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Zacks Small-Cap Research

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Organovo Holdings (ONVO-NASDAQ)

ONVO: Quarterly Results Exceed Forecasts

ONVO is a biotech company with dual revenue paths that compliment one another—3D technology and drug development. We value ONVO at $5.40/share using the discounted cash flow method.

Current Price (11/08/24)	$0.40
Valuation	**$5.40**

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 2Q financial report that showed improved good cash balances and bested estimates. The company continues along two courses of business that we believe have excellent prospects.

SUMMARY DATA

52-Week High	**$1.52**
52-Week Low	**$0.40**
One-Year Return (%)	**-70.25**
Beta	**0.62**
Average Daily Volume (sh)	**73,140**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$8**
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	39 A	30 A	44 E	46 E	170 E
2025	47 E	50 E	50 E	54 E	201 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	-$0.23 A	-$0.14 A	-$0.21 E	-$0.19 E	-$0.77 E
2025	-$0.19 E	-$0.19 E	-$0.20 E	-$0.17 E	-$0.75 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 fiscal second quarter results, which showed the company cash position is a solid $3.2 million, while there was also a notable reduction in administrative-related expenses. This improved cost focus helped the company exceed our earnings estimates and post a loss of $0.14 per share, which was also much improved from the $0.23 per share loss seen in the previous quarter.

As a result of the share issuance that increased the cash available to the company, we are adjusting our price target for ONVO to $5.40, reflecting solely the dilution of shares and not reflecting any downgrade in view of the company, on which we remain quite positive.

Giving us additional confidence, earlier in the year, the company released initial 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. We are looking forward to the Phase 2a trials which are set to begin in 2025.

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.

Company management notes in its quarterly filings that it "expects to broaden its work into additional therapeutic areas over time and is currently exploring specific tissues for development. In the company's work to identify the areas of interest, it evaluates areas that might be better served with 3D disease models than currently available models as well as the potential commercial opportunity. In line with these plans, the company is building upon both its external and in house scientific expertise, which will be essential to its drug development effort."

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.

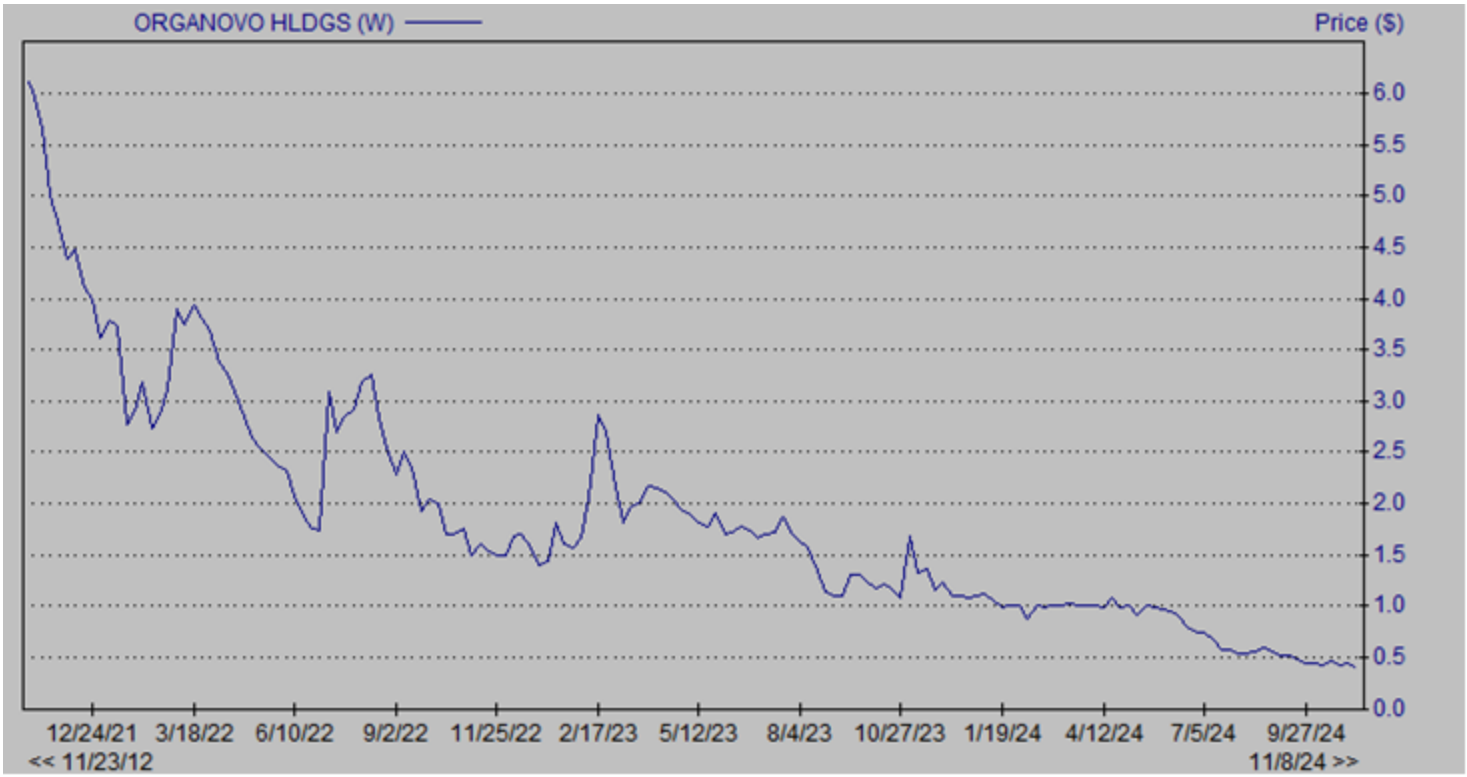
Additionally, many clinical stage companies have no revenue inflows to help offset the costs of developing much needed treatments. However, as already demonstrated, Organovo has the ability to license the company's 3D technology to other companies to aid in their research process, leading to a revenue 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 and good cash on hand 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	1Q2024A	2Q2023A	3Q2023E	4Q2023E	2025E	2026E
Revenue							
Royalty Revenue	109	25	28	28	30	131	157
Product Revenue	0	14	2	16	16	70	75
Total Revenue	109	39	30	44	46	201	232
Cost of Revenue	0	2	1	3	3	16	20
Research and Dev. Expense	5,498	1,402	984	1,335	1,434	5,608	5,720
Selling, general and admin. Expense	9,697	2,021	1,653	2,780	2,251	9,891	10,089
Total cost and expenses	15,195	3,425	2,638	4,118	3,688	15,515	15,829
Gain/(loss) from Operations	(15,086)	(3,386)	(2,608)	(4,074)	(3,642)	(15,314)	(15,597)
Other Income (Expense)							
Interest Income	405	44	59	121	76	459	460
Other Income (Expense)	12	0	0	0	0	20	20
Total Other Income (Expense)	417	44	59	121	76	479	480
Income Tax Expense	2	(2)	0	0	0	3	4
Net Gain (Loss)	(14,671)	(3,344)	(2,549)	(3,953)	(3,566)	(14,832)	(15,113)
Other Comprehensive income	(2)	0	1	(1)	0	7	8
Comprehensive gain (loss)	(14,673)	(3,344)	(2,548)	(3,954)	(3,566)	(14,825)	(15,105)
Gain/(loss) per share	($1.60)	($0.23)	($0.14)	($0.21)	($0.19)	($0.75)	($0.75)
Weighted Avg Shares of Common Stock	9,144,922	14,663,693	17,994,538	18,534,374	19,090,405	19,663,118	20,253,011
Assets							
Current Assets							
Cash and cash equivalents	2,901	6,187	3,174	7,617	5,295	5,401	5,509
Accounts Receivable	33	48	29	55	33	34	34
Other current assets	1,002	1,048	1,580	624	913	931	950
Total Current Assets	3,936	7,283	4,783	8,296	6,241	6,366	6,493
Fixed assets	669	601	545	808	739	746	754
Restricted cash	143	143	143	143	143	143	143
Operating lease right-of-use	1,299	1,194	1,086	1,053	1,022	991	961
Other assets	302	249	197	409	355	359	362
Total Assets	6,349	9,470	6,754	10,709	8,500	8,605	8,714
Liabilities and Stockholder Equity							
Current Liabilities							
Accounts Payable	627	1,119	419	435	471	480	490
Accrued Expenses	727	404	879	666	727	742	756
Operating Lease, current portion	506	510	513	499	502	512	522
Other Current Liabilities	0	0	603	603	603	603	603
Total Current Liabilities	1,860	2,033	2,414	2,203	2,303	2,337	2,372
Operating lease, net of current portion	888	775	660	594	535	481	433
Total Liabilities	2,748	2,808	3,074	2,797	2,838	2,818	2,805
Stockholder Equity							
Common Stock	10	14	15	9	10	9	9
Additional paid-in capital	343,261	349,662	349,227	341,467	342,796	340,317	340,317
Accumulated deficit	(339,669)	(343,013)	(345,562)	(333,564)	(337,144)	(334,540)	(334,417)
Other SE	(1)	(1)	0	0	0	1	0
Total Stockholders' Equity	3,601	6,662	3,680	7,912	5,662	5,787	5,909
Total Liabilities and SE Equity	6,349	9,470	6,754	10,709	8,500	8,605	8,714

HISTORICAL STOCK PRICE



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