Biotechnology

Bionomics Ltd. (BNOX)

EQUITY RESEARCH
March 9, 2023

Price: $3.43
Price Target: $8.00 (From $10.00)

Rating: Overweight

Key Statistics:

Symbol	NASDAQ: BNOX
52-Week Range	$2.49 - $10.90
Market Cap ($M)	28.0
ADV (3 mo)	102,918
Shares Out (M)	8.2

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REV ($AU M)

FYE Jun	2022A	2023E	2024E
1H	0.2	0.3A	-
Prev	-	*0.8E*	-
2H	0.1	0.8E	-
Year	0.3	1.1E	1.6
Prev	-	*1.6E*	-

EPS

FYE Jun	2022A	2023E	2024E
1H	(2.33)	(1.99)A	-
Prev	-	*(1.95)E*	-
2H	(1.16)	(0.81)E	-
Prev	-	-	-
Year	(3.32)	(3.21)E	(3.77)
Prev	-	*(3.26)E*	*(3.24)*

Company Update

BNC210 Data in Social Anxiety: Not Mining, Just Deeper Analysis and Every Good Study Suggests Two Others

Investment Summary. We reiterate our Overweight rating but are lowering our 12-month PT to $8 from $10. Today (3/9), Bionomics presented the full results of the P2 PREVAIL trial of BNC210 ('210) in social anxiety disorder (SAD). Although the company previously reported top-line data that indicated that the study did not meet statistical significance on its primary endpoint during Dec 2022 (note here), the deeper look suggests that the study achieved its objectives for informing a subsequent, possibly pivotal, study.

With data now in hand showing an effective dose, a signal of efficacy, and clear differentiating tolerability/safety relative to standard-of-care (SoC) benzodiazepine anxiolytic medications, we believe additional analyses have demonstrated that '210 may have promising anxiolytic effect in social anxiety. Because this was measured by an acute public-speaking session, efficacy appears not to be limited to the performance period itself, but is present across the entire public-speaking task, including the anticipation phase.

Given that we now see a visible path forward in SAD that is supported by intriguing signals of efficacy and favorable tolerability, we have reintroduced the indication into our valuation matrix, while also incorporating our assumptions of capital and time needed. Thus, our "calculus" results in an incremental reduction in our PT to $8. Our cautiously enhanced perspective on the '210 clinical profile is tempered, however, by our changing our expectation of the launch of '210 in SAD to 2027 from 2026 due to the company needing 1) to meet with the FDA, but likely not until 3Q23; and 2) to design, operationalize, and conduct two pivotal P3 trials in 2024, followed by a long-term safety study to support an NDA filing. In addition, we have increased the discount rate (55% from 45%) as we see a non-zero likelihood of Bionomics needing a capital raise in a possibly still-challenging risk-off market environment.

Our key takeaway from today's conference call. Bionomics management spoke about its deeper analysis of the PREVAIL trial results after the top-line data PR in Dec 2022. Our takeaway was that '210 resulted in the rapid onset of a clinically meaningful reduction in anxiety symptoms comparable to that typically achieved with benzodiazepines, but without the side effect of sedation. Despite the trial not achieving statistical significance, we note that there were consistent trends of numerical improvements in the Subjective Units of Distress Scale (SUDS) score as well as in other clinically relevant measurements, such as the State-Trait Anxiety Inventory (STAI), a psychometrically different measurement from SUDS. Additionally, when combining the 225mg and 675mg doses (which achieved therapeutic responses of similar magnitude, thus boosting 'power'), the combined '210 arm achieved statistical significance in the primary endpoint of SUDS, prompting the company to believe that the study would have been positive if it had had a larger sample size originally.

As a result, we look forward to hearing the FDA's feedback following an end-of-P2 (EoP2) meeting that Bionomics plans to hold in 2H23 to discuss the full results of the PREVAIL study. Considering that the post-hoc analysis demonstrates that the primary endpoint is met when combining SUDS scores assessed throughout the anticipation and speaking periods and given the track record of the FDA extending flexibility for high unmet needs, we believe the dataset may be compelling enough to support the initiation of a larger,

The Disclosure Section may be found on pages 7 - 8.

potentially pivotal, late-stage trial. The company disclosed that it plans to initiate start-up activities for a P3 study in late-2023/early-2024 and that it expects two well-controlled trials, as well as a long-term safety study, will be needed for NDA submission.

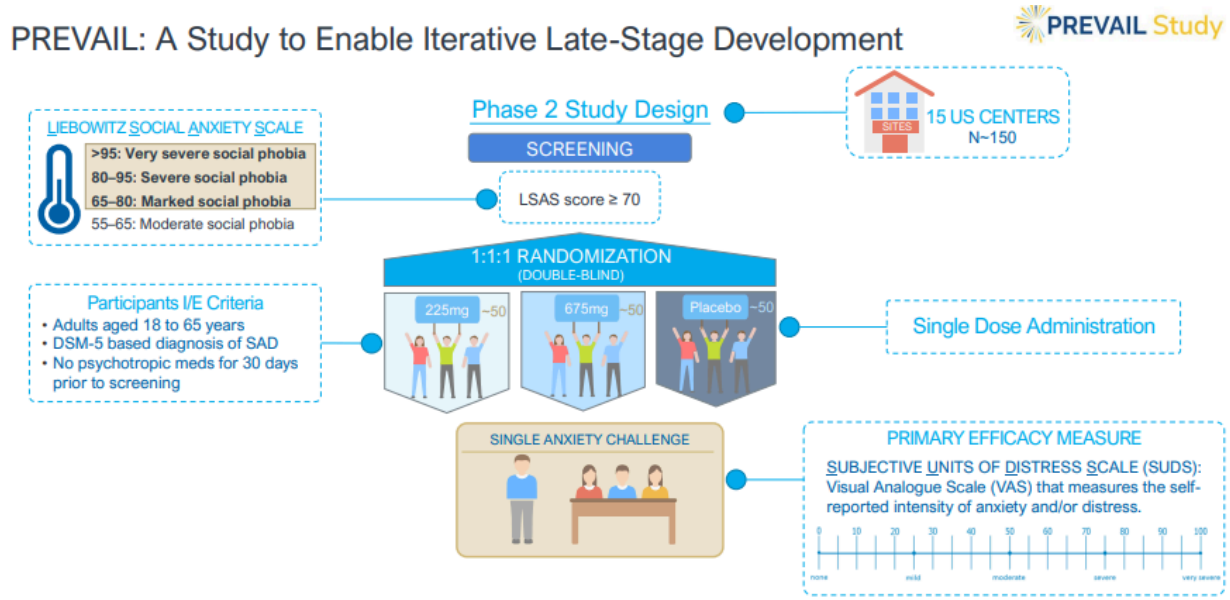
SAD data are no longer somber. The P2 PREVAIL study enrolled 151 patients with severe social anxiety disorder randomized (1:1:1) to receive 225mg or 675mg of BNC210, or placebo. Eligible subjects had a Liebowitz Social Anxiety Scale (LSAS) score >70, which represents SAD patients with marked, severe-to-very-severe social phobia. Patients waited for 60 minutes post-dosing, after which they were subjected to an anxiety-provoking challenge (a recorded speaking engagement on a controversial topic in front of an audience). The primary endpoint was the change from baseline in SUDS score, which measures the self-reported intensity of anxiety and/or distress in SAD patients, during the speaking challenge. Secondary outcome measures included change in SUDS scores during the preparation-anticipation phase and self-assessment with STAI-State, a self-reported questionnaire that is clinically recognized for anxiety disorders.

Although '210 did not meet the primary endpoint, both 225mg and 675mg doses demonstrated numerical improvements in SUDS scores during the anticipation period and throughout the public-speaking challenge (Exhibit 3). As a result, Bionomics presented a post-hoc analysis that showed the average change in SUDS scores measured throughout the performance task-and-anticipation phase (primary and secondary outcomes, respectively); the company believes that the analysis more-accurately reflects the anxiolytic clinical profile of '210. Exhibit 4 demonstrates that the primary outcome was met with statistical significance when combining the SUDS scores of both anticipation and speaking challenge phases of the study. We also highlight that '210 was well-tolerated, with the majority of AEs reported as mild, differentiating it from commonly used benzo' drugs for SAD.

Furthermore, we were interested to learn that the subgroup analyses demonstrated that younger participants (aged ≤30 years) responded more-favorably to '210 than to placebo, as evidenced in the SUDS scores of the anticipation and performance phase (Exhibit 5). This younger cohort may be a clinically relevant subpopulation to target in future trials given that the onset of SAD is typically seen during adolescence or early adulthood. In addition, these patients will likely be treated sooner than older adults following their diagnosis, and thus be less likely to be treatment resistant. As such, we expect Bionomics to stratify the patient population to younger adults, and potentially adolescents, in future studies to increase the likelihood of a positive readout and to further strengthen the regulatory and clinical PoS of the SAD program.

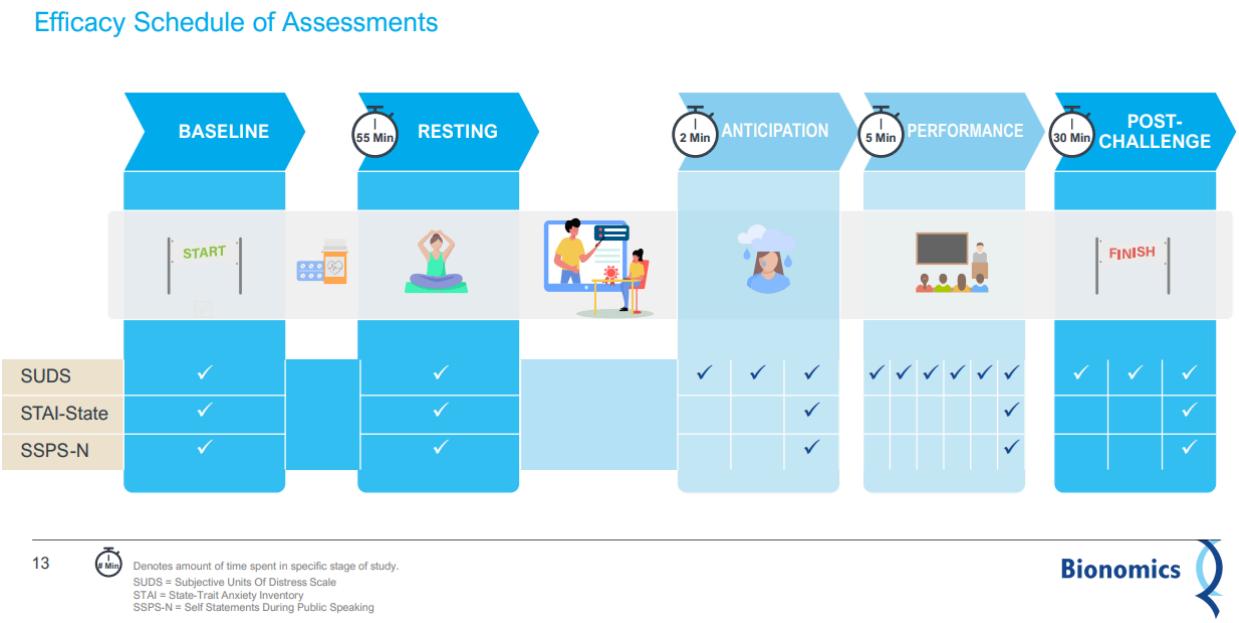
Changes to our model. Based on the recently PR'd financial report, we updated our model for FY1H23 financial results. The company reported a net loss of (A$1.20) per basic and diluted BNO share for the half year, which we calculate to be a net loss of (A$1.99) per BNOX share. Due to the visibility on the path forward for SAD, we have included the SAD program in our valuation of BNOX shares. However, because we believe that two pivotal P3 trials will be required, we have increased our estimate of the discount rate to 55% from 45% and conservatively pushed back the launch of '210 in SAD by a year. We have also increased our estimate of the size of the equity raise ($60M with 10M shares vs. 3M shares previously) that we think may be needed by YE23 to fund the next steps for clinical development of '210. Finally, we have also shifted forward the base year of valuation to end-FY1H24 (Dec 31, 2023). Overall, the net change results in our lowered PT to $8 from $10.

Exhibit 1: Study Design of the P2 PREVAIL Trial



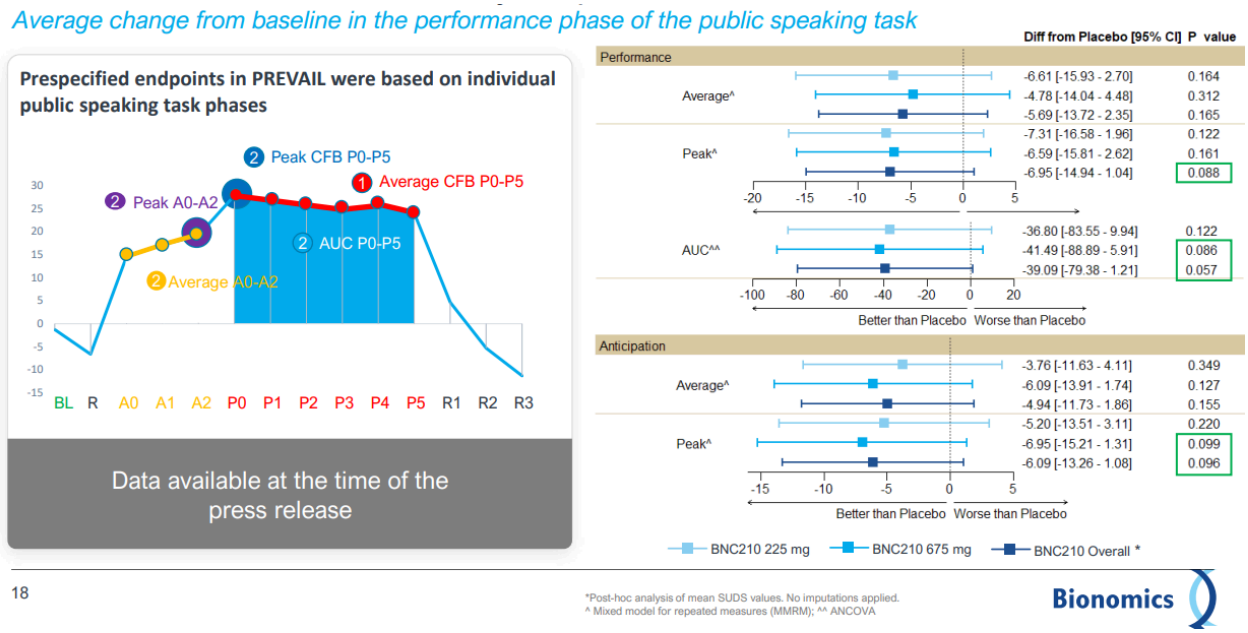
Source: Company Presentation

Exhibit 2: SUDS and STAI-State are assessed throughout PREVAIL



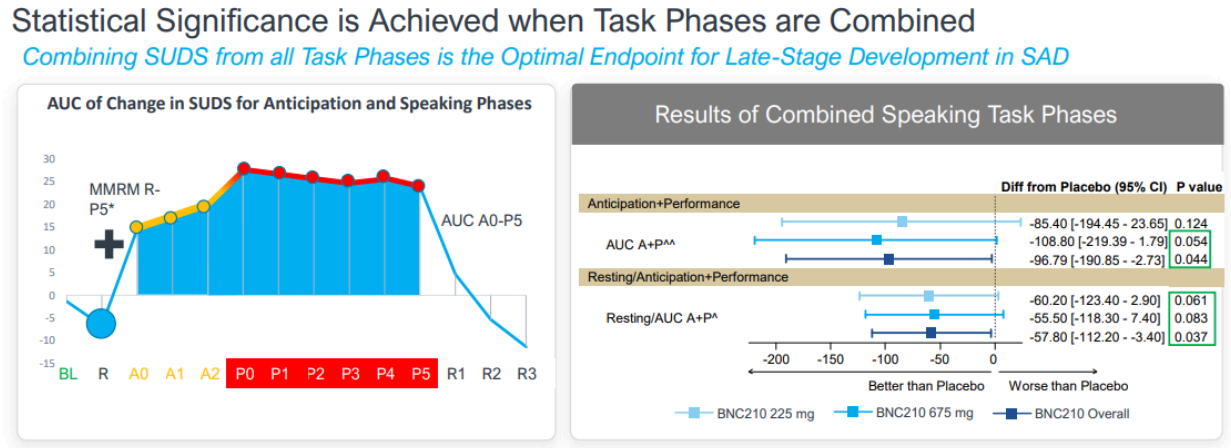
Source: Company Presentation

Exhibit 3: Consistent trends of improvements despite PREVAIL not meeting the primary endpoint



Source: Company Presentation

Exhibit 4: Statistical significance achieved in post-hoc combination of SUDS scores

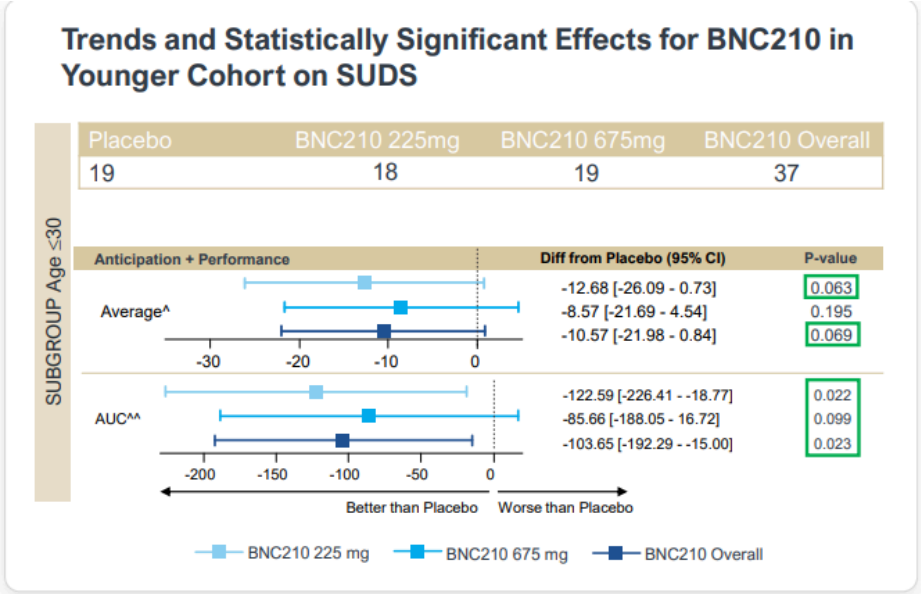


- Statistical significance was observed using the selected primary outcome (SUDS) in task stage analysis in the combined dose arm group (increased power)
- Analysis was based on the observation that BNC210 demonstrated pharmacological activity throughout the public speaking task

225 mg BNC210 was confirmed as the dose for late-stage development**

Source: Company Presentation

Exhibit 5: Younger patients (≤30 years) respond more favorably to BNC210



Source: Company Presentation

Exhibit 6: BNOX Income Statement

Cantor Biotech: Income Statement Charles Duncan, Cantor Fitzgerald, Charles.Duncan@Cantor.com (in A $ '000 except for per share data and where otherwise specified) Fiscal Year Ends on June 30th	FY2020A Jun-20	FY2021A Jun-21	FY1H22A Dec-21	FY2H22A Jun-22	FY2022A Jun-22	FY1H23A Dec-22	FY2H23A Jun-23	FY2023E Jun-23	FY1Q24E Sep-23	FY2Q24E Dec-23	FY3Q24E Mar-24	FY4Q24E Jun-24	FY2024E Jun-24
BNC210 for PTSD	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
BNC210 for SAD	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	$0	**$0**	**$0**	**$0**	**$0**	**$0**
Other revenue	$3,359	$1,308	$177	$87	$264	$325	$800	$1,125	$400	$400	$400	$400	$1,600
Total revenue	**$3,359**	**$1,308**	**$177**	**$87**	**$264**	**$325**	**$800**	**$1,125**	**$400**	**$400**	**$400**	**$400**	**$1,600**
COGS	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
as % of product revenues													
R&D expenses	$5,828	$5,762	$6,955	$9,044	$15,999	$10,760	$8,823	$23,612	$9,706	$10,676	$9,609	$11,530	$41,521
% growth		*-1%*	*125%*	*20%*	*178%*	*55%*	*-18%*	*48%*	*10%*	*10%*	*-10%*	*20%*	*76%*
SG&A expenses	$8,134	$8,703	$5,704	$5,738	$11,442	$6,291	$6,795	$16,407	$7,134	$7,491	$7,116	$7,472	$29,214
% growth		*7%*	*60%*	*5%*	*31%*	*10%*	*8%*	*43%*	*5%*	*5%*	*-5%*	*5%*	*78%*
Operating expenses	**$13,962**	**$14,465**	**$12,659**	**$14,782**	**$27,441**	**$17,051**	**$15,618**	**$40,020**	**$16,840**	**$18,167**	**$16,725**	**$19,003**	**$70,735**
Operating Income	**-$10,603**	**-$13,157**	**-$12,482**	**-$14,696**	**-$27,177**	**-$16,726**	**-$14,818**	**-$38,895**	**-$16,440**	**-$17,767**	**-$16,325**	**-$18,603**	**-$69,135**
Operating Margin													
Other gains and losses	$4,576	$4,273	-$667	$5,893	$5,226	$414	$0	$414	$0	$0	$0	$0	$0
Pre-tax income	-$6,027	-$8,884	-$13,149	-$8,803	-$21,951	-$16,312	-$14,818	-$38,480	-$16,440	-$17,767	-$16,325	-$18,603	-$69,135
Income tax provision (expense)	$208	$187	$95	$97	$192	$104	$0	$104	$0	$0	$0	$0	$0
tax rate %													0%
Loss from continued operations	-$5,819	-$8,697	-$13,053	-$8,706	-$21,759	-$16,208	-$14,818	-$38,376	-$16,440	-$17,767	-$16,325	-$18,603	-$69,135
Loss from discontinued operations	-$1,299	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	**-$7,118**	**-$8,697**	**-$13,053**	**-$8,706**	**-$21,759**	**-$16,208**	**-$14,818**	**-$38,376**	**-$16,440**	**-$17,767**	**-$16,325**	**-$18,603**	**-$69,135**
OCI													
Exchange differences on translation of foreign operations	$531	-$1,169	$395	$672	$1,067	$200	$0	$200	$0	$0	$0	$0	$0
Total comprehensive income (loss)	**-$6,587**	**-$9,866**	**-$12,659**	**-$8,034**	**-$20,692**	**-$16,008**	**-$14,818**	**-$38,176**	**-$16,440**	**-$17,767**	**-$16,325**	**-$18,603**	**-$69,135**
EPS	($2.35)	($2.01)	($2.33)	($1.16)	($3.32)	($1.99)	($0.81)	($3.21)	($0.90)	($0.96)	($0.88)	($1.00)	($3.77)
Shares outstanding - Basic (M)	3,027	4,333	5,598	7,519	6,558	8,160	18,250	11,944	18,342	18,433	18,526	18,618	18,342

Source: Cantor Fitzgerald Research and Company Filings

Exhibit 7: BNOX Valuation

Program	NPV ('000)	NPV/Share	% of Total
BNC210 for PTSD	$60,466	$3.11	40%
BNC210 for SAD	$99,913	$5.13	67%
Collaboration with Merck* Placeholder	$50,000	$2.57	33%
Total	**$149,913**	**$7.70**	**$149,920**

Source: Cantor Fitzgerald Research and Company Filings

BNOX Valuation

In valuing BNOX, we derive our $8 PT by using a discounted NPV probability-adjusted revenue calculation, which yields ~$3/share for BNC210 for PTSD (35% probability of success, 70% contribution margin, 55% discount rate) and $5/share for BNC210 for SAD (35% probability of success, 70% contribution margin, 55% discount rate). In addition, we include a placeholder for Bionomics's collaboration with Merck (OW, covered by L. Chen), which yields ~$3/share.

BNOX Risks

Development, regulatory & commercial risks.

Current pipeline. Clinical trials for BNC210 in post-traumatic stress syndrome, for BNC210 in social anxiety disorder, and for BNC210 in other indications may fail to show efficacy. The clinical studies may be halted due to unforeseen safety and/or tolerability issues.

Additional risks. If approved, new, more-efficacious products may enter the market and may compete for market share for one or all pipeline candidates. The company may fail to secure financing for future studies or commercialization, should any of the products be approved. The company has not yet commercialized any products and would thus need to establish a sales force to do so.

Company Description

Bionomics is a clinical-stage biopharma company developing therapeutics for central nervous system (CNS) diseases, including allosteric modulators for α7 nicotinic acetylcholine receptors (nAChR).

Disclosures Appendix

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Total return is defined as the sum of (1) the percentage difference between the target price and the current price and (2) the expected dividend yield of the stock.

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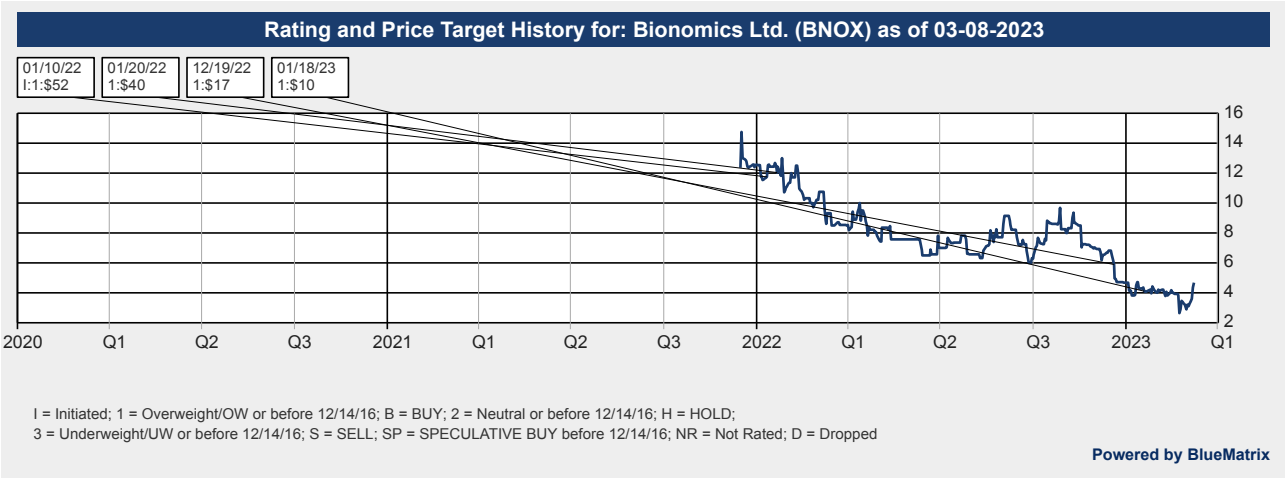

Distribution of Ratings/Investment Banking Services (IB) as of 03/09/23

Cantor

			IB Serv./Past 12 Mos.	
Rating	**Count**	**Percent**	**Count**	**Percent**
BUY [1/B]	**240**	**81.36**	**166**	**69.17**
HOLD [2]	**55**	**18.64**	**27**	**49.09**
SELL [SL/3]	**0**	**0.00**	**0**	**0.00**

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