	1	14,642
Increase (decrease) in cash and cash equivalents	(11,614)	15,160
Cash and cash equivalents beginning of the year	25,621	3,502
Effect of foreign exchange rate on cash and cash equivalents	(539)	(49)
Cash and cash equivalents end of the year	13,468	18,613

ICECURE MEDICAL LTD.

NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share data and per share data)

NOTE 1 - GENERAL

A. Description of the Company:

IceCure Medical Ltd. (“IceCure Medical Ltd.”, the “Company”, “we” or “our”) is a medical device company incorporated in Israel.

The Company’s ordinary shares are listed on NASDAQ and the Tel Aviv Stock Exchange.

Since its establishment, IceCure Medical Ltd., and its wholly-owned subsidiaries, IceCure Medical Inc. in the United States (the “US Subsidiary”), IceCure Medical HK Limited, in Hong Kong (the “Hong Kong Subsidiary”) and IceCure (Shanghai) MedTech Co., Ltd. in China (the “Chinese Subsidiary, and together with the Company, the US Subsidiary and the Hong Kong Subsidiary, the “Group”), have been engaged in the research, development and commercialization of minimally invasive medical devices for cryoablation (freezing) of tumors in the human body, using its propriety liquid nitrogen cryoablation technology, as an alternative to surgical intervention to remove the tumor. The Company received regulatory approvals for marketing its products in the United States, Europe and other territories.

The US Subsidiary was established on April 6, 2011 in the State of Delaware and is engaged in business development, marketing, clinical trial management and sale of the Company’s products in the United States. The Hong Kong Subsidiary was established on September 26, 2018 and commenced its activity in 2021. The Chinese Subsidiary was established on July 14, 2020, and is wholly owned by the Hong Kong Subsidiary. The Chinese Subsidiary in China commenced its operation on January 1, 2021 and is engaged in business development and obtaining regulatory approvals for the Company’s products in China.

The Group’s activities are subject to significant risks and uncertainties, including failing to secure additional funding to commercialize its technology, obtaining regulatory approvals and other risks. In addition, the Group is subject to risks from, among other things, competition associated with the industry in general, other risks associated with financing, liquidity requirements, rapidly changing customer requirements and limited operating history.

B. Going Concern:

As of June 30, 2022, the Company has accumulated losses of \$67,399. In the six months ended June 30, 2022, the Company generated losses of \$8,968 and negative cash flows from operating activities of \$6,845.

To date, management expects the Company to continue to generate substantial operating losses and to continue to fund its operations primarily through utilization of its current financial resources, sales of its products, and through additional raising of capital. As of August 31, 2022, the Company’s cash, cash equivalents and short-term deposits were \$15,388.

Management expects that its cash, cash equivalents and short-term deposits, as of the issuance date of the financial statements, will be sufficient for 12 months of operations.

ICECURE MEDICAL LTD.

NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share data and per share data)

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

A. Basis of presentation

The unaudited interim condensed consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States (“U.S. GAAP”). Accordingly, they do not include all of the information and notes required by U.S. GAAP for annual financial statements. The information included in these condensed interim financial statements should be read in conjunction with the consolidated financial statements and accompanying notes included in the Company’s annual financial statements. In the opinion of management, these unaudited condensed consolidated financial statements reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of results for the interim period. The results for the interim periods are not necessarily indicative of the results to be expected for the full year.

B. Use of estimates:

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Management believes that the estimates, judgments and assumptions used are reasonable based upon information available at the time they are made. Actual results could differ from those estimates.

C. Significant Accounting Policies

The significant accounting policies followed in the preparation of these unaudited interim condensed consolidated financial statements are identical to those applied in the preparation of the latest annual financial statements.

D. New Accounting Pronouncements Not Yet Effective:

In August 2020, the FASB (Financial Accounting Standards Board) issued ASU No. 2020-06, Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity’s own equity. Among other changes, ASU No. 2020-06 removes from U.S. GAAP the liability and equity separation model for convertible instruments with a cash conversion feature, and as a result, after adoption, entities will no longer separately present in equity an embedded conversion feature for such debt. ASU No. 2020-06 also eliminates the treasury stock method to calculate diluted earnings per share and requires the if-converted method. This new standard will be effective for us in fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. We are currently assessing the impact of adopting this standard on our financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which affects general principles within Topic 740, Income Taxes and is meant to simplify and reduce the cost of accounting for income taxes. This standard is effective for annual reporting periods beginning after December 15, 2021, and interim reporting periods within annual reporting periods beginning after December 15, 2022. We are currently reviewing this standard but do not expect that it will have a material impact on our financial statements.

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NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share data and per share data)

NOTE 3 - SHAREHOLDERS' EQUITY

- A. On January 12, 2022, the Company granted 1,720,660 options to purchase an aggregate of 1,720,660 ordinary shares to 59 optionees of the Company, as follows: (i) 333,992 options to the Company's CEO, the Chairman of the board of directors and a member of the board of directors; (ii) 443,674 options to five officers of the Company; and (iii) 942,994 options to 51 employees of the Company, at an exercise price of \$3.63 per share. The options granted to the CEO, chairman of the board, board member and the officers will vest as follows: a quarter after one year and the balance will vest in 12 equal quarterly installments over a period of three years from January 12, 2022. The options granted to the 51 employees will vest in four equal installments over a period of four years from the date of grant. The options are exercisable for 10 years from the date of grant.
- B. On March 23, 2022, the Company granted 30,434 options to purchase an aggregate of 30,434 ordinary shares to five officers of the Company, as follows: (i) 13,720 options for the Company's CEO; and (ii) 16,714 options for four officers, at an exercise price of \$1.98 per share. The options will vest as follows: a quarter after one year and the rest will vest in 12 equal quarterly installments over a period of three years from March 23, 2022. The options are exercisable for 10 years from the date of grant
- C. On June 3, 2022, 1,034,000 pre-funded warrants issued as part of our public offering that closed on December 8, 2021 were exercised into 1,034,000 ordinary shares at an exercise price of \$0.001 per share.

NOTE 4 - REVENUES

The Company's revenues are derived primarily from the sale of consoles and disposables. Revenues from warranty and services are not material and therefore are included in revenue from consoles in the following table.

Composition:

	Six months ended June 30, 2022	Six months ended June 30, 2021
Consoles	361	695
Disposables	667	556
Exclusive distribution agreement	484	822
	<u>1,512</u>	<u>2,073</u>

NOTE 5 - SUBSEQUENT EVENTS

The following are the significant events that took place subsequent to June 30, 2022:

- A. On July 4, 2022, the Company granted 55,222 options to purchase an aggregate of 55,222 ordinary shares to a consultant of the company, at an exercise price of NIS 6.208 (approximately \$1.76) per share. The options will vest as follows: 8 equal quarterly installments over a period of two years from October 4, 2022. The options are exercisable for 10 years from the date of grant
- B. On July 18, 2022, the Company issued 21,000 restricted ordinary shares to a consultant of the Company. The shares shall be restricted from any offer, sale, contract for sale, encumbrance, grant any options for the sale of or otherwise disposed for a period of 12 months from July 1, 2022.

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION
AND RESULTS OF OPERATIONS**

Cautionary Statement Regarding Forward-Looking Statements

Certain information included herein may be deemed to be "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and other securities laws. Forward-looking statements are often characterized by the use of forward-looking terminology such as "may," "will," "expect," "anticipate," "estimate," "continue," "believe," "should," "intend," "project" or other similar words, but are not the only way these statements are identified.

These forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, statements that contain projections of results of operations or of financial condition, expected capital needs and expenses, statements relating to the research, development, completion and use of our products, and all statements (other than statements of historical facts) that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. We have based these forward-looking statements on assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate

Important factors that could cause actual results, developments and business decisions to differ materially from those anticipated in these forward-looking statements include, among other things:

- our planned level of revenues and capital expenditures;
 - our ability to market and sell our products;
 - our plans to continue to invest in research and development to develop technology for both existing and new products;
 - our ability to maintain our relationships with suppliers, manufacturers and other partners;
 - our ability to maintain or protect the validity of our European, U.S. and other patents and other intellectual property;
 - our ability to retain key executive members;
 - our ability to internally develop and protect new inventions and intellectual property;
-

- our ability to expose and educate physicians and other medical professionals about the use cases of our products;
- our expectations regarding our tax classifications;
- interpretations of current laws and the passage of future laws;
- the impact of COVID-19 and resulting government actions on us, our manufacturers, suppliers and facilities in which our ProSense system is used or in which our products are undergoing trials; and
- those factors referred to in “Item 3.D. Risk Factors,” “Item 4. Information on the Company,” and “Item 5. Operating and Financial Review and Prospects” in our Annual Report (as defined below).

These statements are only current predictions and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. For a more detailed description of the risks and uncertainties affecting our company, reference is made to our annual report on Form 20-F for the fiscal year ended December 31, 2021 which we filed with the Securities and Exchange Commission, or the SEC, on April 1, 2022, or the Annual Report, and the other risk factors discussed from time to time by our company in reports filed or furnished to the SEC.

Except as required by law, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this prospectus.

Unless otherwise indicated, all references to “we,” “us,” “our,” the “Company” and “IceCure” refer to IceCure Medical Ltd. and its wholly owned subsidiaries, IceCure Medical Inc., a Delaware corporation, IceCure Medical HK Limited a Hong Kong corporation and IceCure (Shanghai) MedTech Co., Ltd., a subsidiary of IceCure Medical HK Limited.

Our reporting currency and functional currency is the U.S. dollar. Unless otherwise expressly stated or the context otherwise requires, references in this prospectus to “NIS” are to New Israeli Shekels, and references to “dollars” or “\$” mean U.S. dollars.

We report our financial statements in accordance with generally accepted accounting principles in the United States, or U.S. GAAP.

Overview

We are a commercial stage medical device company focusing on the research, development and marketing of cryoablation systems and technologies based on LN2 for treating tumors. Cryoablation is the process by which benign and malignant tumors are ablated (destroyed) through freezing such tumors while in a patient’s body. Our proprietary cryoablation technology is a minimally invasive alternative to surgical intervention, for tumors, including those found in breast, lungs, kidneys and bones and other indications. Our lead commercial cryoablation product is the ProSense system.

Components of Operating Results

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited interim condensed consolidated financial statements and the related notes thereto for the six months ended June 30, 2022, included elsewhere in this Report of Foreign Private Issuer on Form 6-K. The discussion below contains forward-looking statements that are based upon our current expectations and are subject to uncertainty and changes in circumstances. Actual results may differ materially from these expectations due to inaccurate assumptions and known or unknown risks and uncertainties

Revenues

Our revenues primarily consist of (i) selling our ProSense system and its disposables and related services; and (ii) revenues from granting the exclusive distribution rights to our products in Japan and Singapore to Terumo Corporation, which also include providing technical, regulatory and clinical materials and support in obtaining regulatory approvals.

Cost of Revenues

Our cost of revenues consists primarily of salaries and related personnel expenses, materials for production of our products, subcontractors' expenses and other related production expenses.

Gross Margin

Gross margin, or gross profit as a percentage of revenue, is affected by a variety of factors which influence our revenues and the cost of goods sold. Revenues are affected mostly by the different selling prices depending on sales channels, territories and the mix of products and currency fluctuation, mainly the U.S. Dollar against the Euro. The cost of revenues is affected mostly by the changes in cost of materials and import costs, subcontractors' costs, cost of personal, and currency fluctuation, mainly the U.S. Dollar against the NIS. Our gross margin, is also affected by production volumes and production efficiency.

Operating Expenses

Our current operating expenses consist of three components — research and development expenses, marketing and sales expenses and general and administrative expenses.

Research and Development Expenses

Our research and development expenses consist primarily of salaries and related benefits, subcontractor's expenses, materials and other related research and development expenses, clinical studies and regulation expenses.

We expect that our research and development expenses will materially increase as we continue to develop our new products, pursue new regulatory indications in the US and other territories, collect updated clinical data, and recruit additional research and development and regulation employees.

Sales and Marketing

Our sales and marketing expenses consist primarily of salaries and related benefits, payments to consultants, costs associated with conventions, travel and other marketing and sales expenses.

We expect that our sales and marketing expenses will materially increase as we continue to enhance our market penetration efforts and recruit additional sales and marketing employees.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, professional services fees for accounting, legal, directors' fees, facilities, and associate costs, insurance and other general and administrative expenses. We expect our general and administrative expenses to increase as a result of being a public company listed on Nasdaq and the expansion of our business.

Financial expense and income

Financial expenses and income consist primarily of exchange rate differences, interest expenses and income on cash and cash equivalents, deposits and other assets and liabilities which are denominated in NIS and Euros.

Comparison of the Six Months Ended June 30, 2022 and 2021

Results of Operations

The following table sets forth our results of operations for the periods presented.

U.S. dollars in thousands	Six Months Ended June 30,	
	2022	2021
Revenues	\$ 1,512	\$ 2,073
Cost of revenues	694	880
Gross profit	\$ 818	\$ 1,193
Research and development expenses	4,649	2,730
Marketing and sales expenses	1,533	625
General and administrative expenses	3,342	1,584
Operating loss	\$ 8,706	\$ 3,746
Financial expenses, net	262	101
Net loss and comprehensive loss	\$ 8,968	\$ 3,847
Basic and diluted net loss per share	\$ 0.244	\$ 0.156

Revenues

The following table summarizes our revenues by types for the periods presented. The period-to-period comparison of results is not necessarily indicative of results for future periods.

U.S. dollars in thousands	Six Months Ended June 30,	
	2022	2021
Systems	\$ 361	\$ 695
Disposables	667	556
Exclusive distribution agreement	484	822
Total	\$ 1,512	\$ 2,073

The following table summarizes our revenues by geographic region for the periods presented. The period-to-period comparison of results is not necessarily indicative of results for future periods.

U.S. dollars in thousands	Six Months Ended June 30,	
	2022	2021
Japan	\$ 592	\$ 855
United States	346	110
Spain	147	108
Israel	16	12
Thailand	12	415
France	225	181
Other	174	392
Total	\$ 1,512	\$ 2,073

Our revenues for the six months ended June 30, 2022 decreased by 27% to \$1,512 thousand, compared to \$2,073 thousand for the six months ended June 30, 2021. The decrease is attributable to a decrease of 48% in sales of systems and 41% in revenue recognition from our exclusive distribution agreement with Terumo Corporation and Terumo Thailand, respectively, to \$361 thousand and \$484 thousand for the six months ended June 30, 2022 compared to \$695 thousand and \$822 thousand for the six months ended June 30, 2021. This was offset by higher revenues from disposables which increased by 20% to \$667 thousand for the six months ended June 30, 2022 compared to \$556 thousand for the six months ended June 30, 2021.

Accordingly, our revenues in Japan decreased by 31% to \$592 thousand for the six months ended June 30, 2022, of which \$108 thousand are from sales of products, and \$484 thousand are revenues from our exclusive distribution agreement with Terumo Corporation. For the six months ended June 30, 2021, our revenues from sales of products in Japan were \$33 thousand and our revenues from our exclusive distribution agreement with Terumo Corporation were \$822 thousand. Our revenues from sales in the United States increased by 215% to \$346 thousand for the six months ended June 30, 2022, compared to \$110 thousand for the six months ended June 30, 2021. We did not have any sales in China for the six months ended June 30, 2022 since we are in the process to obtain regulatory approvals for our Probes. We also had no revenues from sales of products in Thailand for the six months ended June 30, 2022 mostly due to the slow recovery of the Thailand market from COVID 19. Our revenues from sales in Europe increased by 36% to \$506 thousand for the six months ended June 30, 2022, compared to \$372 thousand for the six months ended June 30, 2021

Cost of Revenues and Gross Profit

The following table summarizes our cost of revenues for the periods presented, as well as presenting the gross profit as a percentage of total revenues. The period-to-period comparison of results is not necessarily indicative of results for future periods.

U.S. dollars in thousands	Six Months Ended June 30,	
	2022	2021
Payroll and related benefits (including Share-based compensation)	\$ 447	\$ 371
Raw materials, subcontractors, and auxiliary materials (including changes in inventories)	56	343
Shipping	36	18
Royalties to IIA	49	62
Others	106	86
Total	\$ 694	\$ 880
Gross profit	\$ 818	\$ 1,193
Gross margin	54%	58%

Our cost of revenues for the six months ended June 30, 2022 decreased by 21% to \$694 thousand, compared to \$880 thousand for the six months ended June 30, 2021. Our gross profit for the six months ended June 30, 2022 decreased by 31% to \$818 thousand, which is 54% of our revenues for the six months ended June 30, 2022. Our gross profit for the six months ended June 30, 2021 was \$1,193 thousand which is 58% of our revenues for the same period. The decrease in gross profit is primarily due to decrease in revenue recognition from our exclusive distribution agreement with Terumo and in sales. The decrease in our gross margin is primarily attributable to the decrease in sales and in revenue recognition from the Terumo distribution agreement.

Research and development expenses

The following table summarizes our research and development costs for the periods presented. The period-to-period comparison of results is not necessarily indicative of results for future periods.

U.S. dollars in thousands	Six Months Ended June 30,	
	2022	2021
Payroll and related benefits (including share-based compensation)	\$ 2,922	\$ 1,683
Raw materials, subcontracted work and consulting	1,052	790
Others	675	257
Total	\$ 4,649	\$ 2,730

Research and development, or R&D, expenses increased by 70% to \$4,649 thousand during the six months ended June 30, 2022, compared with \$2,730 thousand for the six months ended June 30, 2021. The increase is primarily due to an increase in employee related costs, raw materials subcontractors and consulting costs. This increase reflects our strategy to focus on the development of our next generation MultiSense and single probe systems and activity related to clinical data collection and regulatory approvals.

Sales and marketing expenses

The following table summarizes our sales and marketing costs for the periods presented. The period-to-period comparison of results is not necessarily indicative of results for future periods.

U.S. dollars in thousands	Six Months Ended June 30,	
	2022	2021
Payroll and related benefits (including Share-based compensation)	\$ 752	\$ 335
Consultants and professional services	180	76
Travel	153	34
Advertising and promotion expenses	46	42
Sales Commissions	4	26
Others	398	112
Total	\$ 1,533	\$ 625

Selling and marketing expenses for the six months ended June 30, 2022 increased by 145% to \$1,533 thousand, compared to \$625 thousand for the six months ended June 30, 2021. The increase of selling and marketing expenses reflects our strategy to expand our marketing activities, which in 2021 were limited in part due to COVID-19 related restrictions. The increase during the six months ended June 30, 2022 compared to the six months ended June 30, 2021 is mostly due to an increase in salaries and marketing consulting expenses, as well as travel and other expenses.

General and administrative expenses

The following table summarizes our general and administrative costs for the periods presented. The period-to-period comparison of results is not necessarily indicative of results for future periods.

U.S. dollars in thousands	Six Months Ended June 30,	
	2022	2021
Payroll and related benefits (including Share-based compensation)	\$ 1,242	\$ 644
Professional services	2,016	794
Others	84	146
Total	\$ 3,342	\$ 1,584

General and administrative expenses increased by 111% to \$3,342 thousand for the six months ended June 30, 2022, compared to \$1,584 thousand for the six months ended June 30, 2021. This increase is primarily due to higher costs of salaries and related benefits, Insurance, professional services and audit expenses related to our listing on Nasdaq.

Operating loss

Based on the foregoing, our operating loss increased to \$8,706 thousand for the six months ended June 30, 2022 from \$3,746 thousand for the six months ended June 30, 2021.

Financial expenses, net

Financial expenses, net for the six months ended June 30, 2022 were \$262 thousand compared to \$101 thousand for the six months ended June 30, 2021. The increase in our net financial expenses is primarily because of the NIS strengthening against the U.S. dollar on our net NIS denominated assets, including cash and cash equivalents and deposits.

Net loss

Net loss for the six months ended June 30, 2022 increased by \$5,121 thousand or 133%, to \$8,968 thousand, compared with a net loss of \$3,847 thousand for the six months ended June 30, 2021. This increase is primarily attributable to: (i) decrease in revenue and gross profit, increase in operating expenses, and (ii) the increase in net financial expenses, as described above.

Liquidity and Capital Resources

Overview

Since our inception through June 30, 2022, we have funded our operations principally from the issuance of ordinary shares, options, convertible securities, loans, revenues from sale of products and grants received from the Israeli Innovation Authority, or IIA. As of June 30, 2022, we had \$17,725 thousand in cash and cash equivalents and short-term bank deposits, compared with \$25,621 thousand as of December 31, 2021 and \$18,613 thousand as of June 30, 2021.

The table below presents our cash flows for the periods indicated.

U.S. dollars in thousands	Six Months Ended June 30,	
	2022	2021
Net cash used in operating activities	(6,845)	(3,561)
Net cash provided by (used in) investing activities	(4,770)	4,079
Net cash provided by financing activities	1	14,642
Effect of foreign currency exchange rates on cash and cash equivalents:	(539)	(49)
Net increase (decrease) in cash and cash equivalents	(12,153)	15,111

Operating Activities

Cash flows from operating activities consist primarily of loss adjusted for various non-cash items, including depreciation and amortization and share-based compensation expenses. In addition, cash flows from operating activities are impacted by changes in operating assets and liabilities, which include inventories, accounts receivable, other assets, accounts payable and other current liabilities.

Net cash used in operating activities for the six months ended June 30, 2022 was \$6,845 thousand. This net cash used in operating activities primarily reflects a net loss of \$8,968 thousand, which is decreased by non-cash expenses of \$1,551 thousand and by a net change in operating assets and liabilities of \$572 thousand.

The net decrease in changes in operating assets and liabilities for the six months ended June 30, 2022 are attributed mainly to decrease in prepaid expenses and other receivables, trade accounts receivables, other long-term liabilities and increase in other current liabilities and inventories. This net decrease was partially offset by an increase in inventories and a decrease in other long-term liabilities.

Net cash used in operating activities for the six months ended June 30, 2021 was \$3,561 thousand. This net cash used in operating activities primarily reflects a net loss of \$3,847 thousand, which is decreased by non-cash expenses of \$331 thousand and increased by a net change in operating assets and liabilities of \$45 thousand.

The net increase in changes in operating assets and liabilities for the six months ended June 30, 2021 are attributed mainly to an increase in inventories and in prepaid expenses and other receivables. This increase was partially offset by an increase in other current liabilities and in trade accounts payable.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2022 was \$4,770 thousand. This net cash used in investing activities is primarily attributable to investment of \$4,277 thousand in bank deposits and \$493 was attributed to the purchase of property and equipment.

Net cash provided by investing activities for the six months ended June 30, 2021 was \$4,079 thousand. This net cash provided by investing activities is primarily attributable to realization of \$4,621 thousand of bank deposits, which was partially offset due to the purchase of \$247 thousand in property and equipment, and investment in restricted deposits which amounted to \$295 thousand.

Financing Activities

Net cash provided by financing activities for six months ended June 30, 2022 was \$1 thousand, which were attributed to exercise of pre-funded warrants

Net cash provided by financing activities for six months ended June 30, 2021 was \$14,642 thousand, of which \$14,586 thousand is attributed to net proceeds from the issuance of Ordinary Shares pursuant to the January 2021 SPA.

Financial Arrangements

Since our inception through our initial public offering on TASE on February 2, 2011, we have funded our operations primarily through the private sale of equity securities and convertible debt in an aggregate amount of \$8.9 million. Since our inception, we also have received an aggregate of \$2.5 million (including accumulated interest) from the IIA.

Since our initial public offering on TASE through June 2019, we raised an aggregate of \$33.1 million, in public offerings of equity securities, rights offerings and convertible debt, and a private placement to Epoch Investment Partners Limited, or the Epoch SPA, who became our controlling shareholder on February 7, 2015. Pursuant to the Epoch SPA, we received a total of \$5,485 thousand against issuance of 1,892,858 Ordinary Shares and 283,929 warrants. The warrants were not exercised and expired. Since then we performed multiple public offerings and rights offerings.

Since June 2019, we have funded our operations mainly through a number of public and rights offerings in an aggregate amount of \$40.7 million.

On August 12, 2020, we received an unsecured loan under the United States Small Business Administration, or the SBA, PPP pursuant to the Coronavirus Aid, Relief, and Economic Security Act in the amount of \$24,898. The five year SBA-administered PPP loan has an interest rate of 1.0% per annum. According to the terms of the loan, as long as a borrower submits its loan forgiveness application within 10 months of the completion of the covered period of such loan, the borrower is not required to make any payments until the forgiveness amount is remitted to the lender by SBA. If the loan is fully forgiven, the borrower is not responsible for any payments. If only a portion of the loan is forgiven, or if the forgiveness application is denied, any remaining balance due on the loan must be repaid by the borrower on or before the maturity date of the loan. Interest accrues during the time between the disbursement of the loan and SBA remittance of the forgiveness amount. In May 2021, the loan was forgiven.

On January 26, 2021, we entered into the January 2021 SPA with the January 2021 Investors. Pursuant to the January 2021 SPA, on March 9, 2021, we received \$9 million and issued 6,891,418 Ordinary Shares, and on May 9, 2021, we received \$6 million and issued 4,594,279 Ordinary Shares.

On December 13, 2021, we raised gross proceeds of \$17.0 million through a public offering of 3,892,152 Ordinary Shares, inclusive of 578,325 shares offered pursuant to the underwriters' over-allotment option, at a public offering price of \$3.45 per share before underwriting discounts and commissions, and to certain investors in lieu of ordinary shares, pre-funded warrants to purchase up to an aggregate of 1,034,000 ordinary shares at a price to the public of \$3.449 per pre-funded warrant, which represents the per share public offering price for the ordinary shares less the \$0.001 per share exercise price for each such pre-funded warrant. After deducting closing costs, underwriting discounts, commissions and fees, our net proceeds from this offering were \$16.0 thousand. On June 3, 2022, 1,034,000 pre-funded warrants were exercised to 1,034,000 ordinary shares at an exercise price of \$0.001 per share.

Current Outlook

We have financed our operations to date primarily through proceeds from sales of our Ordinary Shares and convertible securities, sales of our products and grants from the IIA. We have incurred losses and generated negative cash flows from operations since inception in 2006. Since 2012, we have generated revenues from the sale of our products and revenues from granting the exclusive distribution rights to our products in Japan and Singapore to Terumo Corporation, which also include providing technical, regulatory and clinical materials and support in obtaining regulatory approvals.

We expect to generate revenues from the sale of our products and other revenues in the future. However, we do not expect these revenues to support all of our operation in the near future. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the development of our MultiSense system, and continue our commercialization efforts. Furthermore, we expect to incur additional costs associated with operating as a Nasdaq public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

As of June 30, 2022, our cash, cash equivalents and short-term deposits were \$17,725 thousand, and we had a working capital of \$17,237 thousand and an accumulated deficit of \$67,399 thousand. We expect that our existing cash, cash equivalents and short-term deposits will be sufficient for the next 12 months of operation; however, we expect that we will require substantial additional capital to continue the development of, and to commercialize our products. In addition, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future capital requirements will depend on many factors, including:

- our ability to sell our products according to our plans;
- the progress and cost of our research and development activities;
- the costs associated with the manufacturing our products;
- the costs of our clinical trials and obtaining regulatory approvals;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the cost of our commercialization efforts, marketing, sales and distribution of our products the potential costs of contracting with third parties to provide marketing and distribution services for us or for building such capacities internally; and
- the magnitude of our general and administrative expenses.

Until we can generate significant recurring revenues and profit, we expect to satisfy our future cash needs through debt or equity financings. We cannot be certain that additional funding will be available to us when needed, on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate research or development plans, and/or commercialization efforts and/or regulatory efforts with respect to our products in different territories. This may raise substantial doubts about our ability to continue as a going concern.

Critical Accounting Policies and Estimates

The preparation of financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. A comprehensive discussion of our critical accounting policies is included in “Critical Accounting Policies and Estimates” under “Operating and Financial Review and Prospects” section in our Annual Report, as well as our unaudited interim condensed consolidated financial statements and the related notes thereto as of and for the six months ended June 30, 2022, included elsewhere in this Report of Foreign Private Issuer on Form 6-K.

We prepare our financial statements in accordance with U.S. GAAP. At the time of the preparation of the financial statements, our management is required to use estimates, evaluations, and assumptions which affect the application of the accounting policy and the amounts reported for assets, obligations, income, and expenses. Any estimates and assumptions are continually reviewed. The changes to the accounting estimates are credited during the period in which the change to the estimate is made.

Use of estimates in the preparation of financial statements:

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Management believes that the estimates, judgments and assumptions used are reasonable based upon information available at the time they are made. Actual results could differ from those estimates.

Share-based compensation

We measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees are required to provide services. Share-based compensation arrangements include options, performance-based awards, share appreciation rights, and employee share purchase plans. We amortize such compensation amounts, if any, over the respective service periods of the award. We use the Black-Scholes-Merton option pricing model, or the Black-Scholes Model, an acceptable model in accordance with ASC 718, Compensation-Stock Compensation, to value options. Option valuation models require the input of assumptions, including the expected life of the stock-based awards, the estimated stock price volatility, the risk-free interest rate, and the expected dividend yield. The risk-free interest rate assumption is based upon the yield from Israel Treasury zero-coupon bonds with an equivalent term. Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the term of the award. Our calculation of estimated volatility is based on historical stock prices over a period equal to the expected term of the awards. The average expected life of options was based on the contractual terms of the stock option using the simplified method. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. The assumptions used in calculating the fair value of share-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future. We recognize the compensation expense for share-based compensation granted based on the grant date fair value estimated in accordance with ASC 718. We generally recognize the compensation expense over the employee's requisite service period. We account for forfeitures when they occur.