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## BioCardia Inc. (BCDA-NASDAQ)

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### BUY: Reports the Quarter with an Interesting IP item

*BioCardia reported steady progress spending on an adjusted basis \$1.5M (GAAP \$3.8M) and ending the period with \$8.9M in cash on the balance sheet. We are hopeful that as clinical progress (partially sponsored by CMS) continues that the company will be in a position to raise needed capital at a higher valuation. We also note that several catalysts in the regenerative medicine space are set to play out over the coming year, all of which could support higher valuations (if positive) for the sector and for BioCardia.*

### Investment Highlights

**Phase 3 Update: DSMB Say's No Safety Issues – Recommends that the trial should continue:** BioCardia announced (August, 2019), that the independent Data Safety Monitoring board (DSMB) has completed its prespecified data review for the Phase 3 pivotal CardiAMP Heart Failure Trial, which included safety follow-up results on 35 patients and all additional data available on the 50 patients randomized in the trial as of the end of August. The DSMB indicated there were no safety concerns with the CardiAMP study results and recommended that the trial continue as planned. The trial is an ongoing multi-center, double-blinded, randomized (3:2), sham-controlled pivotal CardiAMP Heart Failure Trial that is expected to enroll 260 patients at up to 40 centers nationwide. The trial's primary efficacy endpoint is Six-Minute Walk distance at 12 months post-treatment, a measure of a patient's exercise capacity, and incorporates the impact of MACE and other clinically meaningful events. Secondary efficacy endpoints include quality of life as measured by the Minnesota Heart Failure Quality of Life self-assessment, and superiority relative to MACE and survival.

**Heart Disease – Treating the Underlying Issue.** BioCardia strongly believes that stem cells have the power to change the course of cardiovascular disease. This may occur as a result of the trophic effects of these cells when administered directly into the local environment (heart muscle). The cells act like micro-drug factories secreting factors that help to reduce inflammation, reduce scarring and promote micro-angiogenesis (formation of new blood supply to the tissue). In doing such it is hoped in the case of an acute ischemic event, that the cells can help limit the initial damage and in the case of chronic disease may help to arrest the damage and even reverse it partially.

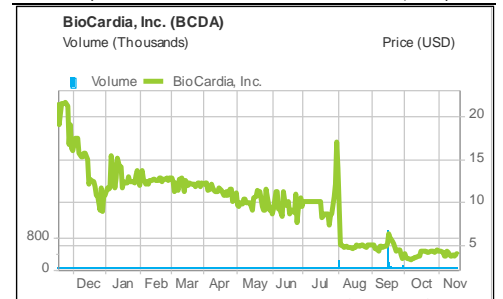
**A Wildcard for Biocardia.** We took note of a recent 8k filing. Biocardia is claiming that a former employee had assigned to a company she founded, nVision Medical, a patent and patent applications she had filed while a BioCardia employee. Our understanding is that the company was later acquired by Boston Scientific (BSX: Not rated) for ~\$275M. This leads us to believe that we could see a settlement down the road for cash.

Current Price \$3.85  
 Price Target \$24.00

Estimates	F2019E	F2020E	F2021E
<b>Expenses (\$000s)</b>	\$ 15,192	\$ 15,568	\$ 16,346
1Q March	\$ 3,903	\$ 3,653	\$ 3,835
2Q June	\$ 3,848	\$ 3,812	\$ 4,002
3Q September	\$ 3,421	\$ 3,972	\$ 4,171
4Q December	\$ 4,020	\$ 4,131	\$ 4,338
	F2019E	F2020E	F2021E
<b>EPS (diluted)</b>	\$ (1.78)	\$ (0.67)	\$ (0.34)
1Q March	\$ (0.08)	\$ (0.27)	\$ (0.10)
2Q June	\$ (0.77)	\$ (0.13)	\$ (0.08)
3Q September	\$ (0.63)	\$ (0.13)	\$ (0.08)
4Q December	\$ (0.30)	\$ (0.14)	\$ (0.09)

EBITDA/Share	(\$0.86)	(\$0.61)	(\$0.34)
EV/EBITDA (x)	0.0	0.0	0.0

Stock Data		
52-Week Range	\$3.15	\$21.69
Shares Outstanding (mil.)	6.8	
Market Capitalization (mil.)	\$26	
Enterprise Value (mil.)	\$26	
Debt to Capital	0%	
Book Value/Share	\$2.62	
Price/Book	1.5	
Average Three Months Trading Volume (K)	6	
Insider Ownership	64.8%	
Institutional Ownership	3.7%	
Short interest (mil.)	0.4%	
Dividend / Yield	\$0.00/0.0%	



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**Delivery Matters.** One of the characteristics that differentiates BioCardia from competitors in the field is the way the cells are delivered. The cells are administered directly to the patient's heart through the use of their Helix Biotherapeutic Delivery System and the Morph steerable guide. The end result is that more cells stay where they are needed versus other systems where the majority of cells are washed away in the dynamic blood flow associated with the heart. To this end it is worth noting that the commercial availability of the AVANCE Bi-Directional Steerable Introducer Sheath is now a reality. In addition, the extension of AstraZeneca (AZN: Not Rated) relationship, the company signed an extension to its existing agreement for its Helix biotherapeutic delivery system catheter) with a \$1 million upfront payment.

**Roughly \$20B is spent per year for hospitalization costs.** Following an operation done on a patient's heart, on average, they are in the hospital for three to four nights spending at least \$10,000 a night. CardiAMP can allow the patient to be released the same day with anticipated savings for the system of up to \$40,000 of unwanted hospital costs.

**BioCardia is Assisted.** The company is conducting numerous clinical trials in heart disease and specifically heart ischemia. Focusing on heart failure consumes a significant amount of a company's resources. BioCardia gets an extra hand as the Centers for Medicare & Medicaid Services (CMS) has funded the ongoing Phase 3 trial of CardiAMP cell therapy system in ischemic heart failure.

**Autologous vs. Allogeneic:** BioCardia is developing treatment using both autologous and allogeneic cells. BioCardia developed a diagnostic assay to determine which treatment is best suited for each patient. Autologous stem cell therapy is the company's leading product, CardiAMP, which is currently in a pivotal Phase 3 trial. Through CardiAMP, the patient's own bone marrow is extracted and is directly administered to the patient's heart to allow the most efficacy. If a patient's CD34 cell count does not reach the requirement for CardiAMP, BioCardia can offer CardiALLO. CardiALLO stands out as an allogeneic stem cell therapy that is based on donated marrow. CardiALLO is designed to be a fast follower behind CardiAMP.

**Valuation:** Our product models run out to the year 2030. For CardiAMP and CardiALLO and all the related cardiac indications, each of which represent blockbuster markets, we haircut the revenues by 70% (assume only a 30% probability of success). In addition, in our free cash flow (FCFF), discounted EPS (EPS), and sum-of-the-parts (SOP) models we apply a risk rate ( $r$ ) of 30% on-top of the 90% risk cut in our models. Our share count is projected for 2030 and assumes multiple raises. Our models are then equal-weighted, averaged and rounded to the nearest whole number to derive our 12 months price target of \$24.00.

**Risks:** Partnership risks, Commercialization risks, Financial risks, Clinical and regulatory risks, and Legal and intellectual property risk.

**Product Modeling Assumptions**

1. We base our market share estimates for BioCardia’s therapies on multiple assumptions around the product attributes associated with product delivery and outcomes. Given the blockbuster size of the U.S. and EU HF markets we apply a 70% risk reduction to the net revenues, suggesting on success there is a lot of upside in our estimates.
2. We assume CardiAMP and CardiALLO will initially launch at \$50,000 per operation. Our projected market share grows over the six-year launch cycle, with CardiAMP consuming up to 25% of the total market in the year 2028 and CardiALLO achieves a 15% share of the total market by the year 2030.
3. Based on BioCardia’s estimation of completing enrollment of the pivotal Phase 3 trial of BCDA-01 in 2H20, we assume standard FDA review time of 10 months with the launch in 1Q22. We expect BCDA-02 to be a fast follower with approval and launch a year after BCDA-01, in 1Q23. To adjust for the risk of approval, we apply a 70% risk cut to our CardiAMP revenue model.
4. We expect that BCDA-03 (CardiALLO) could reach the market by 2027, however, for conservatism, we apply a therapeutic risk cut of 70% in our product model. This suggests that clinical progress could make our numbers too conservative.

**Exhibit 1. Market Models:**

	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
<b>BCDA-01 Heart Failure</b>												
U.S. Prevalence CHF	5,000,000	5,005,000	5,010,005	5,015,015	5,020,030	5,025,050	5,030,075	5,035,105	5,040,140	5,045,180	5,050,226	5,055,276
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	500,500	501,001	501,502	502,003	502,505	503,008	503,511	504,014	504,518	505,023	505,528	506,033
Market Share Penetration	0.0%	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%	20.0%	20.0%	25.0%	25.0%	25.0%
Number of Patients Procedures	0	0	0	10,030	25,100	50,251	75,451	100,702	100,803	126,130	126,256	126,382
Cost of Therapy	\$ 20,040	\$ 20,040	\$ 20,080	\$ 20,120	\$ 20,160	\$ 20,201	\$ 20,241	\$ 20,282	\$ 20,322	\$ 20,363	\$ 20,404	\$ 20,444
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ 61	\$ 152	\$ 305	\$ 458	\$ 613	\$ 615	\$ 771	\$ 773	\$ 775
<b>BCDA-01 Heart Failure</b>												
E.U. Prevalence CHF	9,000,000	9,009,000	9,018,009	9,027,027	9,036,054	9,045,090	9,054,135	9,063,189	9,072,253	9,081,325	9,090,406	9,099,496
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	900,000	900,900	901,801	902,703	903,605	904,509	905,414	906,319	907,225	908,132	909,041	909,950
Market Share Penetration	0.0%	0.0%	0.0%	0	0	0	2.0%	6.0%	10.0%	15.0%	20.0%	20.0%
Number of Patients Procedures	0	0	0	0	0	0	18,108	54,379	90,723	136,220	181,808	181,990
Cost of Therapy	\$ 30,000	\$ 30,060	\$ 30,120	\$ 30,180	\$ 30,241	\$ 30,301	\$ 30,362	\$ 30,423	\$ 30,483	\$ 30,544	\$ 30,605	\$ 30,667
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 165	\$ 496	\$ 830	\$ 1,248	\$ 1,669	\$ 1,674
<b>BCDA-02 Heart Failure</b>												
U.S. Prevalence CHF	5,000,000	5,075,000	5,151,125	5,228,392	5,306,818	5,386,420	5,467,216	5,549,225	5,632,463	5,716,950	5,802,704	5,889,745
Market Size Growth (Annual)	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%
Candidates (Chronic Myocardial Ischemia) for Therapy	200,000	203,000	206,045	209,136	212,273	215,457	218,689	221,969	225,299	228,678	232,108	235,590
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%	20.0%	25.0%	25.0%	25.0%
Number of Patients Procedures	0	0	0	0	4,245	10,773	21,869	33,295	45,060	57,169	58,027	58,897
Cost of Therapy	\$ 20,040	\$ 20,040	\$ 20,080	\$ 20,120	\$ 20,160	\$ 20,201	\$ 20,241	\$ 20,282	\$ 20,322	\$ 20,363	\$ 20,404	\$ 20,444
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ 26	\$ 65	\$ 133	\$ 203	\$ 275	\$ 349	\$ 355	\$ 361
<b>BCDA-02 Heart Failure</b>												
E.U. Prevalence CHF	9,000,000	9,072,000	9,144,576	9,217,733	9,291,474	9,365,806	9,440,733	9,516,259	9,592,389	9,669,128	9,746,481	9,824,453
Market Size Growth (Annual)	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%
Candidates (Chronic Myocardial Ischemia) for Therapy	495,000	498,960	502,952	506,975	511,031	515,119	519,240	523,394	527,581	531,802	536,056	540,345
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	0	0	2.0%	6.0%	10.0%	15.0%	20.0%	20.0%
Number of Patients Procedures	0	0	0	0	0	0	10,385	31,404	52,758	79,770	107,211	108,069
Cost of Therapy	\$ 30,000	\$ 30,060	\$ 30,120	\$ 30,180	\$ 30,241	\$ 30,301	\$ 30,362	\$ 30,423	\$ 30,483	\$ 30,544	\$ 30,605	\$ 30,667
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 95	\$ 287	\$ 482	\$ 731	\$ 984	\$ 994
<b>BCDA-03 Heart Failure</b>												
U.S. Prevalence CHF	5,000,000	5,005,000	5,010,005	5,015,015	5,020,030	5,025,050	5,030,075	5,035,105	5,040,140	5,045,180	5,050,226	5,055,276
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	150,000	150,150	150,300	150,450	150,601	150,752	150,902	151,053	151,204	151,355	151,507	151,658
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%
Number of Patients Procedures	0	0	0	0	0	0	0	0	3,024	7,568	15,151	22,749
Cost of Therapy	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 22,500	\$ 22,545	\$ 22,590	\$ 22,635
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 20	\$ 51	\$ 103	\$ 154
<b>BCDA-03 Heart Failure</b>												
E.U. Prevalence CHF	9,000,000	9,009,000	9,018,009	9,027,027	9,036,054	9,045,090	9,054,135	9,063,189	9,072,253	9,081,325	9,090,406	9,099,496
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	270,000	270,270	270,540	270,811	271,082	271,353	271,624	271,896	272,168	272,440	272,712	272,985
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.0%	10.0%	15.0%	15.0%
Number of Patients Procedures	0	0	0	0	0	0	0	0	5,443	13,622	27,271	40,948
Cost of Therapy	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 29,500	\$ 29,559	\$ 29,618	\$ 29,677
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 48	\$ 121	\$ 242	\$ 365

Source: Dawson James Estimates

**Valuation.** We value BioCardia based on the revenues in our product models, which are reduced by 70% rate cut or a 30% probability of success. This suggests we are leaving a lot of upside in our estimates on good data. We apply assumptions for FDA product approvals, launch dates, and product attributes to estimate revenues. These estimates feed into our income statement through the year 2030. Our price target is derived from an equal-weighted average of free cash flow (FCFF), discounted EPS (EPS), and sum-of-the-parts (SOP) models. For companies that are well established with mature products and revenues, we typically discount at a 10% rate, for companies in the early stages of product commercialization we typically use a higher rate, 15%. For BioCardia, we use a 30% risk rate as the company is not yet profitable. This risk rate is in addition to the therapeutic cut (70%) in our product models. The result of this methodology is a price target of \$24.00 per share.

### Exhibit 2. Discounted Free Cash Flow Model

Average	\$	24
Price Target	\$	23
Year		2019

#### DCF Valuation Using FCF (mln):

units ('000)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(15,110)	(14,975)	(15,724)	14,670	100,982	243,623	610,948	994,814	1,731,539	2,543,011	3,258,277	3,413,956
Tax Rate	0%	0%	0%	10%	18%	20%	24%	24%	24%	28%	30%	34%
EBIT(1-t)	(15,110)	(14,975)	(15,724)	13,203	82,805	194,898	464,321	756,059	1,315,969	1,830,968	2,280,794	2,253,211
CapEx												
Depreciation	101	-	-	-	-	-	-	-	-	-	-	-
Change in NWC												
FCF	(15,009)	(14,975)	(15,724)	13,203	82,805	194,898	464,321	756,059	1,315,969	1,830,968	2,280,794	2,253,211
PV of FCF	(5,255)	(4,033)	(3,258)	2,104	10,151	18,379	33,681	42,187	161,324	172,660	165,445	125,726
Discount Rate	30%											
Long Term Growth Rate	1%											
Terminal Cash Flow	7,847,389											
Terminal Value YE2030	437,873											
NPV	1,156,983											
NPV-Debt	1,016											
Shares out (thousands)	50,677	2030E										
NPV Per Share	\$	23										

Source: Dawson James estimates.

Source: Dawson James

### Exhibit 3. EPS Model

Current Year	2019
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 44.46
NPV	\$ 25.00

Source: Dawson James estimates.

Discount Rate and Earnings Multiple Varies, Year is Constant							
		2030 EPS					
		5%	10%	15%	20%	25%	30%
Earnings Multiple	0	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$ -
	5	\$42.00	\$25.00	\$16.00	\$10.00	\$6.00	\$ 4.00
	10	\$84.00	\$51.00	\$31.00	\$19.00	\$12.00	\$ 8.00
	15	\$127.00	\$76.00	\$47.00	\$29.00	\$19.00	\$ 12.00
	20	\$169.00	\$101.00	\$62.00	\$39.00	\$25.00	\$ 16.00
	25	\$211.00	\$126.00	\$78.00	\$49.00	\$31.00	\$ 20.00
	30	\$253.00	\$152.00	\$93.00	\$58.00	\$37.00	\$ 24.00
	35	\$295.00	\$177.00	\$109.00	\$68.00	\$43.00	\$ 28.00

Source: Dawson James

### Exhibit 4. Sum-of-the-Parts Model

BioCardia	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MMs	Term Val
BCDA-01 CardiAMP cell therapy US	1%	30%	3	30%	\$2,584	\$8,910
NPV						\$9.60
BCDA-01 CardiAMP cell therapy US	1%	30%	3	30%	\$5,581	\$19,245
NPV						\$20.74
BCDA-02 CardiALLO cell therapy US	1%	30%	4	30%	\$1,204	\$4,152
NPV						\$3.44
BCDA-02 CardiALLO cell therapy EU	1%	30%	4	30%	\$3,314	\$11,428
NPV						\$9.47
BCDA-03 CardiALLO cell therapy US	1%	50%	5	30%	\$515	\$1,051
NPV						\$0.33
BCDA-02 CardiALLO cell therapy EU	1%	50%	5	30%	\$1,215	\$2,480
NPV						\$0.77
Net Margin						40%
MM Shrs OS (2030E)						51
Total						\$24

Source: Dawson James

**Risk Analysis**

In addition to the typical risks associated with development stage specialty pharmaceutical companies, potential risks specific to BioCardia are as follows:

**Partnership risk.** The company is also expected to make agreements with partners for additional products, but there can be no assurances that the company will be able to secure favorable partnerships.

**Commercial risk.** There are no assurances that the company will be able to achieve significant sales, market share, or become profitable.

**Clinical and regulatory risk.** Lead products need to complete clinical trials. It is difficult to complete enrollment which could lead to a delay of the trial. Trials may not produce the results expected from previous research or be sufficient for regulatory approval.

**Financial risk.** The company may need to raise capital in the marketplace, and there can be no assurances that the company will be able to successfully raise capital and or do so, at favorable terms.

**Legal and intellectual property risk.** The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and or that the company may infringe on third parties' patents.

**Exhibit 5. Income Statement**

Biocardia Inc: Income Statement (\$000)																	
BCDA: YE December	2018A	1Q19A	2Q19A	3Q19A	4Q19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net product revenue	282	76	62	1	78	300	315	331									
Collaboration agreement revenue	343	140	24	193	25	382	401	421									
BCDA-01 CardiaAMP Cell Therapy revenues US						0	0	0	60,542	151,809	304,530	458,166	612,723	614,562	770,509	772,822	775,142
BCDA-01 CardiaAMP Cell Therapy revenues EU									0	0	0	164,940	496,305	829,659	1,248,224	1,669,295	1,674,306
BCDA-02 CardiaAMP Cell Therapy revenues US										25,677	65,286	132,796	202,586	274,714	349,241	355,188	361,237
BCDA-02 CardiaAMP Cell Therapy revenues EU										-	-	94,590	28,661	482,474	730,959	984,374	994,234
BCDA-03 CardALLO Cell Therapy revenues US													-	20,413	51,185	102,677	154,477
BCDA-03 CardALLO Cell Therapy revenues EU													-	48,174	120,796	242,317	364,566
<b>Total Product Sales</b>	<b>625</b>	<b>216</b>	<b>86</b>	<b>194</b>	<b>103</b>	<b>599</b>	<b>716</b>	<b>752</b>	<b>60,542</b>	<b>177,486</b>	<b>369,816</b>	<b>850,492</b>	<b>1,340,275</b>	<b>2,269,995</b>	<b>3,270,913</b>	<b>4,126,672</b>	<b>4,323,962</b>
<b>Product Sales &amp; Royalties &amp; Milestones</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>60,542</b>	<b>177,486</b>	<b>369,816</b>	<b>590,962</b>	<b>815,308</b>	<b>957,862</b>	<b>1,291,730</b>	<b>1,473,003</b>	<b>1,655,422</b>
<b>Expenses</b>																	
Cost of goods sold	517	106	191	24	141	543	215	226	18,163	44,372	92,454	204,118	308,263	499,399	686,892	825,334	864,792
							30%	30%	30%	25%	25%	24%	23%	22%	21%	20%	20%
Research and Development	8,453	2,166	2,219	2,007	2,308	8,876	9,319	9,785	10,275	10,788	11,328	11,894	12,489	13,113	13,769	14,457	15,180
Selling, general and administrative	5,757	1,631	1,438	1,390	1,572	6,045	6,347	6,664	18,000	22,000	23,100	24,255	25,468	26,741	28,078	29,482	30,956
<b>Total expenses</b>	<b>14,727</b>	<b>3,903</b>	<b>3,848</b>	<b>3,421</b>	<b>4,020</b>	<b>15,192</b>	<b>15,568</b>	<b>16,346</b>	<b>45,872</b>	<b>76,504</b>	<b>126,193</b>	<b>239,544</b>	<b>345,461</b>	<b>538,456</b>	<b>727,902</b>	<b>868,395</b>	<b>910,006</b>
Operating income (Loss)	(14,102)	(3,687)	(3,762)	(3,227)	(3,917)	(14,593)	(14,852)	(15,595)	14,670	100,982	243,623	610,948	994,814	1,731,539	2,543,011	3,258,277	3,413,956
Interest expense																	
Interest Income	118	23	23	69	23	23											
Other expense	(3)	(1)	(1)	(634)	(1)	(1)											
<b>Total other income</b>	<b>115</b>	<b>22</b>	<b>(1)</b>	<b>(565)</b>	<b>(1)</b>	<b>(1)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Pretax Income</b>	<b>(13,987)</b>	<b>(3,665)</b>	<b>(3,740)</b>	<b>(3,792)</b>	<b>(3,895)</b>	<b>(14,571)</b>	<b>(14,852)</b>	<b>(15,595)</b>	<b>14,670</b>	<b>100,982</b>	<b>243,623</b>	<b>610,948</b>	<b>994,814</b>	<b>1,731,539</b>	<b>2,543,011</b>	<b>3,258,277</b>	<b>3,413,956</b>
Income Tax Benefit (Provision)									1,467	18,177	48,725	146,628	238,755	415,569	712,043	977,483	1,160,745
<b>Tax Rate</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>10%</b>	<b>18%</b>	<b>20%</b>	<b>24%</b>	<b>24%</b>	<b>24%</b>	<b>28%</b>	<b>30%</b>	<b>34%</b>
<b>GAAP Net Income (loss)</b>	<b>(13,987)</b>	<b>(3,665)</b>	<b>(3,740)</b>	<b>(3,792)</b>	<b>(3,895)</b>	<b>(14,571)</b>	<b>(14,852)</b>	<b>(15,595)</b>	<b>13,203</b>	<b>82,805</b>	<b>194,898</b>	<b>464,321</b>	<b>756,059</b>	<b>1,315,969</b>	<b>1,830,968</b>	<b>2,280,794</b>	<b>2,253,211</b>
Deemed Dividend on Preferred Stock																	
<b>GAAP-EPS</b>	<b>(0.37)</b>	<b>(0.08)</b>	<b>(0.77)</b>	<b>(0.63)</b>	<b>(0.37)</b>	<b>(0.90)</b>	<b>(0.94)</b>	<b>(0.59)</b>	<b>0.48</b>	<b>2.97</b>	<b>6.97</b>	<b>16.53</b>	<b>26.81</b>	<b>46.47</b>	<b>64.40</b>	<b>79.90</b>	<b>78.62</b>
GAAP EPS (dil)	(0.37)	(0.08)	(0.77)	(0.63)	(0.30)	(0.86)	(0.61)	(0.34)	0.27	1.70	3.99	9.48	15.37	26.65	36.93	45.82	45.09
Weighted shares basic	38,285	43,629	4,848	6,031	10,537	16,261	15,818	26,398	27,758	27,869	27,981	28,093	28,205	28,318	28,432	28,545	28,660
Weighted shares dil	38,285	43,629	4,848	6,031	13,037	16,886	24,331	45,712	48,402	48,596	48,791	48,986	49,183	49,380	49,578	49,776	49,976

Source: Dawson James estimates.

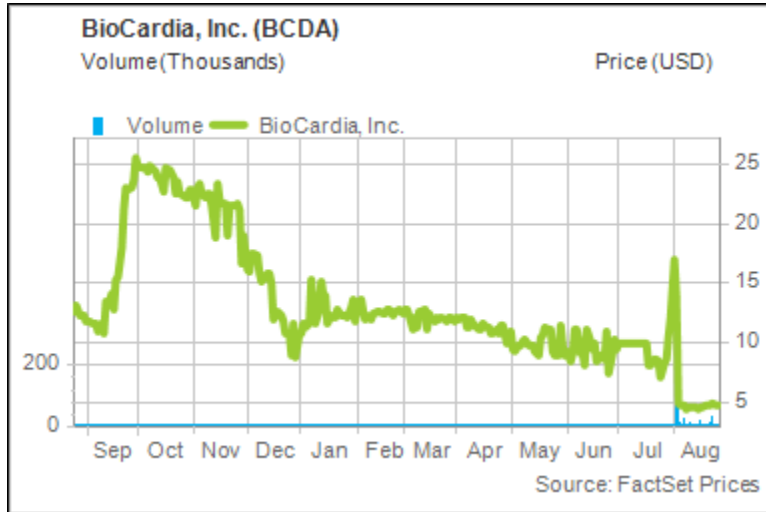
Companies that maybe mentioned in this report:

AstraZeneca (AZN): Not Rated

Boston Scientific (BSX): Not Rated

**Important Disclosures:**

**Price Chart:**



Price target and ratings changes over the past three years:

Initiated – Buy – September 17, 2019 – Price Target \$24.00  
 Company Update – Buy – November 20, 2019 – Price Target \$24.00

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	23	88%	2	9%
Market Perform (Neutral)	3	12%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	26	100%	2	8%

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