

AVID BIOSERVICES, INC.

FORM 8-K (Current report filing)

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Address	2642 MICHELLE DRIVE, SUITE 200 TUSTIN, CA, 92780
Telephone	714.508.6100
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Symbol	CDMO
SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 12, 2018**

AVID BIOSERVICES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of other jurisdiction
of incorporation)

001-32839
(Commission File Number)

95-3698422
(IRS Employer
Identification No.)

2642 Michelle Drive, Suite 200, Tustin, California 92780
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: **(714) 508-6100**

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14A-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On March 12, 2018, Avid Bioservices, Inc. (the “Company”) issued a press release to report the Company’s financial results for the third quarter ended January 31, 2018. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1. No additional information is included in this Current Report on Form 8-K.

The information included in this Current Report on Form 8-K, including the exhibit hereto, shall not be deemed “filed” for purposes of, nor shall it be deemed incorporated by reference in, any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such a filing.

ITEM 7.01 REGULATION FD DISCLOSURE

On March 12, 2018, at 4:30 p.m. EDT/1:30 p.m. PDT, the Company will host a conference call to discuss its third quarter ended January 31, 2018 financial results. The webcast of the conference call will be archived on the Company’s website for approximately 30 days.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits. The following material is filed as an exhibit to this Current Report on Form 8-K:

**Exhibit
Number**

99.1 Press Release issued March 12, 2018.

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 hereunto duly authorized.

AVID BIOSERVICES, INC.

Date: March 12, 2018

By: /s/ Paul J. Lytle
Paul J. Lytle
Chief Financial Officer

EXHIBIT INDEX

**Exhibit
Number**

Description _____

99.1

Press Release issued March 12, 2018.



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Avid Bioservices Reports Financial Results for Third Quarter of Fiscal Year 2018 and Recent Developments

-- Company Remains on Target for Full Year Revenue of \$50.0 - \$55.0 Million --

-- Intensified Business Development Effort Results in New Customer Contract and Strengthened Backlog --

TUSTIN, Calif., March 12, 2018 – Avid Bioservices, Inc. (NASDAQ:CDMO) (NASDAQ:CDMOP), a dedicated contract development and manufacturing organization (CDMO) working to improve patient lives by providing high quality development and manufacturing services to biotechnology and pharmaceutical companies, today announced financial results for the third quarter of fiscal year (FY) 2018 ended January 31, 2018, and provided an update on its contract manufacturing operations, and other corporate highlights.

Highlights Since October 31, 2017

“During and subsequent to our third quarter of fiscal year 2018, Avid completed two primary objectives. We successfully divested the company’s lead immunology assets to an organization with the financial resources and expertise to advance them, and we established a new operational structure that will allow our business to take full advantage of the substantial and growing demand for biologics manufacturing,” said Roger Lias, Ph.D., president and chief executive officer of Avid Bioservices. “With the divestiture of our lead R&D assets, our transition to a dedicated CDMO business is complete, and our team is entirely focused on expanding and diversifying our customer base, as well as strengthening our process development capabilities. At present, we are in late-stage negotiations with several potential new customers and expect to announce the executed agreements before the end of the fiscal year. In recent weeks, we also completed a financing raising \$23.2 million in gross proceeds. These funds are essential as they will support our operations, including upgrading our process development capabilities to ensure that we are fully capable of servicing our customers with the highest quality standards and equipment. We made rapid progress during the third quarter that we believe will allow us to build backlog and achieve sustainable growth in the future.”

Recent CDMO Developments

- Advanced eight current clients, some with multiple projects, through various stages of development.
- Selected by Acumen Pharmaceuticals, Inc. to provide process development and clinical manufacturing services in support of ACU193, which is being developed for the treatment of Alzheimer’s disease.
 - o Avid and Acumen will immediately commence process development work with the goal of creating a robust, cost-effective and scalable process to support cGMP manufacture of ACU193.

Recent Corporate Developments and Financial Highlights

- Changed company name from Peregrine Pharmaceuticals, Inc. to Avid Bioservices, Inc.
 - As the Avid name is recognized in the industry for CDMO excellence and biologics manufacturing expertise, the brand is an important asset in the company's transition to a dedicated CDMO business. The company also adopted the new NASDAQ ticker symbol, "CDMO" (NASDAQ:CDMO).
- Reconstituted board of directors including six independent directors, all with significant CDMO experience.
- Entered into an Asset Assignment and Purchase Agreement with Oncologie, Inc. for Avid's phosphatidylserine (PS)-targeting program including bavituximab.
 - Avid expects to receive an aggregate of \$8.0 million in upfront payments over a period of six months and will be eligible to receive up to \$95.0 million in development, regulatory and commercialization milestones.
 - Oncologie, Inc. will be responsible for all future research, development and commercialization of bavituximab, and related intellectual property costs.
 - Avid will receive royalties on net sales that are upward tiering into the mid-teens.
 - Oncologie will enter into an agreement with Avid for future contract development and manufacturing activities in support of bavituximab.
- Completed a public offering of 10,294,445 shares of common stock raising gross proceeds of approximately \$23.2 million.
 - Avid intends to use the net proceeds from the offering to support the growth of its contract manufacturing business and general corporate purposes.
- The company maintains its manufacturing revenue guidance for the full FY 2018 of \$50.0 million - \$55.0 million.
- The current manufacturing revenue backlog has increased to \$39 million .
- Contract manufacturing revenue from Avid's clinical and commercial biomanufacturing services was \$6.8 million for the third quarter of FY 2018 compared to \$ 10.7 million for the third quarter of FY 2017. The decline was primarily due to lower demand from one of our largest customers.
- Cost of contract manufacturing increased to \$11.0 million in the third quarter of FY 2018 compared to \$ 8.0 million for the third quarter of FY 2017. The current period increase in cost of manufacturing is primarily attributed to idle capacity costs of \$5.3 million due to lower facility and personnel utilization compared to no idle capacity costs reported in the same prior year quarter.
- Selling, general and administrative expenses for the third quarter of FY 2018 were \$4.8 million, compared to \$4.4 million for the third quarter of FY 2017. The current period increase in costs was primarily due to legal and other related fees associated with the settlement agreement with certain investors regarding the composition of the company's board of directors and legal and advisory fees associated with the Asset Assignment and Purchase Agreement with Oncologie, Inc.

- As of January 31, 2018, the company's research and development segment met all the conditions to be classified as a discontinued operation. Accordingly, the operating results of our research and development segment are reported as a loss from discontinued operations for all periods presented.
- Avid's consolidated net loss attributable to common stockholders was \$12.4 million or \$0.28 per share, for the third quarter of FY 2018, compared to a net loss attributable to common stockholders of \$ 9.2 million , or \$0.25 per share, for the same prior year quarter.
- Avid reported \$17.9 million in cash and cash equivalents as of January 31, 2018, compared to \$46.8 million at fiscal year ended April 30, 2017. Following the completion of a public offering during February 2018, the company had cash and cash equivalents of \$41.7 million as of February 28, 2018.

More detailed financial information and analysis may be found in Avid's Quarterly Report on Form 10-Q, which will be filed with the Securities and Exchange Commission today.

Conference Call

Avid will host a conference call and webcast this afternoon, March 12, 2018, at 4:30 PM EDT (1:30 PM PDT).

To listen to the conference call, please dial (877) 312-5443 or (253) 237-1126 and request the Avid Bioservices conference call. To listen to the live webcast, or access the archived webcast, please visit: <http://ir.avidbio.com/events.cfm> .

About Avid Bioservices, Inc.

Avid Bioservices is a dedicated contract development and manufacturing organization (CDMO) focused on development and cGMP manufacturing of biopharmaceutical products derived from mammalian cell culture. The company provides a comprehensive range of process development, high quality cGMP clinical and commercial manufacturing services for the biotechnology and biopharmaceutical industries. With nearly 25 years of experience producing monoclonal antibodies and recombinant proteins in batch, fed-batch and perfusion modes, Avid's services include cGMP clinical and commercial product manufacturing, purification, bulk packaging, stability testing and regulatory strategy, submission and support. The company also provides a variety of process development activities, including cell line development and optimization, cell culture and feed optimization, analytical methods development and product characterization. For more information, please visit www.avidbio.com.

Forward-Looking Statements

Statements in this press release which are not purely historical, including statements regarding Avid Bioservices' intentions, hopes, beliefs, expectations, representations, projections, plans or predictions of the future, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The forward-looking statements involve risks and uncertainties including, but not limited to, the risk the company may experience delays in engaging new clients, the risk that the company may experience technical difficulties in processing customer orders which could delay delivery of products to customers, revenue recognition and receipt of payment or the loss of the customer, the risk that one or more existing customers terminates its contract prior to completion or reduces or delays its demand for development or manufacturing services, the risk that the company may need to use the majority of its cash to fund operations, thereby delaying the contemplated upgrade to its process development capabilities and expansion plans, and the risk that the company may not receive the full \$8 million up front payment from Oncologie. Our business could be affected by a number of other factors, including the risk factors listed from time to time in our reports filed with the Securities and Exchange Commission including, but not limited to, our annual report on Form 10-K for the fiscal year ended April 30, 2017 and subsequent quarterly reports on Form 10-Q, as well as any updates to these risk factors filed from time to time in our other filings with the Securities and Exchange Commission. We caution investors not to place undue reliance on the forward-looking statements contained in this press release, and we disclaim any obligation, and do not undertake, to update or revise any forward-looking statements in this press release except as may be required by law.

AVID BIOSERVICES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

	Three Months Ended January 31,		Nine Months Ended January 31,	
	2018	2017	2018	2017
Contract manufacturing revenue	\$ 6,819,000	\$ 10,747,000	\$ 46,678,000	\$ 39,726,000
Cost of contract manufacturing	10,951,000	7,974,000	47,641,000	26,477,000
Gross profit (loss)	(4,132,000)	2,773,000	(963,000)	13,249,000
Operating expenses:				
Selling, general and administrative	4,824,000	4,365,000	12,273,000	13,602,000
Restructuring charges	—	—	1,258,000	—
Total operating expenses	4,824,000	4,365,000	13,531,000	13,602,000
Operating loss	(8,956,000)	(1,592,000)	(14,494,000)	(353,000)
Other income (expense):				
Interest and other income	42,000	25,000	83,000	71,000
Interest and other expense	(14,000)	(2,000)	(18,000)	(2,000)
Loss from continuing operations	\$ (8,928,000)	\$ (1,569,000)	\$ (14,429,000)	\$ (284,000)
Loss from discontinued operations	(2,076,000)	(6,205,000)	(10,404,000)	(22,603,000)
Net loss	<u>\$ (11,004,000)</u>	<u>\$ (7,774,000)</u>	<u>\$ (24,833,000)</u>	<u>\$ (22,887,000)</u>
Comprehensive loss	<u>\$ (11,004,000)</u>	<u>\$ (7,774,000)</u>	<u>\$ (24,833,000)</u>	<u>\$ (22,887,000)</u>
Series E preferred stock accumulated dividends	(1,442,000)	(1,442,000)	(3,604,000)	(3,558,000)
Net loss attributable to common stockholders	<u>\$ (12,446,000)</u>	<u>\$ (9,216,000)</u>	<u>\$ (28,437,000)</u>	<u>\$ (26,445,000)</u>
Basic and diluted weighted average common shares outstanding (1) :	<u>45,225,804</u>	<u>37,258,794</u>	<u>45,032,335</u>	<u>35,486,782</u>
Basic and diluted net loss per common share attributable to common stockholders (1) :				
Continuing operations	\$ (0.23)	\$ (0.08)	\$ (0.40)	\$ (0.11)
Discontinued operations	\$ (0.05)	\$ (0.17)	\$ (0.23)	\$ (0.64)
Net loss per share attributable to common stockholders	<u>\$ (0.28)</u>	<u>\$ (0.25)</u>	<u>\$ (0.63)</u>	<u>\$ (0.75)</u>

(1) All share and per share amounts of our common stock for all prior fiscal year periods presented have been retroactively adjusted to reflect the one-for-seven reverse stock split of our issued and outstanding common stock, which took effect on July 10, 2017.

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AVID BIOSERVICES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	January 31, 2018	April 30, 2017
	<i>Unaudited</i>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 17,938,000	\$ 46,799,000
Trade and other receivables	7,967,000	7,742,000
Inventories	14,218,000	33,099,000
Prepaid expenses	906,000	1,460,000
Total current assets	41,029,000	89,100,000
Property and equipment, net	26,325,000	26,515,000
Restricted cash	1,150,000	1,150,000
Other assets	1,353,000	1,347,000
Total assets	<u>\$ 69,857,000</u>	<u>\$ 118,112,000</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,911,000	\$ 5,779,000
Accrued clinical trial and related fees	5,503,000	4,558,000
Accrued payroll and related costs	3,876,000	6,084,000
Deferred revenue	6,633,000	28,500,000
Customer deposits	17,602,000	17,017,000
Other current liabilities	749,000	993,000
Total current liabilities	36,274,000	62,931,000
Deferred rent, less current portion	2,064,000	1,599,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock—\$0.001 par value; authorized 5,000,000 shares; 1,647,760 issued and outstanding at January 31, 2018 and April 30, 2017, respectively	2,000	2,000
Common stock—\$0.001 par value; authorized 500,000,000 shares; 45,257,180 and 44,014,040 issued and outstanding at January 31, 2018 and April 30, 2017, respectively	45,000	44,000
Additional paid-in capital	593,621,000	590,971,000
Accumulated deficit	(562,149,000)	(537,435,000)
Total stockholders' equity	31,519,000	53,582,000
Total liabilities and stockholders' equity	<u>\$ 69,857,000</u>	<u>\$ 118,112,000</u>

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