Organogenesis Holdings Inc. Reports Second Quarter and First Half 2019 Financial Results

August 9, 2019

CANTON, Mass., Aug. 09, 2019 (GLOBE NEWSWIRE) -- Organogenesis Holdings Inc. (Nasdaq: ORGO), a leading regenerative medicine company focused on the development, manufacture, and commercialization of product solutions for the Advanced Wound Care and Surgical & Sports Medicine markets, today reported financial results for its second quarter ended June 30, 2019.

Second Quarter 2019 Financial Summary:

- Net revenue of $64.9 million for the second quarter of 2019, up 49% compared to net revenue of $43.6 million for the second quarter of 2018. Net revenue comprised:
  - Net revenue from Advanced Wound Care products of $55.2 million, up 50% from the second quarter of 2018.
  - Net revenue from Surgical & Sports Medicine products of $9.7 million, up 46% from the second quarter of 2018.
- Net revenue from the sale of PuraPly products of $29.7 million for the second quarter of 2019, up 133% from the second quarter of 2018.
- Net revenue from the sale of non-PuraPly products of $35.3 million for the second quarter of 2019, up 14% from the second quarter of 2018.
- Net loss was $9.6 million for the second quarter of 2019, compared to a net loss of $20.0 million for the second quarter of 2018.
- Adjusted EBITDA loss of $4.8 million for the second quarter of 2019, compared to Adjusted EBITDA loss of $11.5 million for the second quarter of 2018.

Second Quarter 2019 and Recent Highlights:

- On May 1, 2019, the Company announced that it received an Innovative Technology contract from Vizient, Inc. for its portfolio of Advanced Wound Care and Surgical & Sports Medicine products.
- On July 1, 2019, the Company announced that the common stock of Organogenesis Holdings Inc. had been added to the Russell 2000®, Russell 3000® and Russell Microcap® Indexes.

“We delivered another strong quarter of significant year-over-year revenue growth across both our Advanced Wound Care and Surgical and Sports Medicine portfolios,” said Gary S. Gillheeney, Sr., President and Chief Executive Officer of Organogenesis. “With continued successful execution against our commercial strategy, we grew our customer base and drove customer and clinician adoption deeper into existing accounts. We are pleased that our second quarter results reflected strong year-over-year growth across all products other than Affinity and also benefited from an increase in our amniotic capacity and an improvement in our ability to meet customer demand. Based on our strong commercial performance and our expectation that our amniotic capacity will increase again in the fourth quarter, we are updating our fiscal 2019 revenue guidance reflecting growth of 29% to 35% year-over-year. We are committed to delivering on our mission to provide integrated healing solutions that substantially improve medical outcomes while lowering the overall cost of care. We remain focused on commercial execution, operational progress – including the continued development of our new product pipeline – and improving our profitability profile.”

Net Revenue Summary:

The following table represents revenue by product grouping for the three and six months ended June 30, 2019:

	Three Months Ended June 30,		**Increase/Decrease**		**Six Months Ended June 30,**		**Increase/Decrease**	
(In thousands)	**2019**	**2018**	**$ Change**	**% Change**	**2019**	**2018**	**$ Change**	**% Change**
Advanced Wound Care	$ 55,211	$ 36,890	$ 18,321	50%	$ 103,055	$ 66,114	$ 36,941	56%
Surgical & Sports Medicine	9,737	6,662	3,075	46%	19,016	12,967	6,049	47%
Net revenue	**$ 64,948**	**$ 43,552**	**$ 21,396**	**49%**	**$ 122,071**	**$ 79,081**	**$ 42,990**	**54%**

Second Quarter 2019 Results:

Net revenue for the second quarter of 2019 was $64.9 million, compared to $43.6 million for the second quarter of 2018, an increase of $21.4 million, or 49%. The increase in net revenue was driven by a $18.3 million increase in net revenue of Advanced Wound Care products and a $3.1 million increase in net revenue of Surgical & Sports Medicine products, representing growth of 50% and 46%, respectively, compared to the second quarter of 2018. The increase in Advanced Wound Care net revenue was primarily attributable to additional sales personnel, PuraPly regaining pass-through reimbursement status for the two-year period effective October 1, 2018 and the continued growth in adoption of our amniotic products. The increase in Surgical & Sports Medicine revenue was primarily due to the expansion of the sales force and penetration of existing and new customer accounts. Net revenue of PuraPly products for the second quarter of 2019 was $29.7 million, compared to $12.8 million for the second quarter of 2018, an increase of $16.9 million, or 133%. Net revenue of PuraPly products represented approximately 46% of net revenue in the second quarter of 2019, compared to 29% of net revenue in the second quarter of 2018.

Gross profit for the second quarter of 2019 was $45.5 million or 70% of net revenue, compared to $26.3 million, or 60% of net revenue for the second quarter of 2018, an increase of $19.2 million, or 73%. The improvement in gross profit and gross profit margin percentage resulted primarily from a more favorable product mix of revenue in the second quarter of 2019, PuraPly regaining pass-through reimbursement status, and volume-based manufacturing efficiencies.

Operating expenses for the second quarter of 2019 were $52.8 million, compared to $43.3 million for the second quarter of 2018, an increase of $9.5 million, or 22%. The increase in operating expenses in the second quarter of 2019 as compared to the second quarter of 2018 was driven primarily by higher selling, general and administrative expenses which increased to $49.0 million, compared to $37.7 million in the second quarter of 2018, an increase of $11.2 million, or 30%. The increase in selling, general and administrative expenses is primarily due to additional headcount, predominantly in the direct sales force, higher sales commissions and increased marketing and promotional expenses for the Company's products. R&D expense was $3.9 million for the second quarter of 2019, compared to $2.0 million in the second quarter of 2018, an increase of $1.8 million, or 89%. The increase in R&D was driven by additional headcount and continued and new investment in clinical programs.

Operating loss for the second quarter of 2019 was $7.3 million, compared to an operating loss of $17.0 million for the second quarter of 2018, a decrease of $9.7 million, or 57%. Total other expenses, net, for the second quarter of 2019 were $2.3 million, compared to $3.0 million for the second quarter of 2018, a decrease of $0.7 million, or 22%. The decrease was driven primarily by a decrease in interest expense and decrease in the change in fair value of warrant liability.

Net loss for the second quarter of 2019 was $9.6 million, or $0.11 per share, compared to a net loss of $20.0 million, or $0.30 per share, for the second quarter of 2018, a decrease of $10.4 million, or 52%.

As of June 30, 2019, the Company had $20.0 million in cash and $90.2 million in debt obligations, of which $17.1 million were capital lease obligations, compared to $21.3 million in cash and $59.3 million in debt obligations, of which $17.7 million were capital lease obligations, as of December 31, 2018.

First Half 2019 Results:

Net revenue for the six months ended June 30, 2019 was $122.1 million, compared to $79.1 million for the first six months of 2018, an increase of $43.0 million, or 54%. The increase in net revenue was driven by a $36.9 million increase, or 56%, in net revenue of Advanced Wound Care products and a $6.0 million increase, or 47%, in net revenue of Surgical & Sports Medicine products compared to the prior year. Net revenue of PuraPly products for the six months ended June 30, 2019 were $55.1 million, compared to $23.4 million for the first six months of 2018, an increase of $31.8 million, or 136%. Net revenue of PuraPly products represented approximately 45% of net revenue for the six months ended June 30, 2019, compared to 30% for the first six months of 2018.

Gross profit for the six months ended June 30, 2019 was $85.6 million or 70% of net revenue, compared to $47.3 million, or 60% of net revenue, for the first six months of 2018, an increase of $38.4 million, or 81%. The largest contributors to the increase in gross margin from the year earlier period were increased sales volume due to the strength in our Advanced Wound Care products, PuraPly regaining pass-through reimbursement status for the 2-year period effective October 1, 2018, and incremental revenue from our Surgical & Sports Medicine products as a result of our NuTech Medical acquisition and the resulting higher margins realized as a result of manufacturing efficiencies associated with our Advanced Wound Care products.

Operating expenses for the six months ended June 30, 2019 were $105.1 million, compared to $84.3 million for the first six months of 2018, an increase of $20.8 million, or 25%. The increase in operating expenses in 2019 as compared to 2018 was driven primarily by higher selling, general and administrative expenses which increased to $97.9 million, compared to $75.9 million in 2018, an increase of $22.0 million, or 29%. The increase in selling, general and administrative expenses is primarily due to additional headcount, primarily in our direct sales force, higher legal, consulting fees and other costs associated with the ongoing operations of our business, and additional amortization associated with the intangible assets from the NuTech Medical acquisition attributable to the higher expected consumption of the related intangible assets' economic benefits. Operating expenses for the six months ended June 30, 2019 were also impacted by higher R&D expense which was $7.2 million, compared to $4.9 million for the first six months of 2018, an increase of $2.4 million, or 49%.

Operating loss for the six months ended June 30, 2019 was $19.4 million, compared to an operating loss of $37.0 million for the first six months of 2018, a decrease of $17.6 million, or 47%. Total other expenses for the six months ended June 30, 2019 were $5.8 million, compared to $5.4 million for the first six months of 2018, an increase of $0.4 million, or 7%. The increase in total other expenses for the six months ended June 30, 2019 was driven primarily by a $1.9 million non-cash loss on the extinguishment of debt related to the write-off of unamortized debt discount upon repayment of the master lease agreement as well as early payment penalties in March 2019, offset partially by a decrease in interest expense of $1.2 million and decrease in the change in fair value of warrant liability of $0.2 million.

Net loss the six months ended June 30, 2019 was $25.3 million, or $0.28 per share, compared to a net loss of $42.5 million, or $0.65 per share, for the first six months of 2018.

Fiscal Year 2019 Revenue Guidance:

The Company is updating its fiscal year 2019 revenue expectations. For the twelve months ending December 31, 2019, the Company expects:

- Net revenue of between $250 million and $262 million, representing growth of approximately 29% to 35% year-over-year, as compared to net revenue of $193.4 million for the twelve months ended December 31, 2018. The Company's prior guidance range for net revenue was $249 million to $262 million, representing growth of 29% to 35% year-over-year.

- The updated 2019 net revenue guidance range assumes:
    - Net revenue from Advanced Wound Care products of between $219 million and $224 million, representing growth of approximately 33% to 36% year-over-year as compared to net revenue of $164.3 million for the twelve months

ended December 31, 2018.
- Net revenue from Surgical & Sports Medicine products of between $31 million and $38 million, representing growth of approximately 6% to 31% year-over-year as compared to net revenue of $29.1 million for the twelve months ended December 31, 2018.
- The 2019 net revenue guidance range also assumes that net revenue from the sale of PuraPly products will represent between $110 million and $120 million of net revenue, representing growth of approximately 58% to 72% year-over-year, as compared to net revenue of $69.8 million for the twelve months ended December 31, 2018.

Conference Call:

Management will host a conference call at 8:00 a.m. Eastern Time on August 9th discuss the results of the quarter and provide a corporate update with a question and answer session. Those who would like to participate may dial 866-795-3142 (409-937-8908 for international callers) and provide access code 6645209. A live webcast of the call will also be provided on the investor relations section of the Company's website at investors.organogenesis.com.

For those unable to participate, a replay of the call will be available for two weeks at 855-859-2056 (404-537-3406 for international callers); access code 6645209. The webcast will be archived at investors.organogenesis.com.

Forward-Looking Statements

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to expectations or forecasts of future events. Forward-looking statements may be identified by the use of words such as "forecast," "intend," "seek," "target," "anticipate," "believe," "expect," "estimate," "plan," "outlook," and "project" and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Such forward-looking statements include statements relating to the Company's expected revenue for fiscal 2019 and the breakdown of such revenue in both its Advanced Wound Care and Surgical & Sports Medicine categories as well as the estimated revenue contribution of its PuraPly products. Forward-looking statements with respect to the operations of the Company, strategies, prospects and other aspects of the business of the Company are based on current expectations that are subject to known and unknown risks and uncertainties, which could cause actual results or outcomes to differ materially from expectations expressed or implied by such forward-looking statements. These factors include, but are not limited to: (1) the Company has incurred significant losses since inception and anticipates that it will incur substantial losses for the foreseeable future; (2) the Company faces significant and continuing competition, which could adversely affect its business, results of operations and financial condition; (3) rapid technological change could cause the Company's products to become obsolete and if the Company does not enhance its product offerings through its research and development efforts, it may be unable to effectively compete; (4) to be commercially successful, the Company must convince physicians that its products are safe and effective alternatives to existing treatments and that its products should be used in their procedures; (5) the Company's ability to raise funds to expand its business; (6) the impact of any changes to the reimbursement levels for the Company's products and the impact to the Company of the loss of preferred "pass through" status for PuraPly AM and PuraPly on October 1, 2020; (7) the Company's ability to maintain compliance with applicable Nasdaq listing standards; (8) changes in applicable laws or regulations; (9) the possibility that the Company may be adversely affected by other economic, business, and/or competitive factors; and (10) other risks and uncertainties described in the Company's filings with the Securities and Exchange Commission, including Item 1A (Risk Factors) of the Company's Form 10-K for the year ended December 31, 2018. You are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made. Although it may voluntarily do so from time to time, the Company undertakes no commitment to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable securities laws.

About Organogenesis Holdings Inc.

Organogenesis Holdings Inc. is a leading regenerative medicine company offering a portfolio of bioactive and acellular biomaterials products in advanced wound care and surgical biologics, including orthopedics and spine. Organogenesis's comprehensive portfolio is designed to treat a variety of patients with repair and regenerative needs. For more information, visit www.organogenesis.com.

ORGANOGENESIS HOLDINGS INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash	$ 20,040	$ 21,291
Restricted cash	119	114
Accounts receivable, net	34,157	34,077
Inventory	18,717	13,321
Prepaid expenses and other current assets	3,113	2,328
Total current assets	76,146	71,131
Property and equipment, net	40,751	39,623
Notes receivable from related parties	516	477
Intangible assets, net	23,844	26,091
Goodwill	25,539	25,539
Deferred tax asset	238	238

Other assets	1,040	579
Total assets	$ 168,074	$ 163,678
Liabilities and Stockholders' Equity		
Current liabilities:		
Deferred acquisition consideration	$ 5,000	$ 5,000
Redeemable common stock liability	-	6,762
Current portion of notes payable	-	2,545
Current portion of capital lease obligations	2,442	2,236
Accounts payable	22,278	19,165
Accrued expenses and other current liabilities	20,679	20,388
Total current liabilities	50,399	56,096
Line of credit	33,484	26,484
Notes payable, net of current portion	-	12,578
Term loan	39,662	-
Deferred rent	456	130
Capital lease obligations, net of current portion	14,655	15,418
Other liabilities	6,220	5,931
Total liabilities	144,876	116,637
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock, $0.0001 par value; 400,000,000 shares authorized; 92,071,270 and 91,261,413 shares issued; 91,342,722 and 91,261,413 shares outstanding at June 30, 2019 and December 31, 2018, respectively.	9	9
Additional paid-in capital	178,412	177,272
Accumulated deficit	(155,223)	(130,240)
Total stockholders' equity	23,198	47,041
Total liabilities and stockholders' equity	$ 168,074	$ 163,678

ORGANOGENESIS HOLDINGS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		**Six Months Ended June 30,**	
	2019	**2018**	**2019**	**2018**
Net revenue	$ 64,948	$ 43,552	$ 122,071	$ 79,081
Cost of goods sold	19,446	17,300	36,426	31,821
Gross profit	45,502	26,252	85,645	47,260
Operating expenses:				
Selling, general and administrative	48,957	37,735	97,850	75,900
Research and development	3,864	2,048	7,235	4,872
Write-off of deferred offering costs	-	3,494	-	3,494
Total operating expenses	52,821	43,277	105,085	84,266
Loss from operations	(7,319)	(17,025)	(19,440)	(37,006)
Other income (expense), net:				
Interest expense, net	(2,187)	(2,781)	(3,965)	(5,191)
Change in fair value of warrants	-	(175)	-	(249)
Loss on the extinguishment of debt	-	-	(1,862)	-
Other income (expense), net	(120)	(2)	12	3
Total other income (expense), net	(2,307)	(2,958)	(5,815)	(5,437)
Net loss before income taxes	(9,626)	(19,983)	(25,255)	(42,443)
Income tax expense	(23)	(27)	(60)	(55)
Net loss	$ (9,649)	$ (20,010)	$ (25,315)	$ (42,498)
Net loss per share—basic and diluted	$ (0.11)	$ (0.30)	$ (0.28)	$ (0.65)
Weighted average common shares outstanding—basic and diluted	90,647,352	66,361,998	90,625,850	65,347,076

ORGANOGENESIS HOLDINGS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Six Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (25,315)	$ (42,498)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,761	1,747
Amortization of intangible assets	2,997	1,834
Non-cash interest expense	154	345
Deferred interest expense	536	111
Deferred rent expense	326	28
Write-off of deferred offering costs	-	3,494
Provision (benefit) recorded for sales returns and doubtful accounts	27	(307)
Provision recorded for inventory reserve	523	1,833
Stock-based compensation	458	568
Change in fair value of warrant liability	-	249
Loss on extinguishment of debt	1,862	-
Changes in fair value of forfeiture rights	-	589
Changes in operating assets and liabilities:		
Accounts receivable	723	5,342
Inventory	(6,087)	(1,648)
Prepaid expenses and other current assets	(785)	(1,857)
Accounts payable	1,473	7,217
Accrued expenses and other current liabilities	122	524
Accrued interest—affiliate debt	-	1,777
Other liabilities	(449)	414
Net cash used in operating activities	(21,674)	(20,238)
Cash flows from investing activities:		
Purchases of property and equipment	(1,251)	(557)
Acquisition of intangible asset	(250)	-
Net cash used in investing activities	(1,501)	(557)
Cash flows from financing activities:		
Line of credit borrowings	7,000	4,827
Proceeds from term loan	40,000	-
Proceeds from long - term debt - affiliates	-	10,000
Proceeds from notes payable	-	5,000
Repayment of notes payable	(17,585)	(10)
Proceeds from the exercise of stock options	54	78
Proceeds from the exercise of common stock warrants	628	-
Redemption of redeemable common stock placed into treasury	(6,762)	-
Principal repayments of capital lease obligations	(557)	(17)
Payment of debt issuance costs	(849)	(131)
Net cash provided by financing activities	21,929	19,747
Change in cash and restricted cash	(1,246)	(1,048)
Cash and restricted cash, beginning of period	21,405	2,358
Cash and restricted cash, end of period	$ 20,159	$ 1,310
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,890	$ 2,507
Cash paid for income taxes	$ 67	$ 62
Supplemental disclosure of non-cash investing and financing activities:		
Debt issuance costs included in accounts payable	$ 75	$ 25
Purchases of property and equipment in accounts payable and accrued expenses	$ 1,638	$ 529
Amounts due related to acquisition of intangible assets included in accrued expenses and other liabilities	$ 500	$ -

Use of Non-GAAP Measures

Our management uses financial measures that are not in accordance with generally accepted accounting principles in the United States, or GAAP, in addition to financial measures in accordance with GAAP to evaluate our operating results. These non-GAAP financial measures should be considered supplemental to, and not a substitute for, our reported financial results prepared in accordance with GAAP. Our management uses Adjusted EBITDA principally as a measure of our operating performance and believes Adjusted EBITDA helps identify underlying trends in our business that could otherwise be masked by the effect of the items that we exclude. Accordingly, we believe that Adjusted EBITDA provides useful information to investors and others in understanding and evaluating our operating results, enhancing the overall understanding of our past performance and future prospects, and allowing for greater transparency with respect to key financial metrics used by our management in its financial and operational decision-making.

We define EBITDA as net income (loss) before depreciation and amortization, net interest expense and income taxes and we define Adjusted EBITDA as EBITDA, further adjusted for the impact of certain items that we do not consider indicative of our core operating performance. These items consist of non-cash equity compensation, mark to market adjustments on our warrant liabilities, change in our contingent asset and liabilities, write-off of deferred offering costs, Avista merger transaction costs and loss on the extinguishment of debt. We have presented Adjusted EBITDA in this press release because it is a key measure used by our management and Board of Directors to understand and evaluate our operating performance, generate future operating plans and make strategic decisions regarding the allocation of capital. In particular, we believe that the exclusion of certain items in calculating Adjusted EBITDA can produce a useful measure for period-to-period comparisons of our business.

Our Adjusted EBITDA is not prepared in accordance with GAAP, and should not be considered in isolation of, or as an alternative to, measures prepared in accordance with GAAP. There are a number of limitations related to the use of Adjusted EBITDA rather than net income (loss), which is the most directly comparable GAAP equivalent. Some of these limitations are:

- Adjusted EBITDA excludes stock-based compensation expense, as stock-based compensation expense has recently been, and will continue to be for the foreseeable future, a significant recurring expense for our business and an important part of our compensation strategy;
- Adjusted EBITDA excludes depreciation and amortization expense and, although these are non-cash expenses, the assets being depreciated may have to be replaced in the future;
- Adjusted EBITDA excludes net interest expense, or the cash requirements necessary to service interest, which reduces cash available to us;
- Adjusted EBITDA excludes the impact of the changes in the fair value of our warrant liability and our contingent consideration forfeiture asset;
- Adjusted EBITDA excludes the write-off of deferred offering costs in connection with an abandoned public offering, as well as merger transaction costs, consisting primarily of legal and professional fees;
- Adjusted EBITDA excludes the loss on extinguishment of debt, which is a non-cash loss related to the write-off of unamortized debt issuance costs upon repayment of affiliate and third-party debt, and related prepayment penalties;
- Adjusted EBITDA excludes income tax expense (benefit); and
- Other companies, including companies in our industry, may calculate Adjusted EBITDA differently, which reduces its usefulness as a comparative measure.

Because of these limitations, we consider, and you should consider, Adjusted EBITDA together with other operating and financial performance measures presented in accordance with GAAP. A reconciliation of Net loss, the most directly comparable measure calculated in accordance with GAAP, to Adjusted EBITDA, has been included below.

	Three Months Ended June 30,		**Six Months Ended June 30,**	
	2019	**2018**	**2019**	**2018**
	(in thousands)		**(in thousands)**	
Net loss	$ (9,649)	$ (20,010)	$ (25,315)	$ (42,498)
Interest expense, net	2,187	2,781	3,965	5,191
Income tax expense	23	27	60	55
Depreciation	859	875	1,761	1,747
Amortization	1,499	917	2,997	1,834
EBITDA	(5,081)	(15,410)	(16,532)	(33,671)
Stock-based compensation expense	234	251	458	568
Change in contingent consideration forfeiture asset (1)	-	-	-	589
Change in fair value of warrant liability (2)	-	175	-	249
Loss on extinguishment of debt (3)	-	-	1,862	-
Write-off of deferred offering costs (4)	-	3,494	-	3,494
Adjusted EBITDA	$ (4,847)	$ (11,490)	$ (14,212)	$ (28,771)

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Organogenesis
Empowering Healing

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