June 4, 2024

Zacks Small-Cap Research

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Organovo Holdings (ONVO-NASDAQ)

ONVO: Annual Report Bolsters Case for Company

ONVO is a biotech company with dual revenue paths that compliment one another—3D technology and drug development. We value ONVO at $8.55/share using the discounted cash flow method.

Current Price (06/03/24)	$1.04
Valuation	**$8.55**

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 released its annual report that showed good cash balances, and also recently released positive Phase 2 results for one of its primary treatments—FXR314. These results are very encouraging and bolster our belief in the future prospects for ONVO.

SUMMARY DATA

52-Week High	**$1.94**
52-Week Low	**$0.90**
One-Year Return (%)	**-38.46**
Beta	**0.68**
Average Daily Volume (sh)	**161,562**
Shares Outstanding (mil)	**10**
Market Capitalization ($mil)	**$10**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
Insider Ownership (%)	**4**
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	0 A	34 A	109 A
2024	27 E	27 E	28 E	30 E	112 E
2025	30 E	35 E	35 E	31 E	131 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	-$0.40 A	-$0.28 A	-$1.60 A
2024	-$0.38 E	-$0.36 E	-$0.35 E	-$0.31 E	-$1.40 E
2025	-$0.33 E	-$0.33 E	-$0.31 E	-$0.26 E	-$1.23 E

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Update

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 company released its annual report for 2023, fiscal year ended March 31, 2024, which showed the company continuing to make progress to both change the way medicines are created and tested, as well as creating it own therapies. As with all clinical stage companies, cash available for operations is one of the key measures that we look at. Having a measure of certainty regarding the ability of the company to continue to operate and make progress toward its goals is a key component of all such companies. Regarding Organovo, we were extremely pleased to see, due to events after the March 31, 2024 cutoff date such as a share issuance, the company had approximately $7.0 million on its balance sheet. This infusion of cash reinforces our belief that Organovo can attract investors and will be able to continue to advance towards its goal.

Giving us additional confidence, the company recently released Phase 2 results for one of the therapies being advanced by ONVO by the name of FXR 314. The trial was to determine the effectiveness of FXR314 in treating metabolic function-associated steatohepatitis (MASH), which is a condition affecting approximately 115 million people worldwide according to the Boehringer Institute, which is expected to increase by roughly 25% by 2050. MASH, briefly, is a condition that can develop when excess fat is stored in the liver and causes inflammation of the liver, which can lead to a variety of problems, including liver failure. The serious nature of this condition is part of the reason we are excited about results from the Phase 2 trial, which showed a significant reduction in liver fat content for trial participants, with a mean reduction of 23% for those with 3 mg doses of FXR314, compared to a 6.1% reduction seen in those participants with a placebo.

Additionally, the company found that FXR 314 was found to be safe and effective. CEO Keith Murphy noted that, “The key findings of this study are that the once daily oral FXR314 demonstrated statistically significant liver fat reduction and excellent tolerability.”

These results reinforce our belief that ONVO is pursuing a path for developing drugs that is more effective and efficient and should prove to produce more impactful treatments.

As mentioned above, the company is a developer of 3D technology as well as a creator of new therapies. It is this dual path and how the two paths can work together that continues to excite 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 are 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.

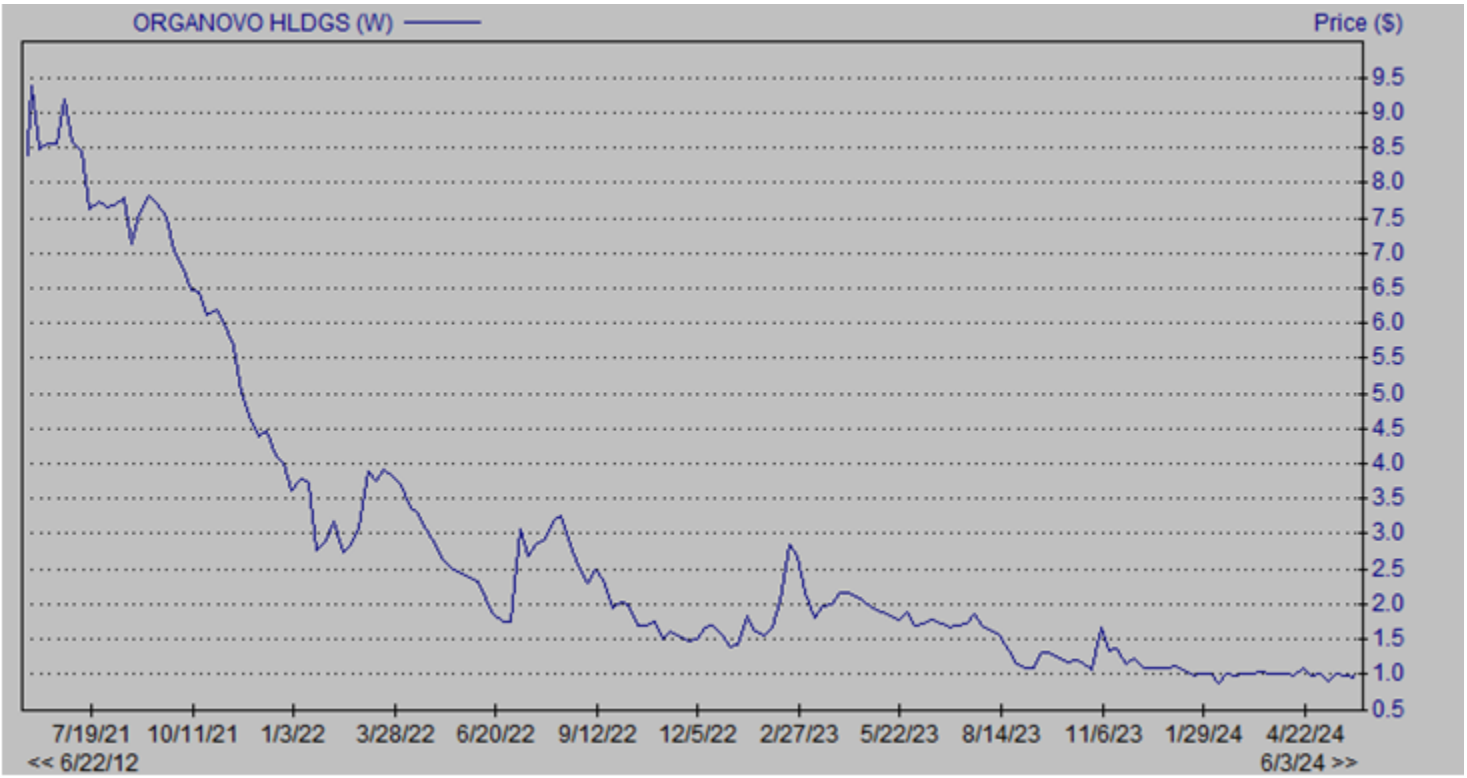
Additionally, many clinical stage companies have no revenue inflows to help offset the costs of developing much needed treatments. However, as already demonstrated, Organovo has the ability to license the company's 3D technology to other companies to aid in their research process, leading to a revenue 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.

We believe Organovo is at a good spot for potential investors, with positive test results providing confidence that the company is on the right track.

PROJECTED INCOME STATEMENT & BALANCE SHEET

Organovo Holdings Income Statement and Balance Sheet							
(in thousands except for share data)							
March 31 Fiscal Year End							
	2023A	1Q2024E	2Q2023E	3Q2023E	4Q2023E	2025E	2026E
Revenue							
Royalty Revenue	109	27	27	28	30	131	157
Sales	0	0	0	0	0	0	0
Total Revenue	109	27	27	28	30	131	157
Research and Dev. Expense	5,498	1,666	1,335	1,335	1,434	5,608	5,720
Selling, general and admin. Expense	9,697	2,604	2,780	2,780	2,251	9,891	10,089
Total cost and expenses	15,195	4,270	4,115	4,115	3,685	15,499	15,809
Gain/(loss) from Operations	(15,086)	(4,243)	(4,088)	(4,087)	(3,655)	(15,368)	(15,652)
Other Income (Expense)							
Interest Income	405	157	121	121	76	459	460
Other Income (Expense)	12	12	(1)	0	0	20	20
Total Other Income (Expense)	417	169	120	121	76	479	480
Income Tax Expense	2	(2)	0	0	0	3	4
Net Gain (Loss)	(14,671)	(4,076)	(3,968)	(3,966)	(3,579)	(14,886)	(15,168)
Other Comprehensive income	(2)	0	0	(1)	0	7	8
Comprehensive gain (loss)	(14,673)	(4,076)	(3,968)	(3,967)	(3,579)	(14,879)	(15,160)
Gain/(loss) per share	($1.60)	($0.38)	($0.36)	($0.35)	($0.31)	($1.23)	($1.22)
Weighted Avg Shares of Common Stock	9,144,922	10,704,922	11,026,070	11,356,852	11,697,557	12,048,484	12,409,939
Assets							
Current Assets							
Cash and cash equivalents	2,901	10,754	7,617	7,617	5,295	5,401	5,509
Accounts Receivable	33	149	55	55	33	34	34
Other current assets	1,002	792	624	624	913	931	950
Total Current Assets	3,936	11,695	8,296	8,296	6,241	6,366	6,493
Fixed assets	669	850	808	808	739	746	754
Restricted cash	143	143	143	143	143	143	143
Operating lease right-of-use	1,299	1,606	1,505	1,505	1,403	1,333	1,266
Other assets	302	462	409	409	355	359	362
Total Assets	6,349	14,756	11,161	11,161	8,881	8,947	9,018
Liabilities and Stockholder Equity							
Current Liabilities							
Accounts Payable	627	488	435	435	471	480	490
Accrued Expenses	727	787	666	666	727	742	756
Operating Lease, current portion	506	495	499	499	502	512	522
Total Current Liabilities	1,860	1,770	1,600	1,600	1,700	1,734	1,769
Operating lease, net of current portion	888	1,210	1,105	1,105	999	1,318	1,319
Total Liabilities	2,748	2,980	2,705	2,705	2,699	3,052	3,088
Stockholder Equity							
Common Stock	10	9	9	9	10	9	9
Additional paid-in capital	343,261	340,792	341,467	341,467	342,796	340,317	340,317
Accumulated deficit	(339,669)	(329,026)	(333,020)	(333,020)	(336,624)	(334,432)	(334,397)
Other SE	(1)	1	0	0	0	1	1
Total Stockholders' Equity	3,601	11,776	8,456	8,456	6,182	5,895	5,930
Total Liabilities and SE Equity	6,349	14,756	11,161	11,161	8,881	8,947	9,018

HISTORICAL STOCK PRICE



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