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Bellus Health - Betting Big On Chronic Cough Treatment

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Ticker	Author rating	Price at publication	Last price	Change since publication	S&P 500 c
BLU	Buy	$3.62	$8.08	123.20%	

Summary

- Bellus' lead drug candidate, BLU-5937, has the potential to capture significant market share if the drug attains commercialization.
- Bellus has adequate cash on its books, lasting until at least the duration of 2022. The company has no long-term debt.
- Bellus claims 100% ownership of the intellectual property rights for both BLU-5937 and related P2X3 antagonists.
- Assuming a base case revenue of $320 million in the year 2028 and a P/S ratio of 6.0x, the company's intrinsic value comes out to be $774 million or $9.80 per share, indicating an upside close to 3x.

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Company Overview

Bellus Health (NASDAQ:BLU) was established in Laval, Canada. The clinical-stage biopharmaceutical company focuses on the development of novel therapeutics. They specialize in the treatment of the chronic cough, chronic pruritus, and other hyper-sensitization disorders.

Bellus Health is led by an impressive team of experts. President & CEO Roberto Bellini, Chief Medical Officer Dr. Catherine Bonuccelli, Ramzi Benamar (Chief Financial Officer), and other key visionaries manage the enterprise. While both the CMO and CFO joined Bellus recently, Roberto Bellini has been with the firm since its inception. Bellini brings a superior level of expertise, acquired by his tenure as vice president at Picchio Pharma.

The company's lead candidate for treatment is BLU-5937, an oral drug to be administered twice daily. BLU-5937 is a highly selective antagonist that inhibits the function of the P2X3 receptor. The receptor is clinically-proven, and linked to hypersensitivity. Hyper-sensitization disorders, such as refractory chronic cough, chronic pruritus, and chronic itch share a common pathophysiology associated with the P2X3 receptor. Thus BLU-5937, serving as an antagonist for this receptor, poses a potential solution to a substantial unmet market need. Bellus Health has launched its Phase 2 trials SOOTHE and BLUEPRINT. These are scientific proofs of concept for the efficacy, safety, and tolerability of the BLU-5937 drug against refractory chronic cough and chronic pruritus, respectively.

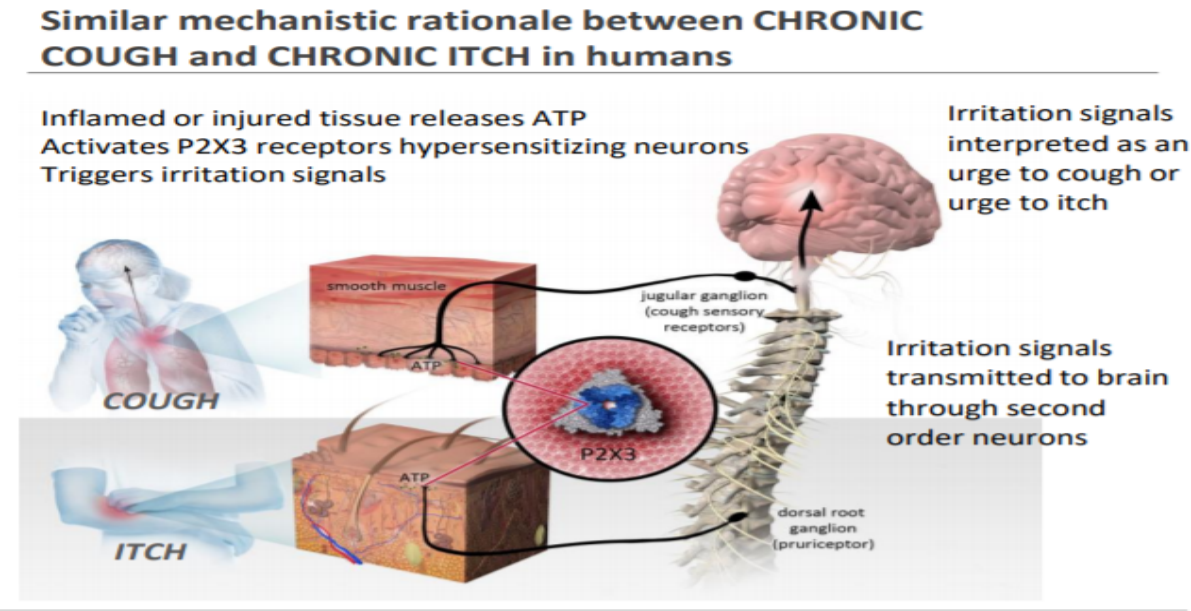

Exhibit 1: MOA between Chronic Cough and Chronic Itch, Source: Bellus Health

The company's strategic focus is on the development of BLU-5937, as the standard medical treatment for both refractory chronic cough and chronic pruritus. Once the development phase has been completed, Bellus intends to maximize the value of BLU-5937 through independent commercialization or partner collaboration. Additionally, the company has plans to utilize its proprietary P2X3 antagonist technology platform to address other hyper-sensitization-related disorders.

Market for BLU-5937

BLU-5937 is currently under development at Bellus Health. The drug is positioned as a potential treatment option for disorders such as refractory chronic cough, chronic pruritus, and chronic itch. Refractory chronic cough, or RCC, is defined as any cough lasting for more than a couple of months. RCC is known to disrupt sleep, negatively impact daily activities, and induce fatigue. Because coughing is identified as one of the symptoms of COVID-19 there remains an added need for new and effective treatment. Chronic pruritus and chronic itch are irritating sensations that last longer than six weeks. Such manifestations may be of other underlying conditions, including atopic dermatitis. This medical condition can be debilitating, and significantly impact the patient's quality of life.

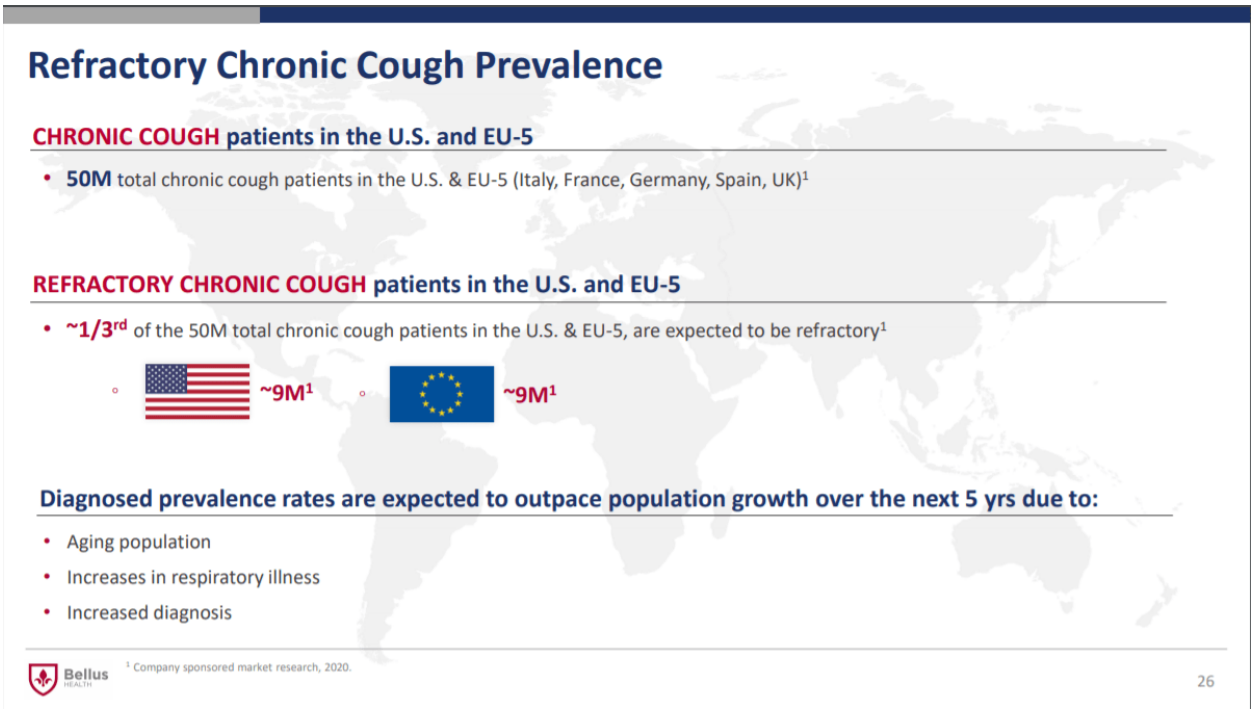

Exhibit 2: Refractory Chronic Cough Prevalence, Source: Bellus Health

A 2017 report from Coherent Market Insights revealed that the market for cough suppressants was valued at $1.1 billion, with an anticipated growth rate of CAGR of 3.7% CAGR by 2026. BLU-5937's target market is primarily adults suffering from chronic cough. Statistics show that 10% of the adult population in the United States suffers from chronic cough, i.e., 26 million people. Furthermore, 30% of this cohort endures side effects commonly associated with RCC. BLU-5937 is also identified as an effective treatment for chronic pruritus, which is expected to expand into a $16.38 billion market by 2025. The total market opportunity for BELLUS Health is estimated at around $2 billion.

Intellectual Property Rights

In February 2017, Bellus Health was granted exclusive, global licensing rights from the NEOMED institute, for the IPR&D of BLU-5937. In March 2020, the company acquired the totality of the BLU-5937 IPR&D asset from adMare BioInnovations (formerly the NEOMED institute). Thus, the company is no longer obliged to share revenue, or extend royalties to any third party. The company currently possesses 100% ownership of BLU-5937 and the intellectual property rights for its related P2X3 antagonists, with no future obligatory payments. The IPR covers the composition of the BLU-5937 matter, with a maturity date of 2034. The method of patent use has an expiration date of 2038.

Competitive Landscape

Other major competitors in the development of a P2X3 approach to RCC treatment include Merck & Co. (MRK), Bayer (OTCPK:BAYZF), Shionogi, Sanofi (SNY), and Novartis (NVS). Bellus Health's competitive advantage is that the BLU-5937 drug touts best-in-class selectivity against the P2X3 receptor.

	1ST IN CLASS P2X3 ANTAGONIST	2ND GENERATION P2X3 ANTAGONISTS		BEST IN CLASS SELECTIVITY FOR P2X3
Company	MERCK	BAYER	SHIONOGI	Bellus HEALTH
Candidate	MK-7264	BAY 1817080	S-600918	BLU-5937
Stage of Development	phase 3	phase 2	phase 2	phase 2
Dosing	BID	BID	QD	BID
P2X3 vs. P2X2/3 Selectivity	3-7x[2]	~20x[3]	~ 250x[4]	**~ 1500x**

Exhibit 3: Competitive Profile, Source: Bellus Health

Merck completed two Phase 3 trials in September 2020. The study involved approximately 2,000 patients, and reported the same at ERS in September 2020. The results of the Phase 3 trials were as follows: a high dose (45mg BID) of MK-7264 achieved a statistically significant result in treating a 24-hour cough and yielding an 18% and 16% reduction in the 12-week COUGH-1 and 24-week C-2 trials, respectively. Note that the reduction is charted post-placebo adjustment. Also identified were significant rates of taste disturbance, i.e., 58% in the COUGH-1 trial and 69% in the COUGH-2 trial.

In October 2019, at the European Respiratory Society (ERS), Shionogi announced the results of its Phase 2a clinical trial. The research involved the testing of the drug S-600918 amidst patients suffering from refractory chronic cough. After the placebo adjustment, the drug had a 32% reduction in 24-hour cough frequency and a 6.5% reduction in taste disturbance. The baseline of average coughs per hour was identified as 56C. For the Phase 2b trials, Shionogi utilized a subgroup where the cough frequency was greater than 32C per hour. The results of the trial will be presented at the company's designated R&D day on September 29, 2021.

Bayer, in April 2020, released their top line results gathered from its Phase 2a clinical trial. This trial was conducted to evaluate the efficiency and safety of BAY 1817080. The study showed that higher doses of the drug significantly reduced both 24-hour cough counts and severity levels amongst patients suffering from RCC (15-25% reduction compared to placebo). Also identified was an adverse effect in taste disturbance in 5 to 21% of participants, and these were dose-dependent. Bayer launched a Phase 2b clinical trial of 236 RCC participants, in October 2020, to study the impact of three doses of the drug.

Product Pipeline

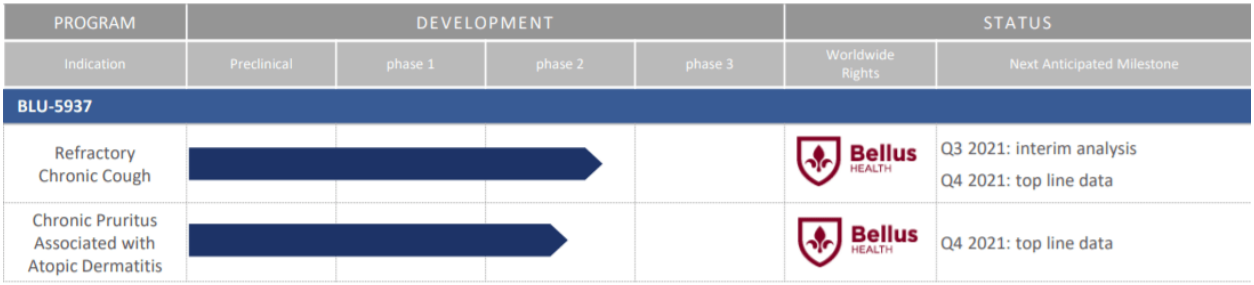

Exhibit 4: Drug Pipeline, Source: Bellus Health

The company is currently overseeing Phase 2 trials of BLU-5937 for the treatment of refractory chronic cough and chronic pruritus in association with atopic dermatitis.

A Phase 2b SOOTHE clinical trial for 300 participants suffering from RCC was initiated on December 7th, 2020. The clinical trial is expected to be completed by September 2021. The primary outcome measure changes from baseline in the 24-hour cough frequency. The study is designed to assess the efficacy and safety of the drug based on key learnings from the proof-of-concept RELIEF trial which was completed in July 2020.

The intended result of the RELIEF trial, i.e., the reduction in cough symptoms post-placebo adjustment, was not achieved here. As a result, the company lost significant favor amongst its investors. The trial population constituted a small number, at 62 patients, so that, coupled with a numerical difference in favor of the drug, must be observed. Consequently, the Phase 2b trials (SOOTHE) may prove to redeem the company.

The Phase 1 clinical trial yielded positive results for its 90 healthy volunteers. BLU-5937 demonstrated favorable tolerability, within patient cohorts suffering from 20-32+ coughs per hour. The results showed a clinically meaningful reduction in placebo-adjusted cough frequency. A statistically significant correlation was identified between the treatment effect and the average cough frequency.

RELIEF: Limited Taste Disturbance Adverse Events

INCIDENCE OF TASTE DISTURBANCE ADVERSE EVENTS (SAFETY POPULATION)

	Placebo (n=61)	25mg BID (n=61)	50mg BID (n=61)	100mg BID (n=60)	200mg BID (n=58)	Total BLU-5937 (n=61)
Taste Disturbance	2 (3.3%)	3 (4.9%)	5 (8.2%)	5 (8.3%)	4 (6.9%)	5 (8.2%)
Partial Taste Loss	1 (1.6%)	2 (3.3%)	2 (3.3%)	2 (3.3%)	2 (3.4%)	2 (3.3%)
Complete Taste Loss	0	0	0	0	0	0
Total Taste AEs[1]	3 (4.9%)	4 (6.5%)	6 (9.8%)	6 (10.0%)	5 (8.6%)	6 (9.8%)

Exhibit 5: Relief Trial Data, Source: Bellus Health

Noted were the limited (<=10%) taste adverse events at all dose levels, zero “complete loss of taste” events at any dose, and no occurrences of severe taste adverse events overall; also, there were no obvious effects on ECG, vital signs, or laboratory measures.

Phase 2 BLUEPRINT is a multi-dose clinical trial devised to test the safety, efficacy, and tolerability of BLU-5937 in 128 adult patients suffering from chronic pruritus (related to atopic dermatitis). The study began on December 9, 2020, and is estimated to be completed in September 2021. The participants are randomly split in a 1:1 ratio between two treatment arms. Each will receive either 200mg BID of BLU-5937 or a placebo for the month-long treatment period. The BLUEPRINT clinical trial is currently underway across 30 centers spanning the United States and Canada. The measured outcome is based on a weekly “mean worst itch,” and tracked according to a numeric rating scale referred to as the WI-NRS score. The top line results are anticipated in the fourth quarter of 2021.

Financials

On December 31, 2020, the net losses were cited at $31,757,000 compared to $26,008,000 of the previous year. This differential can be attributed to higher research and development expenses incurred throughout the BLU-5937 drug. The R&D costs stood at $23,222,000, an increase from the previous year's $19,178,000, and a result of the added workforce and elevated stock-based compensation expenses. The increased R&D costs are expected to continue in the near future. General expenses also increased by 48%, largely due to the costs associated with publicly listing the company on NASDAQ, a one-time expense. It is pertinent to note that some of the R&D costs arose from the acquisition of BLU-5937 rights from adMare, in March of 2020.

Bellus' cash equivalents and short-term investments totaled $98,260,000 on the firm's management efforts. These monies are sufficient to fund their operating plan until 2022, at which point additional capital will need to be raised for the continued development of BLU-5937. In October 2020, Bellus Health succeeded in raising $40.3 million by issuing common shares at a price of $2.25 per share for a total of 17,888,889 shares, out of which $5.8M has been utilized as of Dec 31. Noteworthy is the company's lack of both long-term debt and pre-arranged credit facilities or sources for cash financing. Below is a snapshot of the company's obligations.

	Payments Due by Period (All amounts in thousands of dollars)				
Contractual Obligations	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**	**Total**
Long-Term Debt Obligations	Nil	Nil	Nil	Nil	Nil
Lease Liabilities	184	368	Nil	Nil	552
Purchase Obligations	34,621	2,038	Nil	Nil	36,659
Other Long-Term Liabilities Reflected on the Company's Balance Sheet	Nil	Nil	Nil	Nil	Nil
Total	34,805	2,406	Nil	Nil	37,211

Exhibit 6: Company's Debt Obligations, Source: Bellus Health Annual Report

Risk Factors

The company and business are exposed to a moderate level of risk. The most substantial are highlighted below:

- The company has been operating at a loss since its inception. As mentioned earlier, the company's cash reserve will sustain until the end of 2022. They will be compelled to raise additional capital through previously utilized or new channels and at favorable or unfavorable terms. Even unfavorable cases are not guaranteed, and it is possible that they will not succeed in raising the necessary funds. If this occurs, Bellus may be required to scale back, delay or potentially abandon the development of BLU-5937.

- The company is reliant on third parties for conducting its clinical trials and manufacturing the APIs required for the development of BLU-5937. If these parties do not perform their agreed-upon duties, the business may be adversely impacted.

- Small pharma companies receive a large number of Complete Response Letters (CRLs). A CRL indicates that the FDA is unsatisfied with the data review within the NDA, ANDA, or BLA submission, and cannot approve the application. If Bellus receives any such CRLs, it may pose a negative effect on its share value.

- The competition in the biopharmaceutical industry is fierce, and future developments by competitors may render the company's main product as redundant.

Conclusion

The refractory chronic cough is a multibillion-dollar market with treatment options that are inadequate and non-specific. Given the size of the market, Bellus' lead drug candidate, BLU-5937, has the potential to achieve peak sales north of $1b - $1.25billion, just for its refractory cough benefit. If all goes as planned, I expect the company to conclude its Phase 3 trials by 2023, and obtain approval by the end of 2024 and commercialization by early 2026. The drug's other benefit, for sufferers of chronic pruritus associated with atopic dermatitis, could also be favorable for Bellus, if the Phase 2 results prove positive.

		2028E Revenue (in millions)				
		$240.00	$280.00	$320.00	$360.00	$400.00
P/S ratio	5	$483.78	$564.41	$645.04	$725.67	$806.30
	5.5	$532.15	$620.85	$709.54	$798.23	$886.92
	6	$580.53	$677.29	$774.04	$870.80	$967.55
	6.5	$628.91	$733.73	$838.55	$943.37	$1,048.18
	7	$677.29	$790.17	$903.05	$1,015.93	$1,128.81

Exhibit 7: Sensitivity Table

The above sensitivity table presents Bellus' 2026E revenue and expected P/S ratio. Assuming a base case revenue of $320 million and a P/S ratio of 6x, the company's intrinsic value is calculated to be $774 million or $9.80 per share, indicating an upside of close to 3x. The value calculated takes into account the time and risk associated using a discount rate of 15%. There is always a possibility that things could go wrong.

Assuming the dilution risk, delay in approvals, or commercialization hold-up, there could be a downside moving forward. Currently, Bellus' market value appears to discount the potential value that the company is expected to generate. The risk versus reward scenario looks favorable to investors, given the opportunity and valuations at which the company is presently trading.

I remain bullish on Bellus Health.

This article was written by

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