November 13, 2023

Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

Brad Sorensen
312-265-9574
bsorensen@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Organovo Holdings (ONVO-NASDAQ)

ONVO: Earnings Verify Company Remains on Track

ONVO is a biotech company with dual revenue paths that compliment one another—3D technology and drug development. We value ONVO at $12.15/share using the discounted cash flow method.

Current Price (11/10/23)	$1.21
Valuation	**$12.15**

OUTLOOK

Organovo is a biotech company that has 3D technology enabling the company to produce various human tissues, allowing the company to target diseases and accelerate the drug development process.

The company continues along the approval path and reported fiscal 2Q results that were inline with estimates and confirm the company remains on the right track.

SUMMARY DATA

52-Week High	**$3.20**
52-Week Low	**$1.05**
One-Year Return (%)	**-16.67**
Beta	**0.84**
Average Daily Volume (sh)	**153,476**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$12**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**N/A**
P/E using 2025 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.**
Type of Stock	**Small-Value**
Industry	**Biotech**

ZACKS ESTIMATES

Revenue
(in thousands of $)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2022	N/A	N/A	N/A	N/A	370 A
2023	75 A	0 A	75 E	75 E	225 E
2024	100 E	100 E	120 E	124 E	444 E
2025	130 E	130 E	130 E	143 E	533 E

Earnings

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2022	N/A	N/A	N/A	N/A	-$1.98 A
2023	-$0.46 A	-$0.46 A	-$0.41 E	-$0.42 E	-$1.75 E
2024	-$0.46 E	-$0.46 E	-$0.50 E	-$0.49 E	-$1.91 E
2025	-$0.45 E	-$0.45 E	-$0.46 E	-$0.49 E	-$1.85 E

© Copyright 2023, Zacks Investment Research. All Rights Reserved.

Update

Organovo reported its fiscal 2Q earnings and results were roughly inline with our expectations and illustrate to us that the company continues to progress toward bringing important products to market. Specifically, the company reported:

- Earnings of -$0.46 per share, inline with estimates as expenses remained steady.
- Cash and cash equivalents of $7.6 million, allowing the company to continue move forward in the face of tighter credit conditions.

Organovo Holdings is a biotechnology company that is both a developer of 3D tissue technology that has the potential to change the way treatments are discovered and tested, as well as being a creator of new therapies using that technology, the focus of which is currently around the intestinal area and inflammatory bowel disease—something which impacts over 3 million Americans according to the CDC.

It is this dual path and how the two paths can work together that excites us about Organovo. Regarding the 3D technology, Organovo's advances in the area include cell type-specific compartments, prevalent intercellular tight junctions, and the formation of microvascular structures. Management believes these attributes can enable critical complex, multicellular disease models that can be used to develop clinically effective drugs across multiple therapeutic areas. The company's technology, known as NovoGen Bioprinters, are automated devices that enable the fabrication of 3D living tissues comprised of mammalian cells. The Company believes that the use of its bioprinting platform as well as complementary 3D technologies will allow it to develop an understanding of disease biology that leads to validated novel drug targets and therapeutics to those targets to treat disease. To this point, the company's technology has been used to create a wide variety of tissues such as: healthy liver, NASH (nonalcoholic steatohepatitis) liver, kidney, intestine, skin, vascular, bone, skeletal muscle, eye, breast and pancreatic tumor.

There are two avenues that we believe the company can benefit from this technology. First, Organovo can use the technology internally to develop drugs that able to be tailored more specifically to the targeted condition because the company can manipulate the 3D created tissues to reflect the disease as it would appear in actual human tissue. This also allows the company to move through the initial stages of research and testing in a more rapid and precise manner, which makes the process more efficient and cost effective and the treatments potentially more effective.

Additionally, many clinical stage companies have no revenue inflows to help offset the costs of developing much needed treatments. However, as already demonstrated, Organovo has the ability to license the company's 3D technology to other companies to aid in their research process, leading to a revenue stream coming into Organovo as it continues to push to bring treatments to the market. According to company management, any deal achieved with a pharma company, Organovo intends to avoid "fee for services" revenue, which it believes provides limited benefit. Instead, the company will target deals with large, up-front payments, followed by milestone payments that the company believe could be in the hundreds of millions of dollars. These deals will involve the company working with the pharma partner to push novel drugs to the market. The partner company would own the rights to the drug, but Organovo would expect to earn milestone payments as a drug advances and royalties upon a drug's commencement of commercial sales. These deals can be hard to predict the timing or probability of, but when achieved they have the potential to provide further validation of the company's science and approach, as well as being a potential catalyst for investors.

The other path is the drug development path, which is obviously complemented and fueled by the 3D technology side of the business. Organovo has the potential to develop drugs in a more cost-effective manner and at a quicker rate by using 3D-created tissue as opposed to animal subjects. This ability also has the potential to provide more effective treatments due to the testing being done

on human tissue as opposed to animal tissue, which also has the advantage of saving the animal as well.

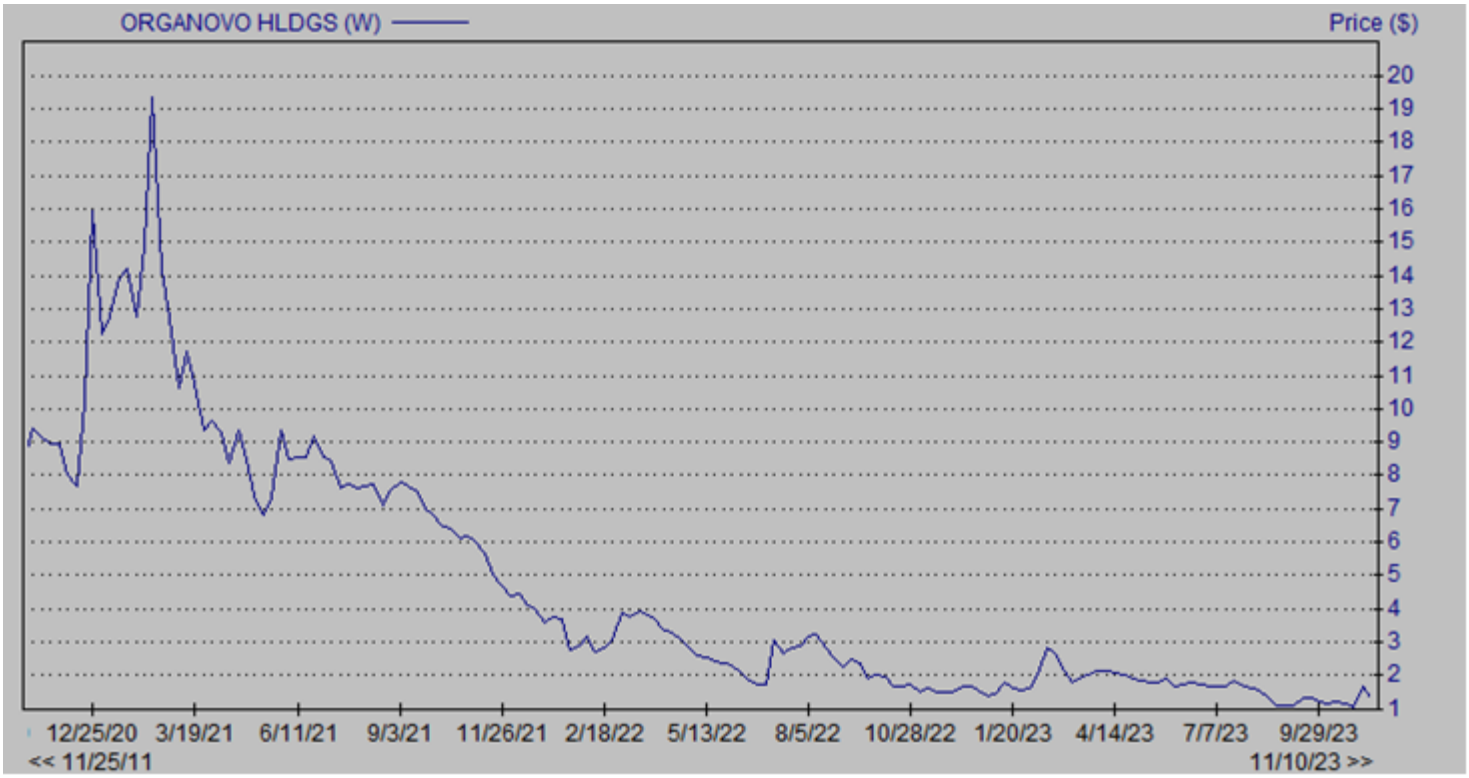
As mentioned, the company is currently focusing on treatments surrounding IBD and the initial test results look promising and a Phase 2 trial for its signature treatment is approved to proceed by the FDA and will get started soon.

We believe Organovo is at a good spot for potential investors, with a proven technology that is bringing in revenue and is about to begin human testing on a treatment for a condition that millions of people are dealing with.

PROJECTED INCOME STATEMENT & BALANCE SHEET

Organovo Holdings Income Statement and Balance Sheet							
(in thousands except for share data)							
March 31 Fiscal Year End							
	2022A	1Q2023A	2Q2023A	3Q2023E	4Q2023E	2024E	2025E
Revenue							
Royalty Revenue	370	75	0	75	75	444	533
Sales	0	0	0	0	0	0	0
Total Revenue	370	75	0	75	75	444	533
Research and Dev. Expense	8,885	1,666	1,335	1,348	1,362	9,063	9,244
Selling, general and admin. Expense	9,216	2,604	2,780	2,808	2,836	9,400	9,588
Total cost and expenses	18,101	4,270	4,115	4,156	4,198	18,463	18,832
Gain/(loss) from Operations	(17,731)	(4,195)	(4,115)	(4,081)	(4,123)	(18,019)	(18,299)
Other Income (Expense)							
Interest Income	454	157	121	457	458	459	460
Other Income (Expense)	20	12	(1)	20	20	20	20
Total Other Income (Expense)	474	169	120	477	478	479	480
Income Tax Expense	(2)	(2)	0	1	2	3	4
Net Gain (Loss)	(17,259)	(4,028)	(3,995)	(3,603)	(3,643)	(17,537)	(17,815)
Other Comprehensive income	2	0	0	5	6	7	8
Comprehensive gain (loss)	(17,257)	(4,028)	(3,995)	(3,598)	(3,637)	(17,530)	(17,807)
Gain/(loss) per share	($1.98)	($0.46)	($0.46)	($0.41)	($0.42)	($1.91)	($1.85)
Weighted Avg Shares of Common Stock	8,713,032	8,717,232	8,718,502	8,718,502	8,718,502	9,154,427	9,612,148
Assets							
Current Assets							
Cash and cash equivalents	15,301	10,754	7,617	7,769	7,925	8,083	8,245
Accounts Receivable	152	149	55	56	57	58	60
Other current assets	1,595	792	624	636	649	662	675
Total Current Assets	17,048	11,695	8,296	8,462	8,631	8,804	8,980
Fixed assets	902	850	808	816	824	832	841
Restricted cash	143	143	143	143	143	143	143
Operating lease right-of-use	1,705	1,606	1,505	1,430	1,358	1,290	1,226
Other assets	515	462	409	413	417	421	426
Total Assets	20,313	14,756	11,161	11,264	11,374	11,491	11,615
Liabilities and Stockholder Equity							
Current Liabilities							
Accounts Payable	331	488	435	444	453	462	471
Accrued Expenses	2,848	787	666	679	693	707	721
Operating Lease, current portion	492	495	499	509	519	530	540
Total Current Liabilities	3,671	1,770	1,600	1,632	1,665	1,698	1,732
Operating lease, net of current portion	1,313	1,210	1,105	1,316	1,317	1,318	1,319
Total Liabilities	4,984	2,980	2,705	2,948	2,982	3,016	3,051
Stockholder Equity							
Common Stock	9	9	9	9	9	9	9
Additional paid-in capital	340,317	340,792	341,467	340,317	340,317	340,317	340,317
Accumulated deficit	(324,998)	(329,026)	(333,020)	(332,011)	(331,935)	(331,852)	(331,763)
Other SE	1	1	0	1	1	1	1
Total Stockholders' Equity	15,329	11,776	8,456	8,316	8,392	8,475	8,564
Total Liabilities and SE Equity	20,313	14,756	11,161	11,264	11,374	11,491	11,615

HISTORICAL STOCK PRICE



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Brad Sorensen, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.